D1.1 Roadmaps and Certifications for Adjacent Sectors Transition

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Executive Summary

Deliverables D1.1 reports an overview of the standards and certifications adopted in the sectors of the four use-cases and defines the roadmap for the sector transition identifying limitations and opportunities. The purpose of the document is to well-define the as-is sector situation in terms of standards and certifications and specific features of the supply chain that need to be carefully taken into account to understand the potential to-be and opportunities of the reconfiguration process for the considered use-cases.

The document is the results of the activities conducted by "Task 1.1 - Strategic Analysis, roadmap and certification for adjacent sectors and sector transition". The followed methodology to gather all the reported information consists in:

- Desk studies of the use-cases sectors, with particular attention to the vertical certification requirements, manufacturing system and scientific literature specific to the manufacturing environment subject of the analysis.
- Detailed studies of the norms and standards for data management, manufacturing and standards related to the use-case under analysis.
- Interviews with the use-case providers beneficiaries and the technology development responsible beneficiaries.
- Specific surveys provided to the use-case providers and to external stakeholders.

Together with D1.2, this document gives an exhaustive and detailed characterization of the sectors under analysis and a reliable and efficient cross-sectorial approach capable to drive whatever sector of manufacturing to any potential landing sector.

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1. Introduction

The chapter 1 gives an overview of the deliverable, explaining briefly RaRe^2 – Project, the purpose, the methodologies and the structure of the deliverable.

1.1. RaRe^2 – Project Overview

RaRe^2 – Project has the global objective to create a flexible and resilient Holistic Ecosystem Platform to make the European manufacturing landscape sustainably robust to fast changing scenarios. Thanks to the research and development of RaRe^2, the European organisations could adopt efficient and well-planned strategies to react to market and legal changes as well as to every kind of crises (political, pandemic, etc.) and possible disturbances on the production chain.

The Project purpose is built on several key pillars that allow to develop step by step the innovative digital solutions and methodologies for the dynamic adaptation process.

- Develop an Early Detection software of upcoming issues to decrease the time of strategic and operational decisions. The early detection will be based on structured and analysed data from internal and external resources managed by Artificial Intelligence technologies.
- Provide to the companies an interactive decision support tool on multiple levels of hierarchy.
- Develop a systemic digital twin for fast simulation with adjustable indicators. The analysis tool allows the generation, evaluation and optimization of possible and alternative reconfigurations of the production chain, allowing the companies to easily adapt to every changing scenario.
- Design a new approach to detect skill gaps and define the most effective up-reskilling path depending on the specific technological and sector needs.
- Provide secured and standardized core services for data acquisition, aggregation, storage, transmission and analysis. This is fundamental for the developed technologies to be flexible and manageable by very different companies and sectors.
- Validate the solutions with Demonstration in 4 representative sectors and roll out to value chain.

The Project will be ensured to be robust through a three-step testing: small-scale, demo case and value chain. Then, the reliable developed solutions could be continuously adopted in Europe creating a strong network of organizations interested in cooperating in rapid reconfiguration events. This network can react flexibly to external factors and can be reconfigured rapidly, considering social, market, legal, sustainability and economic factors.

1.2. Deliverable Purpose and Methodology

The deliverable D1.1 has the objective to give an overview of the relevant standards and certifications for the sector transition and discuss the main characteristics of the case studies to assess the feasibility of the change. Depending on the sector and unforeseen events, several change possibilities are discussed.

The limitations and possibilities of the dynamic process of adaptation and change are the results of several actions:

- Desk studies of the state-of-the-art of the sectors and the manufacturing landscape, with particular attention to the standards and certifications needed for the change;

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- Overview and studies of specific standards useful for the dynamic process of adaptation;
- Internal beneficiaries interview and surveys to internal beneficiaries and external stakeholders to assess the specifications, opportunities and limits to be duly taken into account when planning the diversifications and changes according to the project.

The reported methodology allowed to gather enough information to understand the as-is situation of the manufacturing landscape and the possible development opportunities of the dynamic process of adaptation.

1.3. Deliverable Structure

The document is organized in 4 Chapters, in addition to the introduction Chapter 1.

Chapter 2 gives an overview of the use cases sectors and possible adjacent sectors, with particular attention to the needed standards and certifications.

Chapter 3 introduces possible standards useful for the development of the project to further investigate in future activities.

Chapter 4 reports an overview of the limitations and possibilities to carry out efficiently the dynamic process of adaptation and an analysis of the European organisation management facing different change factors.

Chapter 5 concludes this report with further considerations.

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2. Standards and Certifications for Sector Transition

The chapter 2 gives an overview of the followed standards and obtained certifications by the demonstrators' organisation of RaRe^2 Project. Thanks to the analysis of the Use-case sectors in terms of standards and certification, possible adjacent sectors are defined and discussed to point out the changes and standards needed for the transition.

2.1. Relevant Standards

The International Organisation for Standardisation (ISO) is an independent, non-governmental organization that develops and publishes International Standards that provide frameworks, guidelines and requirements in several technical and non-technical fields. ISO is a global network of national standards bodies, such as DIN - Deutsches Institut für Normung for Germany or AFNOR - Association française de normalisation for France.

ISO standards are followed by multiple industries and companies mainly, for example, for quality, safety and environmental management. Management systems standards help the organisation to better control its processes, well defining how work is done, the desired outcomes and monitoring activities. Indeed, the most followed ISO standards belong to the following three families:

- ISO 9000 family – Quality Management
- ISO 14000 family – Environmental Management
- ISO 45000 family – Occupational Health and Safety Management

ISO is not involved in the certification process. Therefore, a company or organisation can be certified by external certification bodies, whose activities are controlled by an independent body, called accreditation body, that verifies the certification body operates according to international standards.

The certification process is regulated by the ISO/IEC 17021:2015. Considering ISO/IEC 17021, the certification is issued following an audit, review, resolution and control process of the certified organisation according to the requirements of the standard of interest. The process, depicted in **Fehler! Verweisquelle konnte nicht gefunden werden.**, generally follows these steps:

- initial certification audit, divided into two stages;
- decision (or resolution) of certification by the body;
- a surveillance audit in the first year (it must be performed within one year of the end of the stage 2 audit);
- a surveillance audit in the second year;
- a certification renewal audit in the third year, before the expiry date of the certificate.

As discussed before, there are three ISO Standards that have to be duly considered by organisations: ISO 9001:2015 Quality management systems — Requirements; ISO 14001:2015 Environmental management systems — Requirements with guidance for use; ISO 45001:2018 Occupational health and safety management systems — Requirements with guidance for use.

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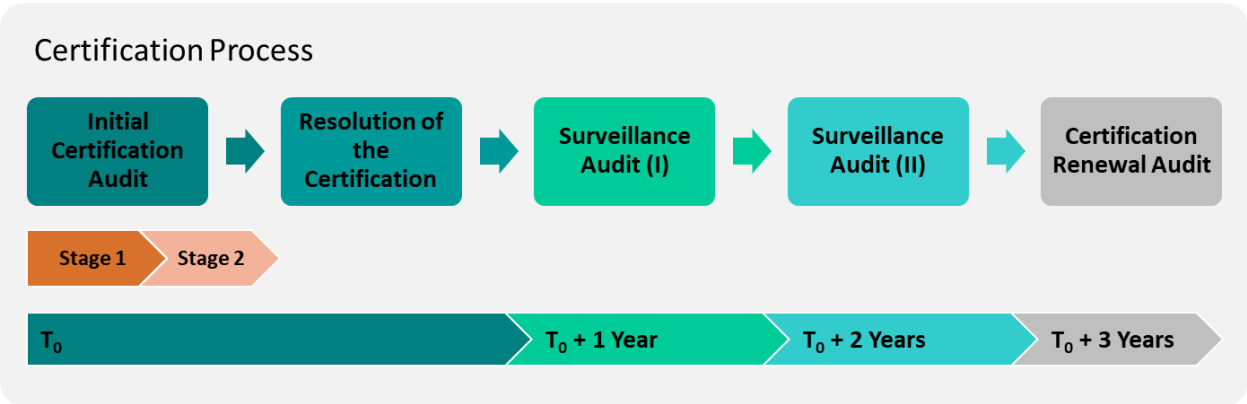

Figure 1: Certification Process regulated by the ISO/IEC 17021:2015

2.1.1. ISO 9001 – Quality Management Systems

ISO 9001:2015 [[1] is the global quality standard usable by any organisation, regardless of its type or size, to demonstrate its ability to provide products and services that satisfy customer and regulatory requirements. ISO 9001 is based on the Plan-Do-Check-Act (PDCA) cycle, shown in Figure 2, that can be applied not only to the management system, but also to each individual process to provide a continuous improvement.

An organisation that wants to adopt ISO 9001 Quality Management System will increase its competitiveness demonstrating its attention to internal and external customers. In order to obtain ISO 9001 certification from a certification bodies, an organisation must satisfy the requirements of the standard together with the additional elements indicated by the accreditation bodies.

In particular, to obtain Management System certification, the following five requirements must be fulfilled:

- Quality Management Systems (QMS): well-defined system having documented process, procedures and responsibilities to achieve quality objectives;
- Management Responsibility: definition of responsibilities, quality policy and objectives etc.;
- Resource Management: documented resources the organisation provides to the employees;
- Product Realization: plan for the product and/or service realisation;
- Measurement, Analysis and Improvements: the organisation needs tools to understand the effectiveness of its QMS.

Moreover, the organisation has to prepare the documentation requested by the ISO 9001 standard, such as:

- Internal audit program
- Results of internal audits
- Records of the design and development processes (inputs, outputs, controls)
- Product and/or service characteristics

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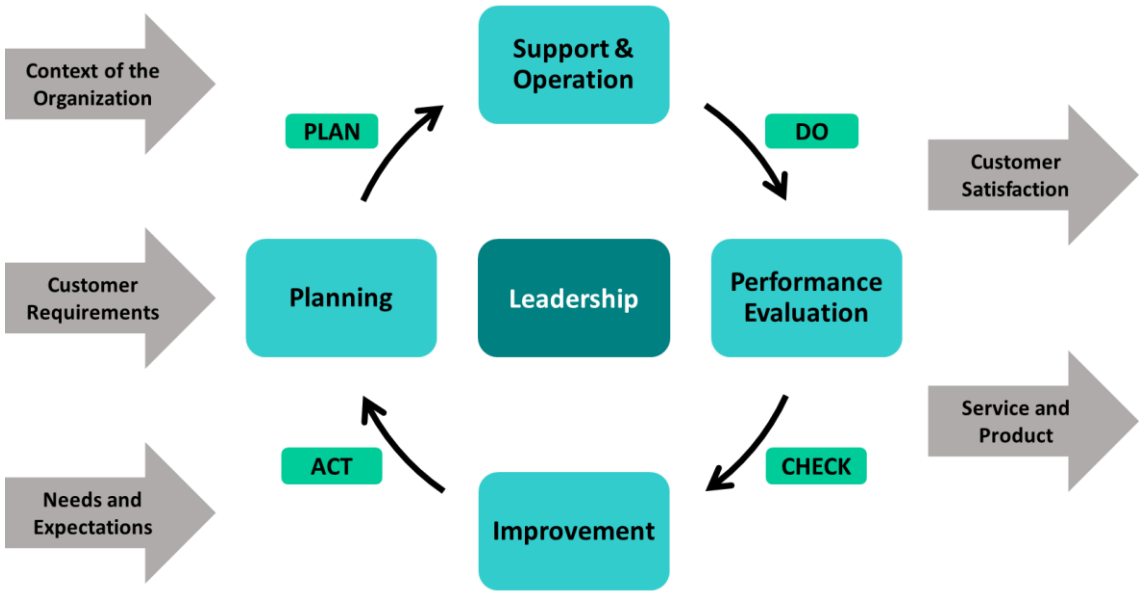

Figure 2: PDCA model ISO 9001:2015

2.1.2. ISO 14001 – Environmental Management Systems

ISO 14001:2015 [2] defines the requirements for an environmental management system to assure an organisation environmental impact is being measured and improved. Any organisation, regardless of size, type and nature, can apply this standard for its activities, products and services.

ISO 14001 certification, so the implementation of an environmental policy, allows organisations to make their activities more sustainable, reducing their environmental impact. Moreover, the constant monitoring of the progress and the plan to manage risks and emergency situations allows to improve the environmental sustainability too. Therefore, a company could become truly competitive thanks to the implementation of the ISO 14001 reducing cost (higher efficiency), creating new market opportunities, improving the organisation image and the environmental responsibility, with a subsequent higher customers' trust and confidence.

To obtain the ISO 14001 certification, organisation has to follow the usual steps of the audit process taking into consideration the specific requirements and documentations requested by ISO 14001 standard. In addition to general requirements defined by the ISO 9001 such as the context of the organisation and the planning, there are other requirements such as:

- Defined environmental policy;
- Identification of the environmental impacts;
- Definition of the environmental objectives and planning to achieve them;
- Plan to monitor and measure the progresses with respect to the defined objectives;

The organisation has to provide also supporting documentation such as:

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- Internal audit program
- Results of internal audits
- Evidence of the evaluation of the performance of the Environmental Management System (EMS)
- Records of the design and development processes
- Documented information about the EMS as for example:
    - Organizational charts
    - Process description
    - Work and test instructions
    - Inspection plans

2.1.3. ISO 45001 – Occupational Health and Safety Management Systems

ISO 45001:2018 [3] specifies the requirements for an occupational health and safety (OH&S) management system. It helps the organisation to provide safe and healthy workplaces, eliminating hazards and minimizing the risks. This standard replaced and is based on the OHSAS 18001:2007.

It is applicable to all organisations, regardless of size, industry and nature of business. ISO 45001 allows to reduce workplace incidents, absenteeism and cost of insurance premiums, to create a health and safety culture and to improve staff morale. Therefore, obtaining a certification is strongly recommended. Here are few initial steps to consider implementing ISO 45001:

- Analyse the organisation context about the OH&S.
- Define the scope, objectives and policy of the OH&S management system.
- Determine the gaps and the timeline to perform the needed changes.

ISO 45001 has been developed to be integrated into the organisation management processes together with the other two relevant standards previously described ISO 9001 and ISO 14001.

2.2. Demonstrator #1: MMM

MMM has been a European leader in development and manufacturing of Reprocessing Units for Medical Devices (RUMEDs) for 65 years. The RUMEDs are one of the most important and most sensitive areas of a hospital and create the basic prerequisite for patients to be treated safely, quickly and successfully. The European Medical Device Regulation (MDR) 2017/745 [4] defines “reprocessing” as a:

“Process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilization and related procedures, as well as testing and restoring the technical and functional safety of the used device”. [Article 2(39) of the MDR]

Therefore, reprocessing has to be performed by a certified facility, as the RUMED are, whose construction, reconstruction and operation follow a multitude of laws, regulations and guidelines as well as various DIN, EN and ISO standards.

The main standards to consider are the following ones:

- ISO 13485 - Medical devices -- Quality management systems -- Requirements for regulatory purposes

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- EN ISO 14971 – Medical devices – Application of risk management to medical devices; 2014.
- EN ISO 15883 – Washer disinfectors
    - Part 1: General requirements, terms and definitions and tests; 2012
    - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.; 2009.
    - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers; 2009.
    - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes; 2009.
    - Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment; 2011.
    - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment; 2014.
- ISO/TS 15883 – Washer-disinfectors – Part 5: Test soils and methods for demonstrating cleaning efficacy; 2005.
- EN ISO 17664 – Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices; 2004.
- EN ISO 17665-1 – Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices; 2006.
- EN ISO 9000 – Quality management systems – Fundamentals and vocabulary; 2005.
- ISO/TS 11139 – Sterilization of health care products – Vocabulary; 2006.

Moreover, each country could have different requirements for the modular units for what concerns the HVAC, electrical, drainage and water systems. An overview of the standards for the countries of interest is reported in Table 1.

As can be seen in Table 1, for what concerns the HVAC system for cleanroom, the majority of the countries follows the ISO 14644. This standard regulates the use of cleanrooms, defining several classes from Class 1 to Class 9, where the Class 1 has the most stringent cleanliness requirements, as shown Table 2. ISO 14644 is composed by 14 parts and defines specific requirements for designing, manufacturing and maintaining of cleanrooms. The critical parameters of a cleanrooms to consider are the following:

- air cleanliness, exchange rate, volumes
- cleanroom class choice
- clothing in cleanrooms
- air filters
- planning of access areas

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Table 1: Standards overview for the modular units depending on the country

Country	Standardization Organization	HVAC*	Electrical installation	Drainage system	Fire protection	Water installation
Germany	DIN - Deutsches Institut für Normung	DIN 1946-4 ISO 14644	DIN VDE 0100 DIN VDE 0107	DIN 1986-100 DIN EN 12056	MLAR 03/2000	DIN 1988
Switzerland	SNV - Schweizerische Normen-Vereinigung	ISO 14644	IEC 63044	SN EN 12056		
France	AFNOR - Association française de normalisation	ISO 14644	NF C15-100		NF EN 54 NF S61-940	
Belgium	NBN – Bureau voor Normalisatie/ Bureau de Normalisation	NBN EN 16798 CEN/TS 17441	NBN C 30-004 NBN C 61-142 T 013/IA	NBN EN 12056 NBN EN 12109 NBN EN 1253-4	NBN ISO 20710 NBN EN ISO 19353 NBN EN 54	NBN EN 13443
Netherland	NEN - Royal Netherlands Standardization	NEN-EN 13053 NEN-EN 13779 NEN-EN 15780 NEN-EN 16798-3	NEN 1010 NEN 3140 NEN 3840 NEN 4010	NEN 3215+C1 NEN-EN 12056	NEN-EN 13501-1:2019 NEN 2654-1+C1:2018 NEN 2535:2017	NEN 1006+A1:2018
Luxemburg	ILNAS - Institut Luxembourgeois de la Normalisation, de l'Accréditation, de la Sécurité et qualité des produits et services	EN 15240 EN 378 I.S. EN 13141:2004	IEC 60364 IEC TC64 IEC TC61	DIN 1988 DIN 1986 DIN EN 1717 ILNAS-EN ISO 6412-3:2018	ILNAS-EN 12845 ITM-SST 1500.3ITM-SST 1501.5ITM-SST 1503.4	I.S. EN 1717: 2000 I.S. EN 12201 CEN/TC 164 ISO/TC 282 CEN/TC 165
Ireland	NSAI - National Standards Authority of Ireland	HTM 03-01 HBN-13 I.S. EN 13141:2004 BS 5250 BS 5925 Technical Guidance Documents: Part F-2009 CCA Commissioning Code A	NSAI ETC TC1 NSAI ETC TC2 IEC TC64 IEC TC61	I.S. EN 12056 I.S. EN 12109 I.S. EN 12201	Technical Guidance Documents: Part B-2006 BS 5588 I.S. 3218:2013 B.S. 5839 **BS 7974**	CCW Commissioning Code W Technical Guidance Documents: Part H-2016 I.S. EN 1717: 2000 I.S. EN 12201
Austria	ASI - Austrian Standards International	ÖNORM H 6020	ÖVE/ÖNORM HD 60364	ÖNORM B 2501 ÖNORM EN 12056-5		ÖNORM EN 806
Botswana (Africa)	BOBS – Botswana Bureau of Standard	ISO 14644 BOS 498	BOS 51	BOS 93:2012: BOS 260-1:2008 BOS ISO 15877-2:2009 **BOS 94-1: 2016 ed.2** BOS 275:2008	BOS 254-2:2018 Edition 2.0 BOS 701: 2016 BOS 394: 2010 BOS 65-2: 2015 ed.2	**BOS 136-1:2012 ed. 2** **BOS 56: 2002 ed.1**

*Heating, Ventilation and Air Conditioning
** ANS Construction - V3.0 is the document reference for constructions redacted by ILNAS

Focusing on the application for reprocessing of medical devices, the requested cleanroom class should be at least ISO 5 following the guidelines provided by ISO 13485 and the World Health Organization (WHO). A non-exhaustive overview of the guidelines of the WHO [5] is reported in Table 3.

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Table 2: ISO 14644-1 Cleanroom Classification [6]

Class	Maximum Particles/m³					
	≥0.1 um	≥0.2 um	≥0.3 um	≥0.5 um	≥1 um	≥5 um
ISO 1	10	2				
ISO 2	100	24	10	4		
ISO 3	1,000	237	102	35	8	
ISO 4	10,000	2,370	1,020	352	83	
ISO 5	100,000	23,700	10,200	3,520	832	29
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO 7				352,000	83,200	2,930
ISO 8				3,520,000	832,000	29,300
ISO 9				35,200,000	8,320,000	293,000

Table 3: World Health Organization guidelines for the Sterilization Unit

Layout of the Sterilization Unit	Areas physically separated with a clear unidirectional workflow from dirty to clean. Some basic criteria: • Entrance and corridors – public areas • Dirty area receiving of used medical devices – dirty area • Sterilization area – sterilizers
Air quality	Medical quality, free of bacteria, chemicals and large particles of dirt. Considering ISO 8573 air quality standard and ISO 12500 compressed air filter standard, recommended ISO 8573.1 Class 2 air quality (that corresponds to ISO 14644 Class 5) and a 1.0 micron particulate filter.
Water quality for cleaning and sterilization	Ideally the water should be soft, with low mineral and salt content. Water can be softened with filtration method or reverse osmosis. Processing water can be expensive, so it is recommended only for the final rise.
Water quality for steam sterilizers	Proper steam quality prolongs the life of the reprocessed medical devices, since rust or salt, for example can lead to stress corrosion, pitting and discolouration of the device.
Environment	
Surfaces	Smooth, straight and easy to clean. Must be made of waterproof materials, no wood and laminates. Stainless steel recommended for work surfaces.
Walls	Smooth, straight and coated with washable paint or material
Floors	Straight, smooth and able to withstand loads.
Ventilation	Mechanical or controlled ventilation is recommended. No less than 20 air changes per hour. Dirty area under negative pressure compared with the clean area so the flow is from the clean to the dirty area.
Relative humidity	40-50% recommended
Ambient temperature	Decontamination area 18-20 °C Clean area 18-23 °C Sterile storage 15-25 °C

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2.2.1. General Rules on Reprocessing of Medical Devices

After recent widespread epidemics and growing concerns over antimicrobial resistance, numerous countries are directing more attention and resources towards strengthening infection prevention and control (IPC) infrastructures and enhancing practices. Within this context, the World Health Organization (WHO) [5] has issued crucial guidelines to health managers and workers regarding the infrastructures and standard procedures needed to effectively reprocess medical devices. The decontamination of medical devices plays a critical role in the prevention of healthcare-associated infections, encompassing essential processes such as cleaning, disinfection, and sterilization. These decontamination procedures are complex and demand specific infrastructures and equipment, involving multiple sequential steps that must be executed accurately, going from device collection and receipt by the decontamination unit to processing, storage, and distribution throughout the facility. In order to ensure the proper functioning of the equipment, quality control procedures (e.g., validation) at each decontamination step hold paramount importance. WHO's recommendations on reprocessing of medical devices are designed to address the potential risks associated with improper reprocessing practices, such as the transmission of infections and the compromise of patient safety. These recommendations are based on evidence-based practices and are regularly updated to align with advances in medical technology and infection control.

The reprocessing cycle can be divided in 5 steps, each with more detailed description depending on the specific devices that has to be reprocessed. In general, the process goes as follows:

The first step, Receipt and Transportation, takes place in the dirty area. Here, healthcare professionals remove gross soil and sharps from the devices at the point of use, preparing them for transport to the decontamination. The contaminated equipment is then transported in clearly labelled, fully enclosed, leak-proof containers to prevent any potential hazards during transportation. To preserve the integrity of the devices, it is essential to keep soiled instruments moist using enzymatic spray or a water-moistened towel. However, soaking the devices in saline or hypochlorite solution must be avoided as it can cause damages.

Cleaning is the second step in the reprocessing process and is carried out in the dirty area as well. Manual cleaning is a critical aspect of this step, as devices must be free from visible soil before proceeding to mechanical washing. Healthcare professionals use clean, lint-free cloths, soft bristle brushes, spray guns, and flushing devices during the cleaning process. During the cleaning process, devices are disassembled to facilitate the cleaning of all surfaces effectively with detergent solutions compatible with the instrument/device. Regular inspection of medical devices during the cleaning process ensures that all soil has been removed. Following cleaning, instruments and equipment are rinsed with tap water and dried using mechanical means or lint-free cloth, depending on the design of the instrument/device.

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Following, Inspection, Assembly, and Packaging occurs in a clean area with healthcare professionals paying particular attention on minimizing the risk of contamination. In this step, instruments are inspected for cleanliness, damage, and proper functioning and if recommended by the manufacturer's instructions, instruments are assembled before proceeding to the packaging stage. To facilitate inspection, an internal chemical indicator is placed inside the package, and an external chemical indicator is used to differentiate between clean and sterile instruments. The package is labelled with its contents, expiry date, sterilization date, and load number for easy identification.

High-level Disinfection or Sterilization, depending on the requirements of the medical devices, is performed before and/or after packaging. This procedure involves all surfaces of the devices being immersed in the disinfectant, adhering to the recommended contact time. Instruments do not require high-level disinfection or sterilization. For sterilization, healthcare professionals use steam sterilization as the preferred method for heat-stable devices. Low-temperature methods such as ethylene oxide, gas plasma, or hydrogen peroxide are used if steam sterilization is not an option. Sterilization is validated through monitoring and documentation of process indicators, including physical parameters (time, temperature, and pressure), internal and external chemical indicators for each package, and biological indicator tests performed daily.

Finally, in the Storage step, instruments are stored in a dry, clean, and dust-free environment with no water tapping or drain points. Packages should be kept off the floor and away from walls and ceiling to avoid contamination. Ideally, the storage room's temperature should be maintained between 15°C and 25°C, with humidity between 40% and 50%. Regular checks of the expiry dates of sterilized instruments are performed to ensure their effectiveness when used.

Single-use devices (SUDs) represent a special case in this context, with WHO discouraging their reprocessing, stating that SUDs should strictly adhere to the manufacturer's recommendations and they should never be reused. In fact, these items usually did not undergo thorough sufficient testing, validation, and documentation to guarantee their safety for reprocessing and reuse. Nevertheless, the reprocessing of SUDs in general is not forbidden, and scientific community has developed a system to classify the potential risk deriving from reprocessing medical devices.

Classification	Definition	Decontamination method	Examples
High risk (critical)	Medical devices involved with a break in the skin or the mucous membrane, or surgically invasive medical procedures.	Sterilization	Surgical instruments, delivery sets, dental instruments
Intermediate risk (semi-critical)	Medical devices not involving penetration of tissues, items in contact with mucous membranes or non-intact skin.	High-level disinfection	Respiratory and anaesthetic equipment, reusable vaginal specula, endoscopes
Low risk (non-critical)	Items in contact with intact skin only	Low-level disinfection (i.e., cleaning with detergent and disinfectant).	Blood pressure cuffs, stethoscopes, and electrocardiogram lead.

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The reprocessing of medical devices in Europe is regulated by the European Union's Medical Devices Regulation (MDR) [4] with its main contribution coming from the ISO 17664:2017 - Processing of health care products. National authorities can of course add additional requirements to the reprocessing procedures in a way that the result is comprehensively guaranteed and the safety and health of patients, users and third parties is not endangered. For example, the German Commission for Hospital Hygiene and Infection Prevention divides medical devices in three groups. Especially high requirements (DIN EN ISO 13485, 14971, 17664) are needed for Group C devices, including those in which the efficiency of the cleaning procedure cannot be directly evaluated by means of inspection or those which effects of reprocessing on the device influencing functional safety cannot be excluded or those for which the number of uses or the number of reprocessing procedures is limited by the manufacturer. Other countries like Austria, France, and Switzerland fully prohibit the reprocessing of SUDs.

Regarding Botswana, the "Botswana Medicines Regulatory Authority" (BOMRA) has not yet provided specific legislation on reprocessing of medical devices thus implicitly allowing it.

2.2.2. Adjacent Sector: Prefabricated and Modular Building

Prefabrication and modular construction are building methods that allow to produce structures in a factory and transport them in a construction site to finalize the assembly. To clarify, modular construction is a particular type of prefabrication which involves 2D or 3D structures (called modules) manufactured in a factory and then transported on a site for installation. Prefabrication covers different categories of structures, such as modular, panelised and hybrid construction. Therefore, all modular buildings are prefabricated, but not all prefabricated buildings are modular.

The market of these construction methods has been constantly growing in the recent years, since they provide several advantages:

- Possibility to automatize the production of structure components in the factory.
- Facilitate the manufacturing process standardizing the overall structures design.
- A fast construction.
- Reduced risk of construction, reducing the time spent at construction site and facilitating the monitoring of unsafe activities.
- Limited noises and reduced impact of the construction site on the urban environment.
- Less complexity of the construction.
- Recycling, reuse, circular economy, optimization of the use of materials.

Despite these advantages, the main disadvantage that this kind of construction methods have is the need of transportation of the prefabricated structures. The design of such structure has to also consider the transportation phase requirements and, as a consequence, module size can be limited. Moreover, the transportation cost could be higher and risky for the possibility of the structures to be damaged during the travel. Other disadvantages are the lifting and handling limitations on the design of such structures. In fact, the dimensions and weights have to be carefully designed in order to allow a practical and easy onsite installation.

The presence of qualified personnel is required on the construction site. Therefore, a well-established training course is needed to form about the operations for the construction and the regulatory to follow.

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Focusing on the manufacturing process, a common way to manufacture building modules is reported:

1. Material supply and management.
2. Floor framing and decking, wall framing.
3. Roof framing and mounting, interior partition installation, rough plumbing system.
4. Sheetrock and rough electrical and HVAC system (walls)
5. Sheetrock and rough electrical and HVAC system (ceiling) and insulation.
6. Exterior sheathing and rough cleanup.
7. Exterior sheathing and interior finishing (e.g. paint).
8. Finishing plumbing, electrical and HVAC systems and floor installation.
9. Windows and siding installation.

The previous phases are not the only way to build modules, since manufacturers could have different processes to be duly considered in the production line.

The market can be divided into commercial, healthcare, educational & institutional and other applications. More than the 70% of the global market is shared among commercial, healthcare and educational & institutional modular constructions. Therefore, an organisation selling the modular buildings for a specific application, could be interested in joining other applications to enlarge the number of customers.

Since MMM is producing healthcare modular building for the reprocessing of medical devices, other possible applications could be:

1. **Healthcare centres**: the rapid expansion of healthcare industry and the necessity of a fast and removable construction strategy make prefabricated building a valid option to create emergency buildings, laboratories, diagnostic centres among others.
2. **Commercial offices**: lots of large and small companies use temporary modular office space, both as temporary purpose and permanent building as satellite headquarters or administrative buildings.
3. **Educational facilities**: modular facilities can be used to easily accommodate the growth of the school district or to provide school facilities where is needed.
4. **Retail offices**: this kind of modular building allows companies to starting up or growing their business with a financially sustainable way.

Other common prefabricated and modular buildings are homes, storage buildings, portable medical labs.

Healthcare Centres

Modular construction of healthcare facilities has rapidly been adopted all over the world in the recent years in response to the COVID-19 pandemic. Therefore, various strategies and innovations have been studied to assure and optimize the availability of healthcare facilities for public hospital under emergency situation. The adoption of prefabricated systems allowed to speed up the process mitigating the health risks. All these research and industry efforts brought to several results and practical solutions improving cost and time efficiency for the design and production of such facilities. For an organisation already in the sector, producing a particular healthcare facility, such as MMM, could be easier to adapt the production

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to other types of facilities including infirmary, intensive care units, operating rooms, rehabilitation clinics, hospital extensions, emergency rooms, laboratories and diagnostic centres.

For what concerns the RUMED, this modular unit has to be capable of reprocessing medical devices following the step explained in Section 2.2.1. Therefore, the modular unit are composed of several areas:

- Entrance and corridors: these areas should directly lead to the staff changing areas.
- Staff changing rooms: changing rooms for men and woman must be provided.
- Office/administration rooms.
- Dirty area: an area to receive used devices physically separated by the clean areas.
- Disinfection and cleaning area.
- Preparation and packing area: once the devices have been cleaned, they can be handled safely and inspected, assembled, replaced and packed for sterilization.
- Sterilisation area.
- Sterile storing area: once the packs have been removed from the sterilizers, they can be stored in this restricted area.

RUMED has to be carefully designed to assure a correct use of the previously mentioned areas with all the needed equipment and machines, such as cleaning machines, sterilizers, packing tables, heating, ventilation and climate control, air compressor. The production of the modular unit could require 12 months and the installation 2 weeks.

The other healthcare centres follow the same production steps of the RUMED, but the design and equipment to integrate are obviously different. Therefore, the main differences between the several healthcare centres raise during the design phase considering the different requirements. The different healthcare facilities have to be designed with a different technical setup (electrical, plumbing, air conditioning and especially medical gases and water treatment). These technical setups are hidden “in the walls” and in the “ceilings” and can be very complex depending on the facility application. For example, RUMED, operating rooms (OR) and intensive care units (ICU) are more complex than laboratories. RUMED, operating rooms and ICU have high hygiene requirements and they need airlock systems to separate different areas and a more sophisticated ventilation system providing different pressure levels between different areas to prevent the spreading of germs and particles.

Focusing on the OR, the ventilation system is quite similar to the RUMED one, since it has to maintain constant air quality by eliminating aerosols and particles within the room and maintain certain air pressure between communicating rooms (positive pressure is required in the operating room). An OR requires at least an ISO Class 7 and, in some cases, also an ISO Class 5 (see Table 2). Moreover, ideally around 20 air changes per hour are recommended and high efficiency particulate air filters are mandatory in many countries. To prevent hypothermia in the patient the temperature in the OR is recommended to be between 24°C and 26°C, or not below 23°C. An OR module is composed by the following functional areas:

- Admission/reception and holding area: to receive patients and visitors to the unit with a constant control to ensure the security of the unit. This area could include:
    - Reception and waiting areas.
    - Interview room.

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- Staff station.

- Operating room area: to perform procedure on the patients. Several equipment is necessary in this area such as anaesthesia machine, surgical table, defibrillator etc.
- Support areas such as blood store, cleaners' room, storage areas etc.
- Recovery areas: to assist patients through the recovering process. It includes patients' beds, bays for blanket, clean and dirty utilities.
- Administrative and staff areas: offices are required to undertake administrative functions or facilitate research activities and appropriate changing room, toilets and showers shall be provided.

For what concerns the ICU, the usual requirements are a temperature range from 16°C to 25°C, recommended relative humidity of 40% to 60%, minimum 20 air change per hour and positive or neutral pressurization. An ICU is usually composed by the following functional areas:

- Entry/ reception/ waiting areas.
- Treatment areas: it includes patients' bed, bays, bathrooms and specific equipment for the procedure to perform on the patients. The room size should be sufficient to accommodate the equipment and the personnel.
- Support areas: biomedical workshop, laboratory facilities, storage area etc.
- Administrative and staff area: offices are required for administrative purposes and changing room, bathroom shall be provided.

All the healthcare facilities can be implemented in the modular design, duly considering the different requirement during the design phase since the production and installation follows almost the same steps. The specific equipment and areas of the facilities are other inputs to consider during the design phase. Concerning the production, the possibility to easily reconfigure the length and width of the modules could allow a fast reconfiguration of the production depending on the type of use of the building and so a parametrization approach should be integrated in the production line. Another fundamental aspect is the different legislation in different countries that could result in a higher production effort due to a more complex system, such as the fire protection one. Therefore, a rapid reconfiguration of the production is feasible for the modular building of healthcare facilities.

2.3. Demonstrator #2: FON

Fontana Group is a leader in luxury and sports car sector thanks to the strong expertise and ability to shape aluminium with ambitious styles and high-quality standards. The process chain includes the entire engineering and production process from the feasibility and design to dies manufacturing, including stamping of class A full body panels, outer and inner body parts and assembly of complete body in white sub-assembly of closures and fixed components.

To guarantee the customer the best service, Fontana Group gives importance to quality and demonstrates this by adopting high-level international standards, with rigorous and precise criteria. They implemented certified quality management systems and also obtained the certification for environmental, and safety as reported in Table 4.

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The company also adopted important measures on information protection and security by following the reference standards TISAX (Trusted Information Security Assessment Exchange), specific for the automotive sector.

Table 4: Fontana Group Certifications

Certification	Title
Certificate VDA-6.4:2017	Quality Management System - Production Equipment
Certificate IATF-16949:2016	Quality management systems — Particular requirements for the application of ISO 9001 for automotive production and relevant service part organizations
Certificate ISO-9001:2015	Quality management systems — Requirements
Certificate ISO-14001:2015	Environmental management systems — Requirements with guidance for use
Certificate ISO-45001:2018	Occupational health and safety management systems — Requirements with guidance for use

2.3.1. Automotive Standards

Focusing on the automotive sector, this section gives an overview of the fundamental standards and certifications to be considered to enable enhancement in the automatization processes. For what concerns, ISO 9001, ISO 14001 and ISO 45001, they are discussed in detailed in Section 2.1. The VDA 6.4 and IATF 16949 standards instead are described and discussed hereafter.

VDA 6.X Standards

The German Automotive Industry Association (Verband der Automobilindustrie – VDA [7]) consists of more than 600 companies involved in production for the automotive industry in Germany and, among the many activities, is dedicated to the development of methods and systems of quality management for the automotive industry. In particular, the VDA Quality Management Centre developed the VDA 6.X Standards for automotive organisations involved in serial production of parts, production of equipment or offering services in or for the automotive industry. Despite the VDA 6.X series groups several standards, certification is only possible for three of them:

- VDA 6.1 - QM System requirements for manufacturers with serial production
- VDA 6.2 - QM System requirements for service organisations
- VDA 6.4 - QM System requirements for manufacturers of production equipment

An overview of VDA 6 rules is shown in *Figure 3*.

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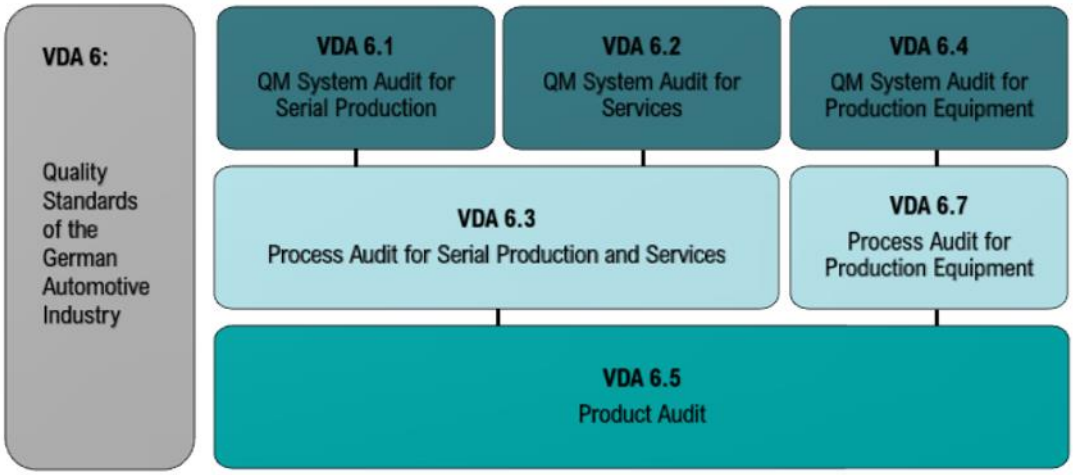

Figure 3: Overview of VDA 6 Rules

VDA 6.1

VDA6.1 was developed for organisations in the automotive industry that:

- manufacture cars, trucks, buses, motorbikes and other vehicles
- manufacture assemblies, production materials and spare parts for the above-mentioned vehicles

As stated before, it is an industry standard, not an ISO standard. However, it follows ISO 9001 adding additional requirements for the automotive industry. Therefore, a VDA 6.1 certification can be combined with an ISO 9001 certification if needed.

The organization that is certified VDA 6.1 undergoes to several benefits:

- Greater acceptance by automobile manufacturers
- Demonstration of the efficiency of the organisation
- Optimization of the processes and the supply chain
- Development of a strategic business plan and secured project management.

The VDA 6.1 requirements are stated as a catalogue of questions that includes for example:

- quality system requirements – quality policy (goals, customer satisfaction, improvement process), organization information (responsibilities, authorities, resources), business plan and others;
- quality system – procedures, documentation and others;
- design control – design and development planning, design inputs and output, design optimization and others.

VDA 6.2

VDA 6.2 was developed for service organisations in the automotive industry such as automotive traders, logistic companies, vehicle repairers and maintenance companies.

The organisation that obtained the VDA 6.2 certification has the same benefits of the VDA 6.1 and a higher attention to the relationship customer-supplier.

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It is a technical standard developed by considering ISO 9001:2015, such as the IATF 16949. However, specific additional requirements are inserted as for example:

- strategic short-term, medium-term and long-term business planning
- consideration of possible risks
- higher requirements placed on marketing and sales
- identification of customer and employee satisfaction (motivation)

VDA 6.4

VDA 6.4 was developed for organisation that manufacture production equipment for automotive industry, e.g., manufacturers of special machinery, toolmakers, test equipment. These manufacturers cannot be certified to VDA 6.1 or IATF 16949, therefore VDA 6.4 is a real alternative to fulfil the specific requirements through the supply chain. Moreover, the VDA 6.4 represents a supplement to the ISO 9001 certification with a higher level of demonstration of the quality of the management system.

It follows ISO 9001 with additional requirements that include:

- short/medium/long-term business plan
- financial and control reports
- process map design and specification
- additional requirements for marketing and sales
- product development
- customer support and service

IATF 16949

The International Automotive Task Force (IATF) [8] is an international "ad hoc" group of globally operating automotive manufacturers and their respective National Automotive Industry Associations. The IATF purposes are:

- the definition of international fundamental Quality Management System requirements
- to develop common policies and procedures for IATF third party registration scheme
- to provide training to support IATF 16949 requirements and registration scheme

IATF 16949:2016 is a standard that provides the requirements for an Automotive Quality Management System. It is based on the ISO 9001 with additional requirements related to the automotive sector and it replaced the ISO/TS 16949. For example, the additional requirements cover the design and development, production and installation services of automotive-related products. The IATF 16949:2016 has to be implemented as a supplement of the ISO 9001:2015 and can be used by any automotive supplier.

An organisation that obtains the IATF 16949 certification has the following benefits:

- Consistently meet customer expectations and comply with relevant laws, regulations, and product safety standards.
- Enhance customer satisfaction by effectively implementing the certified system.
- Clearly define the organization's overall context, identify stakeholders, and understand their expectations.

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- Increase customer retention, attract new clients, and expand business opportunities.
- Access new markets that require IATF 16949 certification for business engagement.
- Improve productivity and efficiency, leading to cost reduction.

As for the previous standards based on the ISO 9001, the IATF 16949 also requires some additional documents for its acquisition process. Some of them are:

- Documented process for the management of product safety related products and manufacturing processes
- Results of risk analysis
- Preventive action record
- Contingency plan
- Documented process for managing calibration/verification records
- Maintenance and calibration record
- Record retention policy

2.3.2. Adjacent Sector: Rail

For the transitioning process to the railway sector, there are many certifications that could be applicable, each playing a crucial role in making a company more reliable and trustworthy in the railway market. These certifications include:

- ISO 27001: Information Security Management Systems - Protects sensitive information and manages security risks in an increasingly connected and digitalized railway industry.
- ISO 50001: Energy Management Systems - Helps manage energy consumption, identify energy-saving opportunities, and promote sustainable practices in the railway sector.

There are then specific standards for the railway sector which are crucial to ensuring the safety, reliability, and compliance of systems and equipment used in rail transportation. Some of them include:

- ISO 3834: Certification for Welding Level CL 1
- ISO 25239-5: Certification for Friction Stir Welding
- EN 15085: defines the classification levels for welded components, the types of activity typically undertaken and the requirements to be fulfilled to demonstrate conformance.
- EN 50126 - "Railway applications - The specification and demonstration of Reliability, Availability, Maintainability and Safety (RAMS)" This standard establishes methods for assessing the risks associated with railway systems, including requirements for risk analysis, safety assessment, and risk management in the railway sector.
- EN 50128 - "Railway applications - Communication, signalling, and processing systems - Software for railway control and protection systems" This standard defines the requirements for the development of software used in railway systems, with a particular focus on safety.
- EN 50129 - "Railway applications - Communication, signalling, and processing systems - Safety-related electronic systems for signalling" This standard addresses the safety of train control and protection systems, establishing requirements for the design, implementation, verification, and validation of such systems in the railway sector.

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- EN 50155 - "Railway applications - Electronic equipment used on rolling stock" This standard specifies the technical requirements for electronic equipment used in rolling stock, including requirements for reliability, insulation, resistance to environmental conditions, and electromagnetic compatibility.

In addition to all these certifications, there is ISO/TS 22163, also known as IRIS, which is probably the most important one for transitioning to the railway sector. The International Railway Industry Standard (IRIS) [9] is a global system for the evaluation of rail sector companies. According to IRIS Certification® Conformity assessment:2020, the “rail sector” refers to the entire supply chain whose scope is the design, manufacture and maintenance of products used in railway applications. This is also extended to the entire supply chain of rolling stock, products for signalling and for infrastructures. Therefore, the ISO/TS 22163 or IRIS certification is fundamental to promote a greater quality image for all railway stakeholders, such as equipment manufacturers, system integrators, operators, and business partners.

ISO/TS 22163 can be considered as an upgraded and more specific version of ISO 9001, and is specifically tailored to the railway industry, covering various aspects of the rail supply chain, including design, manufacturing, and maintenance. It sets the standard for quality management system requirements in the railway sector. ISO/TS 22163 certification for railway sectors brings international recognition and enhances reputation worldwide and obtaining ISO increases a company's reputation by showcasing a commitment to meeting internationally recognized standards of excellence.

The IRIS standard comprises the ISO 9001 requirements and other additional requirements specific for the railway industry such as:

- Quality Management System: knowledge management, management of multi sites projects;
- Management Responsibility: customer relationship management;
- Resource Management: product design skills, employ motivation and empowerment, training and others;
- Product Realization: supply chain management, production scheduling, production documentation and others.

This standard requires 22 documented procedures, including 5 procedures for process performance evaluation, to be controlled thanks to KPI to monitor, analyse and improve the performances. The 22 mandatory IRIS procedures are listed in Table 5.

Table 5: IRIS Procedures

TS Section	Procedures	Note
6.1.3	Risk and opportunities	
7.1.1.1	Resources budgets	
7.1.5.3	Monitoring and measuring resources	
7.2.1	Competence	
7.5.3.3	Control of documented information	
8.1.1	Planning for the outsourcing of transfer of processes	

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8.1.2	Tender management	
8.1.3	Project management	Mandatory for process performance evaluation
8.1.4	Configuration management	
8.1.5	Change management	
8.2.5	Requirements for products and services	Mandatory for process performance evaluation
8.3.1	Design development of product services	Mandatory for process performance evaluation
8.4.1.1	EPPPS (Externally Provided Process, Product and Services)	Mandatory for process performance evaluation
8.5.1.1	Control of production and service provision	Mandatory for process performance evaluation
8.5.1.2	Special processes	
8.5.5.1	Post-delivery activities	
8.7.3	Control of nonconforming outputs	
8.8	RAMS/LCC (Reliability, Availability, Maintainability, Safety / Life Cycle Costing)	
8.9	First article inspection	
8.10	Obsolescence management	
9.2.3	Internal audit	
10.2.3	Nonconformity and corrective action	

To obtain an IRIS certification, it is mandatory to satisfy all the applicable requirements the assessment sheet and the IRIS Certification® Conformity assessment:2020 as shown in the scheme in *Figure 4* where IRIS Certification Technology (Audit-Tool, IRIS Portal and IRIS Certification database) is reported too. The IRIS Certification® Conformity assessment:2020 defines rules and procedures that must be followed in order to be awarded the certificate. IRIS Technology is necessary for awarding and maintaining the IRIS Certification scheme and supporting the companies for the audit.

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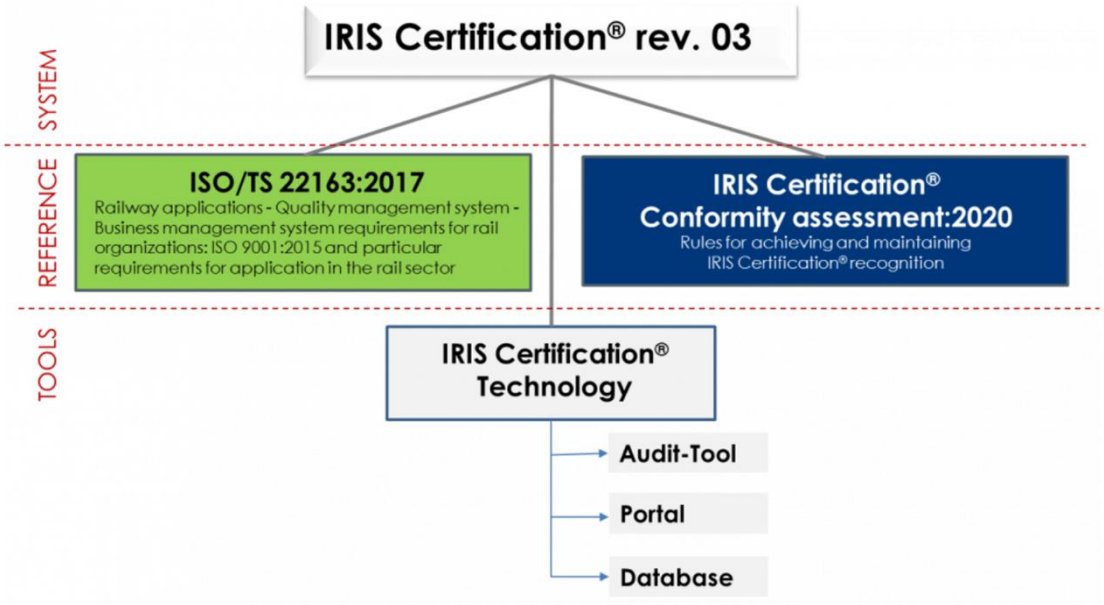

Figure 4: IRIS Certification Scheme [10]

In order to obtain the ISO/TS 22163/IRIS certification, a company must follow a structured process as shown in Figure 5. This process typically includes:

1. Registration for membership at the UNIFE portal
2. Pre-audits to verify potential gaps in compliance with the IRIS standard. In this phase, an initial review is performed to validate a set of pre-requisites (Readiness Review). The objective is to evaluate the adaptability of the Management System towards the objectives of the Certification.
3. Certification audit, including a documentation review and on-site assessment. A full on-site audit is performed to verify the compliance of the Quality Management System.
4. Implementation of necessary changes to address any gaps.
5. Issue of the certification. If the assessment has a positive outcome, the Certification is issued by the certifying body chosen by the company.
6. Annual supervision audits. During the three years following the issue of the Certification, periodic surveillance audits are performed (annually) with the aim of verifying the maintenance of the quality standards as per the Certification itself.
7. Recertification audit (after three years). After a period of three years, the Certification must be obtained again through the procedure described in the previous points.

The process to obtain the IRIS certification, which has been mandatory for sales in Europe since 2009, could last on average 6-12 months depending on the size of the organisation. The certification audit must be conducted on-site and at least 6 months of data and records relating to the activities covered by the IRIS Certification must be made available. Therefore, a rapid reconfiguration from the automotive to the rail sector covered by the IRIS certification is not feasible.

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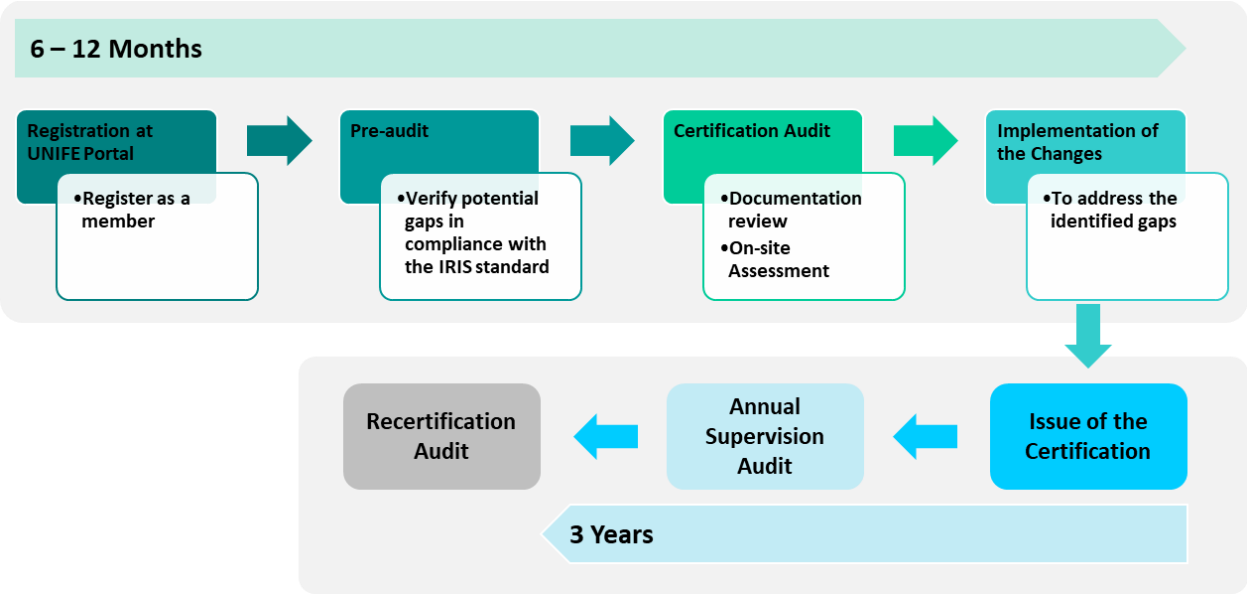

Figure 5: IRIS certification process example

2.3.1. Adjacent Sector: Aerospace

The aerospace sector is driven by technological innovation and advanced engineering in the field of aviation and space exploration. It encompasses the design, production and operation of aircraft, rockets, satellites, and spacecraft. Due to its complexity and strategic significance, aerospace is of high economic and scientific importance. The automotive and aerospace sectors both involve high-level technologies and rely on higher and higher quality requirements. There are several similarities between these two industries:

- Advanced engineering and materials design: both industries invest heavily in research and development to incorporate cutting-edge technologies and materials into their products. This includes advancements in aerodynamics, lightweight materials, and fuel efficiency.
- High-rate production: both sectors strive for efficient production processes to meet market demands, with large and complex supply chains emphasizing precision in the manufacturing process, in order to produce complex and specialized components.
- Integrated technologies: Both sectors rely on the integration of multiple systems and technologies to ensure optimal performance and functionality. This includes sophisticated electronics, control systems, and advanced sensor technologies.

Despite these similarities, there are also differences to consider allowing a fast and efficient transition from one sector to the other:

- Volume: The automotive industry typically involves high-volume production to meet mass market demands. In contrast, the aerospace sector often deals with lower production volumes due to the complexity and specialized nature of aircraft and spacecraft manufacturing.
- Time to market: The automotive industry often focuses on rapid product development and shorter timeframes to introduce new models or technologies. On the other side, the aerospace

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industry tends to have longer development and certification cycles due to stringent safety and regulatory requirements.

- Regulation: Automotive regulations cover vehicle safety, emissions, and fuel efficiency, while aerospace regulations focus on flight safety, air traffic management, and aircraft certification. Automotive regulations typically address a larger number of vehicles, while aerospace regulations are more specific and stringent.

A further comparison of the two sectors is reported in Table 6.

Table 6: Automotive and Aerospace sector comparison.

Element	Aerospace	Automotive
Systems and sub-systems	Complex multi-disciplinary structures managed with precision during the joint definition phase.	Competency-cantered approach with complex management and early supply chain engagement.
Electronics and embedded	Advanced technology for in-flight experience and instrumentation, offering a competitive advantage through connectivity.	Competitive edge with new technologies and connectivity.
Requirements	Complex contractual requirements.	Opportunities for introducing changes.
Materials	Composites and advanced alloys, including complex hybrid materials.	Lightweight materials like aluminium and composites.
Product life-cycle	Long life-cycles, improving with robust service management.	Shorter life-cycles, with frequent model-year introductions.
Security	Critical data access and security, especially in defence programs and compliance with ITAR regulations.	Limited data security across the supply chain

As for the other sector, the fundamental certifications needed to demonstrate an aerospace company is trustworthy are the following:

- ISO 9001: Quality Management Systems
- ISO 14001: Environmental Management Systems
- ISO 45001: Occupational Health and Safety Management Systems
- ISO 27001: Information Security Management Systems
- ISO 50001: Energy Management Systems

In addition, there are specific standards for aerospace organisations that enable them to grow in terms of efficiency, productivity and competence provided by the International Aerospace Quality Group (IAQG) [11].

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The IAQG is an international non-profit association whose purposes are to establish and maintain a dynamic and trusty cooperation between aerospace & defence companies and to continuously improve the supply chain efficiency, delivering high-quality products.

Among the several standards developed by the IAQG, the EN 9100, EN 9110 and EN 9120 are the fundamental ones that an aerospace organisation has to follow to achieve significant improvement in the quality management system. These standards are based on the ISO 9001, adding specific requirements regarding safety, reliability and aerospace navigation:

- EN 9100 - Quality Management Systems - Model for Quality Assurance in Design, Development, Manufacturing, Installation and Assistance
- EN 9110 - Quality Management Systems - Model for Quality Assurance for Aerospace Maintenance Organisations
- EN 9120 - Quality Management Systems - Requirements for Organisations that Distribute/Sell Parts, Components and Materials to Aerospace Customers

These certifications are not mandatory by law or government regulations. However, the EN 9100 certification is often required as condition of doing business with major aerospace, aviation and defence industries that exclusively pursue suppliers with the certification. Therefore, depending on the business an automotive organisation wants to reach the rapid reconfiguration to the aerospace sector could be feasible or not, since the certification process requires at least 3 months. In the following, these standards are discussed more in detail to help in the certification process.

EN 9100

The EN 9100 standard, also referred to as AS9100, is a globally recognized quality management system designed specifically for the aerospace industry. Building upon the ISO 9001 standard, it incorporates additional requirements and practices to meet the unique needs of aerospace manufacturers and suppliers.

EN 9100 certification is also considered a vital requirement which is imposed by aerospace industry Original Equipment Manufacturers (OEM) on their suppliers and subcontractors. It serves as proof of an organization's ability to meet essential quality standards and fulfil customer needs effectively.

Obtaining EN 9100 certification offers the multiple advantages for organizations operating in the aerospace sector. Here are the key benefits:

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Figure 6: EN 9100 specific requirements

EN 9100 introduces specific requirements that address the unique challenges and risks associated with the aerospace industry. These requirements include, but are not limited to:

- Product Safety: Rigorous identification and management of product safety risks throughout the product lifecycle.
- Configuration Management: Robust processes to control and document changes, ensuring product integrity and traceability.
- Risk Management: Comprehensive approach to identifying, assessing, mitigating, and monitoring risks specific to the aerospace industry.
- Supply Chain Management: Emphasis on supplier control and performance evaluation to ensure the quality and reliability of supplied components and materials.
- Continuous Improvement: Proactive measures to drive continuous improvement, including performance monitoring, root cause analysis, and corrective actions.

These additional requirements are reflected into the additional documentation that has to be provided in order to obtain the certification. Some of these are listed below:

- Process for control of non-conforming products and services
- Process for nonconformity and corrective action management
- Record of results of production process validation
- Operational risk management procedure
- Configuration management procedure
- Records of corrective actions

In Figure 7 the possible steps of the certification process are shown. The timeline to obtain the certification depends on the size of the company, smaller the company faster is the certification process. Generally, the implementation of EN 9100 could take up to 3 months for companies of 10 employees or even 20 months for companies with more than 200 employees.

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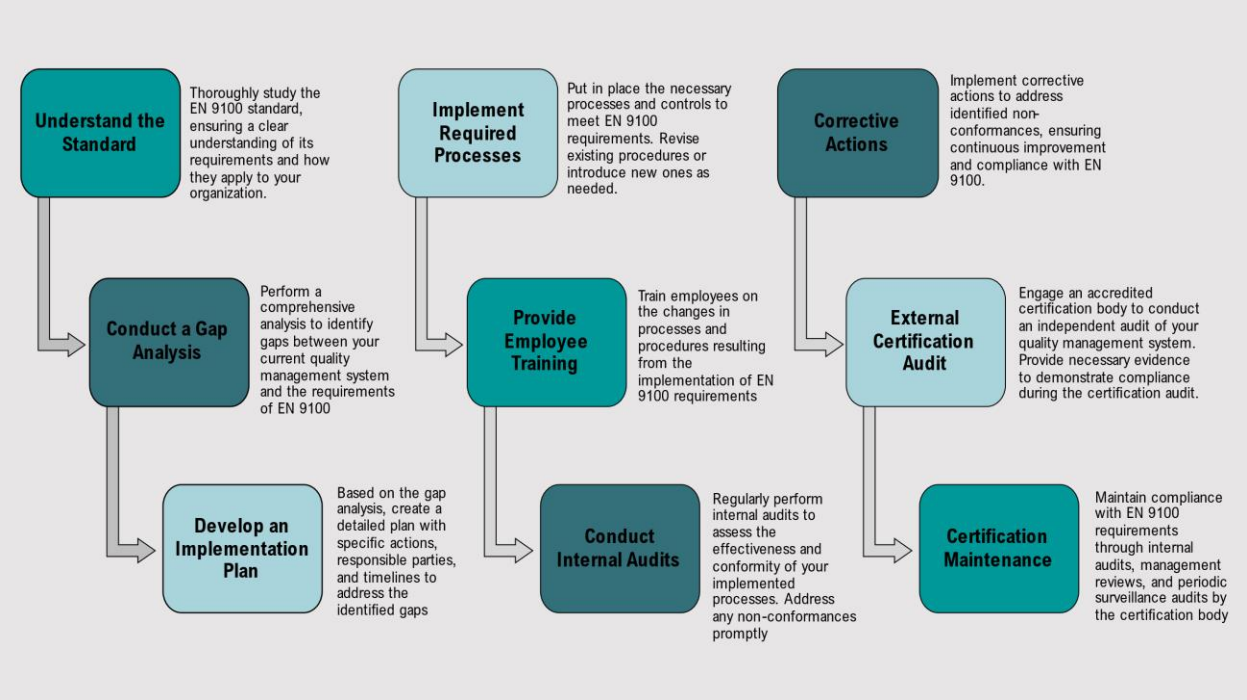

Figure 7: EN 9100 certification process example.

EN 9110

EN 9110 certification plays a critical role in the aerospace maintenance, repair, and overhaul (MRO) sector. The standard, also known as AS9110, is an industry-specific standard that establishes quality management system requirements for organizations operating in the aerospace MRO sector.

The EN 9110 certification ensures that companies involved in aerospace MRO activities meet essential quality standards and comply with customer requirements. This certification covers a wide range of areas in the aerospace supply chain, including maintenance, repair, and overhaul of aircraft, components, and associated equipment. By adhering to the EN 9110 standard, companies in the aerospace MRO sector can enhance their overall quality image and strengthen their reputation among various stakeholders, including equipment manufacturers, operators, and business partners.

Similarly, to other sector specific standards, EN 9110 builds upon the requirements of ISO 9001 and introduces additional criteria specific to the aerospace maintenance sector. These requirements encompass various aspects, including:

- Quality Management System: This includes knowledge management, multi-site project management, and ensuring effective customer relationship management.
- Resource Management: It covers aspects such as product design skills, employee motivation and empowerment, and comprehensive training programs.
- Product Realization: This encompasses supply chain management, production scheduling, meticulous production documentation, and other related processes.

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Acquiring EN 9110 certification involves a structured process very similar to the one needed for the acquisition of EN 9100.

EN 9120

EN 9120 is an aerospace industry standard that focuses on quality management system requirements for organizations engaged in aerospace distribution activities. It is tailored to the unique needs of aerospace stockist distributors and complements ISO 9001.

EN 9120 certification demonstrates an organization's commitment to meeting stringent quality standards in aerospace stockist distribution. It enhances supply chain efficiency, mitigates risks, and establishes a reputation for excellence in this specialized field.

The standard introduces over 100 additional requirements specific to distributors handling aircraft components like fasteners, electronics, gaskets, etc. It ensures proper handling of materials and accurate tracking of every part from OEM to customer.

Among the most differentiating factors and benefits of EN 9120 certification there are:

- ISO 9001 Complementarity: EN 9120 builds upon the foundation of ISO 9001, integrating its requirements for quality management systems. However, it goes beyond ISO 9001 by incorporating additional challenges and requirements specific to this sector, including inventory management, product handling, and traceability.
- Improved Supply Chain Efficiency: EN 9120 certification enhances the efficiency of the aerospace supply chain by ensuring robust stockist distribution practices. It helps organizations maintain accurate product traceability, manage nonconforming products effectively, and optimize inventory control processes.
- Streamlined Processes: The implementation of EN 9120 requirements encourages organizations to streamline their distribution processes. It promotes efficient stock management, effective product handling, and adherence to strict traceability standards, leading to operational excellence and cost savings.
- Risk-Based Thinking: EN 9120 emphasizes the importance of risk-based thinking by explicitly incorporating it into the entire management system. The standard ensures that risk is considered from the initial stages and throughout the organization's operations. It integrates risk prevention into strategic and operational planning, including factors such as new customers, new markets, company partnerships, business localizations, and other relevant aspects.
- Counterfeit Parts Prevention: the standard includes specific requirements to mitigate the growing threat of counterfeit and fraudulent products. It acknowledges the emerging counterfeit/fraudulent statutory and regulatory requirements on aerospace quality management system (AQMS) processes. The standard provides guidelines and measures to prevent the use of counterfeit parts, safeguarding the integrity and reliability of aerospace components.
- Product Safety: strong emphasis is put on product safety considerations throughout the entire product lifecycle. The standard includes requirements to address and prioritize product safety, ensuring that potential hazards and risks are identified, assessed, and mitigated effectively.

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2.4. Demonstrator #3: KAR

Karwala is a European leader for car child seats, strollers and spare part for such applications and guarantees high-quality solutions thanks to the many years of experience and the continuous effort in the development of new designs, creating and producing new injection moulds.

Injection moulding is one of the main processes in Karwala production chain. This process is one of the most common and important processes in plastic components production since it is versatile and capable of mass-producing complicated plastic-parts with a high level of precision. Injection moulding industry covers three stages: mould design, mould making and the injection moulding process. In particular, the process consists in simple steps (also shown in Figure 8): melt the plastic through an injection melting machine, flow the melt into the mould that defines the shape, cooling and solidification of the plastic into the product, extract the product.

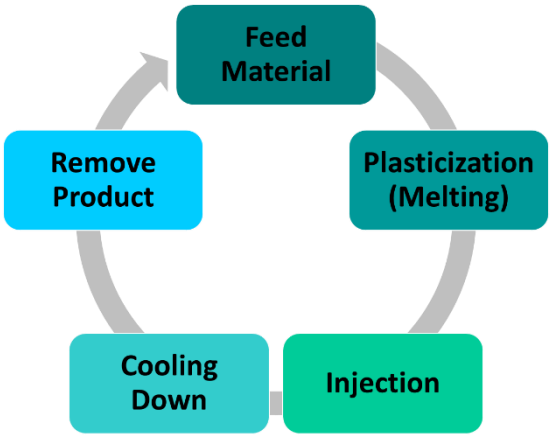

Figure 8: Injection moulding steps

Despite the simple steps, the interactions between production assets and setting parameters is quite complex and, as a consequence, defining an optimal operation point in a specific machine is challenging. The operation point of the machine is influenced by several setting parameters such as the processing temperature, the volume flow, the switching from the injection phase to the holding pressure phase. Moreover, the performance of a machine is instable due to the fact that each machine is unique and the machine condition changes in time when the production proceeds. Therefore, the quality of the moulded parts could not be consistent.

A constant data acquisition from sensors and statistical analyses are required to understand how to set the parameters to operate the machine in the optimal point and get high-quality products. Therefore, the development of a digital twin able to constantly analyse data could allow automatically to satisfy quality requirements.

For what concerns the standards, the organisation demonstrates its attention to quality by obtaining the following certifications:

- ISO 9001-2015 certification for Quality management System

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- AGR seal of approval: awarded by AGR (Aktion Gesunder Rücken) to verified back-friendly products after the verification of a testing committee made of experts from several medical discipline.

Moreover, the child seats are produced according to the ECE Regulation N° 44 (ECE-R-44) or N° 129 (ECE-R-129) to ensure the greatest possible safety. In order to be granted ECE approval important requirements must be met, for example regarding weight class, body size, frontal-, rear- and side- impact, construction and production conformity standards.

2.4.1. Child Seats and Injection Moulding Standards

Focusing on the child seats production, this section gives an overview of the fundamental standards and certifications to consider. For what concerns, ISO 9001, ISO 14001 and ISO 45001 are discussed in Section 1. AGR seal of approval and ECE Regulations, and injection moulding standards are discussed hereafter.

AGR

The Aktion Gesunder Rücken (AGR) or Campaign for Healthier Backs is a German association for healthier backs, whose objectives are to promote research related to back pain prevention and to share the knowledges acquired from the research. It is strictly linked to numerous medical professional associations. They are an independent body of experts (doctors, therapists and other specialist) that test the product to verify the actual prevention of the back pain. Only with their agreement the AGR can award to back-friendly products the "AGR seal of approval".

The AGR activities are widely accepted in the medical world. Therefore, a manufacturer obtaining for a product the "AGR seal of approval", demonstrates to the customers the product is high quality and back-friendly. To be awarded, a manufacturer has to follow these steps:

- Apply to AGR with an informal letter and a completed questionnaire
- Discuss with the AGR the steps to test the product
- The product has to be tested by medical association (an independent committee of doctors and therapist)
- Present the mode of action of the product and provide evidences
- Enter into a contract with the AGR

After all the previous steps, a manufacturer can use the quality steal on the tested product.

ECE Regulation

The United Nations European Commission for Europe (UNECE, abbreviated ECE) is a regional commission composed mainly by European State. The ECE has the objective to stimulate economic and social development in Europe and in doing that it cooperates with organisations to provide regulations related to economic, technical and environmental fields.

In particular ECE-R-44 [12] and R-129 [13] are developed for child restraint systems for installation in vehicles. ECE establishes a number of relevant standards for design, construction and manufacture that the products have to follow for approval and comply with European safety standards. Currently, it is

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allowed to use either R-44 or R-129 car seat, but the R-44 car seat is going to be prohibited from September 1st 2024.

The ECE-R-44 groups the child restraint system into five weight groups. Meanwhile, the Regulation No. 129, called "i-Size" systems, classifies the child restraint system in accordance with the size of the child. Classifying the child seat with the length of the child ensures a better safety with respect to the weight classification. Moreover, R-129 introduced more requirement for head and neck protection and also side-impact crash test results are required.

Injection Moulding Standards

As stated before, injection moulding is one of the most important processes in the massive production of plastic product. There are several standards that covers the three stages of injection moulding industry, standards for the mould design and production, moulding compounds and the injection moulding process. Some of the ISO standards for injection moulding industry are reported in Table 7.

Table 7: Injection moulding standards

Standard	Title
ISO 20457:2018	Plastics moulded parts — Tolerances and acceptance conditions
ISO 2818:2018	Plastics — Preparation of test specimens by machining
ISO 15252:1999	Plastics — Epoxy powder moulding compounds (EP-PMCs)
ISO 14529:1999	Plastics — Melamine/phenolic powder moulding compounds (MP-PMCs)
ISO 16916:2016	Tools for moulding — Tool specification sheet for injection moulds
ISO 10072:2004	Tools for moulding — Sprue bushes — Dimensions
ISO 8693:2011	Tools for moulding — Flat ejector pins
EN 201:2009	Plastics And Rubber Machines. Injection Moulding Machines. Safety Requirements
EN 289:2014	Plastics and rubber machines - Presses - Safety requirements
EN 1114-1:2011	Plastics and rubber machines. Extruders and extrusion lines Safety requirements for extruders
EN 1114-2:2008	Plastics and rubber machines. Extruders and extrusion lines Safety requirements for die face pelletisers
EN 1114-3:2019	Plastics and rubber machines. Extruders and extrusion lines Safety requirements for haul-offs
EN 1417:2014	Plastics and rubber machines. Two-roll mills. Safety requirements
EN 12012:2018	Plastics and rubber machines. Size reduction machines Safety requirements for blade granulators and shredders

2.4.2. Adjacent Sectors

The expertise and the capability to design injection moulds could allow Karwala, or an equivalent organisation, to make an easy transition to sectors linked to such types of production processes:

- **Automotive**: not only for child seats, but also for the production of car interior (air vents, interior surfaces, instruments) and exterior plastic parts (light housings, fenders, bumpers, door panels)
- **Rail**: train seats, safety signs, pipes and fitting.

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- **Food and beverage**: products to process and store food and beverage. These products must meet high Food and Drug Administration (FDA) standards.
- **Consumer goods**: toys, equipment housing, cell phones cases and others
- **Medical industry**: beakers, test tubes, surgical tools, syringes and others.

The transition to one of the possible listed adjacent sectors makes necessary the integration of new suppliers for the raw materials. A non-exhaustive list of common materials with possible applications is reported in Table 8. Further information for the transition and the standards is discussed hereafter, except for the automotive and rail sector already discussed in Section 2.3. For the transition to the rail sector the IRIS certification is mandatory and as a consequence a fast reconfiguration is not feasible. Meanwhile, for the transition to the automotive sector at least the IATF is strongly recommended since many suppliers are asked by car manufacturers to be certified as minimum requirement. However, business opportunities are possible, even if limited, without the IATF certification and so a fast transition to the automotive sector could be feasible.

Table 8: Injection moulding materials with possible applications

Material	Automotive	Railway	Food and Beverage	Consumer Goods
Acrylonitrile butadiene styrene (ABS)	Bumpers, dashboards, door panels, steering wheels, gear shifters	Train seats, handrails, window frames	Food containers, cups, cutlery	Toys, cell phone cases, electronic devices
Polyamide (PA)/ Nylon	Gears, bearings, seals, hoses	Train wheels, train seats	Food containers, bottles, cups, cutlery	Appliance housings, cell phone cases, electronic devices
Poly (methyl methacrylate) (PMMA)	Headlights, taillights, instrument panels, sunroofs	Train windows, headlights, taillights	Food containers, bottles, cups, cutlery	Toys, eyewear, medical devices
Polypropylene (PP)	Fuel tanks, oil pans, air intake manifolds	Train seats shells, safety signs, window frames	Food containers, bottles, cups, cutlery	Toys, bags, packaging
Polyurethane (PU)	Bumpers, dashboards, door panels, steering wheels, gear shifters	Train seats, cushions	Food containers, bottles, cups	Mattresses, pillows, shoes, foam insulation
Polyvinyl chloride (PVC)	Fuel tanks, oil pans, air intake manifolds	Pipes and fittings	Food containers, bottles, cups, cutlery	Toys, bags, packaging, raincoats
Polycarbonates (PC)	Headlights, taillights, sunroofs	Train windows, headlights, taillights	Food containers, bottles, cups, cutlery	Toys, eyewear, medical devices, watches
Polyethylene (PE)	Fuel tanks, oil pans, air intake manifolds	Pneumatic Tubes for Pantographs, Bearings	Food containers, bottles, cups, cutlery	Toys, bags, packaging

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Polystyrene (PS)	Headlights, taillights, instrument panels, sunroofs	-	Food containers, bottles, cups, cutlery	Toys, packaging
Polyethylene terephthalate glycol (PETG)	Displays, windshields	Security signals	Food containers, bottles, cups, cutlery	Toys, bags, packaging, 3D printing material
Thermo Plastic Elastomers (TPE)	Bumpers, dashboards, door panels, steering wheels, gear shifters	Train seats, handrails, window frames	Food containers, bottles, food processing equipment	Toys, sporting goods, furniture

Food and Beverage Packaging

Food packaging and packaging materials are fundamental elements to provide safe and nutritious food to the consumers that nowadays are finding more and more refrigerated and other prepared foods. Therefore, several regulations have been developed to ensure that packaging and contact materials protect food against any form of contamination and microorganisms, preserving the physical, chemical and health integrity of the products.

About 50% of Europe's food is packed in plastic packaging, because plastics offer a wide range of properties and performances perfect for that purpose, such as:

- Flowability and mouldability.
- Usually chemical inert.
- Cost effective.
- Light weighting.

Plastics are used as containers (such as bottle, jars and others) or films in the form of bags, lids and caps. Therefore, the market of plastic packaging is quite large and the transition in this sector can be very economically advantageous. In order to join this market, raw materials suppliers and regulations have to be duly taken into account.

Some types of plastics used in food-packaging are listed hereafter:

- Polyethylene – PE
- Polypropylene – PP
- High-Density Polyethylene – HDPE
- Polyethylene Terephthalate – PET or PETE in some markets
- Polyethylene Terephthalate Glycol Copolyester – PETG
- Polyvinyl Chloride – PVC
- Polystyrene – PS
- Styrene-Butadiene – SB
- Polymethylpentene – TPX
- High Nitrile Polymers – HNP

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In Europe, PE constitutes the biggest slice of the market, followed by PP, PET and PS.

Focusing on the manufacturing of plastic packaging, and in particular on manufacturing through injection moulding, the possible plastics that can be used are the following:

- PP: it is used to realize pots for yogurt, ice cream, butter and margarine. Another typical application is the realization of closures for bottles and jars.
- HDPE: this material is exploited in different types of packaging, but its main use is for milk containers.
- PET: the main application of this material is in the production of bottles for mineral water and beverages
- PS: utilized for a wide range of packaging
- SB: with this material, packaging with high resistance and transparency similar to glass are realized
- TPX: this material is used in applications requiring high chemical resistance and transparency.
- HNP: this material is exploited to realize the inner layer in blow-moulded bottles co-extruded with HDPE.

Considering the raw materials listed before, integrating new supplier could be necessary to join the food packaging market.

In the European Union the minimum requirements applicable to most types of packaging materials, are defined by the Regulation 1935/2004/EEC, such as:

- Safety.
- Produced with good manufacturing practices, consistent with the requirements of Regulation 2023/2006/EC.
- Traceability through the production chain.
- Do no alternate the chemical composition of the food, taste and odour.
- Bear the EU's "glass-and-fork" symbol or certify the compliance with the requirements.

A great contribution in terms of quality and safety for food packaging comes from the Brand Reputation Compliance Global Standard (BRCGS) [14] organization that develops standards GFSI benchmarked (Global Food Safety Initiative). BRCGS was founded in 1996 to harmonise the food safety standards across the supply chain. This organization defines several standards that help companies demonstrating the quality and safety of their products through the application of quality/product management systems, hygienic control (HACCP) and good manufacturing practices (GMPs). Indeed, the BRCGS Packaging Materials is globally considered an industry benchmark and it is not only used by food packaging producers but also for other packaging applications. It is applicable for operations, such as, production and supply of packaging materials and manufacturing and supply of other unconverted or semi-converted and used or incorporated packaging materials. It is a standard for the hygienic and sanitary safety of food packaging, materials in contact with food or other packaging uses.

Therefore, becoming BRCGS Packaging Materials certified is an important step for an organisation bringing several benefits:

- Prove that the necessary safety precautions have been taken.

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- Comply with the current hygiene regulations.
- Improve organisation reputation, image and relations with food safety authorities.
- Improve food safety, operational efficiency, commercial growth.
- Get access to the BRCGS Service Package (suite of tool to improve performances).
- Integrate the requirements of BRC Packaging with other industry certifications.

In order to obtain the certification, a BRCG registered Certification Body has to be contacted to perform the audit and register the BRCGS certification. It is possible to download the self-assessment tool from the BRCG Help and Guidance page and preliminarily measure the organisation operations against the requirements of the Standard. This procedure helps the organisations to prepare the certification audit. A not exhaustive list of requirements of the Standard is listed hereafter:

- The company that must be subjected to the Audit must be characterized by an internal organizational structure that provides adequately effective communication lines, to be able to guarantee the quality of the products, with particular attention to the regulatory, legal and safety-related aspects.
- A specific Team must be in place within the company to deal specifically with aspects related to risk and hazard assessment.
- A hazard management and risk assessment System must be in place within the company to ensure the identification of specificities related to product quality, regulatory, legal and safety aspects.
- A detailed description of the product must be included, aided by the use of graphical methodologies such as flow graphs. The information that must be reported may vary from case to case, but, as a guide, there must be information on the composition of the product, the origin of the raw materials and the intended use of the packaging.
- Specifications regarding raw, intermediate, and finished material must be present, declined in order to allow the assessment of quality, integrity and regulatory aspects.
- The company must possess and be able to show documentation relating to its suppliers of materials, subcontractors and outsourced processes.

To be prepared and ready for the audit process, the QMS has to be compliant with the standard and 3 months of records must be available. All the needed implementations could require more than three months (generally 12 months) therefore a fast reconfiguration to the food packaging sector could not be feasible also because the BRC certificate is one of the main supplier selection criteria.

Consumer Product

Consumer products are products that people buy for their own use. Injection moulding is widely used for the production of such products since, for example, it allows to create identical plastic products for children's toys, or components for electronic devices (i.e., cell phones cases).

For what concerns the consumer products, the European Commission approved the new General Products Safety Regulation (EU) 2023/988 [15] in May 2023. This Regulation has the objective to improve the functioning of the internal market while providing for high level of consumer protection, laying down rules on the safety of the products.

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This Regulation will be effective in December 2024 replacing the General Product Safety Directive 2001/95/EC which has been revised to update the safety in non-food consumer products. The following are some of the main points introduced:

- Hazards of the new technologies.
- Safety for the products sold online, including a specific article (art 22) for the online marketplace.
- A European standard drafted in support of the Regulation.

Focusing on specific products, there are standards and regulations to carefully consider for their production.

Toys

Plastic is a perfect material for manufacturing toys since it is lightweighting, colourful, strong and mouldable. Therefore, injection moulding is widely used for the production of toys and toys parts, allowing to realize products with high level of quality and details. This process allows compliancy with the tolerances of toy industry demanding higher and higher quality in terms of appearance and play experience. Moreover, injection moulding is environmentally friendly since it allows to waste very little amount of material.

A company whose main production process is injection moulding can therefore easily join the Toy Industry. Since the products must be safe to use for children, companies manufacturing toys must be compliant with the European Toy Safety Directive (TSD) 2009/48/EC [16], which aims at establishing minimum safety standards for toy features, flammability, substances, documentation and others. The TSD formulated the EN 71 standard to ensure the safety of children toys and prevent harmful products to enter in the European market.

The EN 71 is composed of the following parts:

- EN 71-1: Mechanical and physical properties
- EN 71-2: Flammability
- EN 71-3: Specification for migration of certain elements
- EN 71-4: Experimental sets for chemistry and related activities
- EN 71-5: Chemical toys (sets) other than experimental sets
- EN 71-6: Graphical symbols for age warning labelling
- EN 71-7: Finger paints
- EN 71-8: Swings, slides, and similar activity toys for indoor and outdoor family domestic use
- EN 71-9: Organic chemical compounds – Requirement
- EN 71-10: Organic chemical compounds – Sample preparation and extraction
- EN 71-11: Organic chemical compounds – Methods of analysis
- EN 71-12: N-Nitrosamines and N-Nitrosatable Substances
- EN 71-13: Olfactory board games, cosmetic kits, and gustative games
- EN 71-14: Trampolines for domestic use

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A manufacturer and supplier can be EN 71 certified if the company has tested its product and is able to ensure it satisfies the requirements defined in the standard. The EN 71 certification covers the 14 parts of the standards, meaning all the tests have been successfully passed. For example:

- The EN 71-1 requires that the toys do not collapse or have sharp point or edges during the test. Therefore, some of the test to be conducted are pressure test, bending test, impact test or sharp edge test.
- The EN 71-2 reports the prohibited flammable materials. Additionally, it defines the requirements of burning time and speed for the usable materials.
- The EN 71-3 defines the tests to simulate the digestion of any toy part.

The tests are conducted on 2-3 samples by a third-party company that issues a test report once all the tests are completed. Obtaining the EN 71 certification allows to demonstrate the quality and safety of the products, to gain reputation and competitive advantage and to improve customer reliability.

Moreover, the *Registration, Evaluation, Authorisation and Restriction of Chemicals* (REACH), a European Union regulation, establishes a mandatory registration system for chemical substances to trace chemical substances in goods sold in Europe. Toys industries must follow the regulation to reduce the risks associated with certain hazardous substances (lead, cadmium, mercury).

The compliance with the EN 71 and the REACH regulation allows to affix the CE marking to the product, that is mandatory to sell toys in Europe. Therefore, due to the necessity of conducting the tests for safety a fast reconfiguration to the toys production could not be feasible.

Components for Electronic Devices

Another important market for companies dealing with manufacturing through injection moulding is the electronics sector, significant user of high-performance thermoplastic and thermosetting polymers. Even without going into elaborate reconfigurations of production chain to adapt to the very high standards for manufacturing of hardware involving active electronics and circuits, there is a still huge slice of market for components of electronic devices not needing advanced electronic competences. A lot of consumer goods products for the electronics sector is in fact made of plastics, which is often considered of elevate utility for its capability to interface with electronic products safely. Some of the most appreciated characteristics are its electrical and heat insulation capabilities, lightweight, durability, cost, freedom of design and energy efficiency. Among these daily-use products we can list:

- CDs and DVDs, having among others a polycarbonate plastic substrate and a clear protective coating of acrylic plastic.
- Headphones and earphones, made of PVC, polyurethane, memory foam and others.
- Computer mouses outer shell and most of its internal mechanical parts are typically produced with ABS.
- Computer housings and cases, usually manufactured with HDPE, acrylic, PVC, polypropylene, ABS, SEBS or polyamide.
- Keyboards, usually made of polyethylene, polypropylene, PET, PVC, and others.
- Smartphone cases, typically made of polycarbonate, TPU or polypropylene.
- Connecting cables outer jacket, produced with PVC, polyurethane, polyethylene or TPE.

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As other markets described within this document, the production of consumer goods for electronics is also regulated by international standards in order to ensure that information technology equipment is safe to use and does not pose any significant risks to users, operators, or the environment during normal operation and foreseeable misuse. Some major examples are described followingly.

ISO 15270:2008: this standard provides specific guidelines and specifications covering plastics waste recovery, including recycling. The standard establishes the different options for the recovery of plastics waste arising from pre-consumer and post-consumer sources. It also establishes the quality requirements that should be considered in all steps of the recovery process.

IEC 62321 specifies the testing and determination of hazardous substances, including heavy metals and flame retardants, in electrotechnical products.

IEC 62474:2018 outlines the process, content, and format for material declarations required from companies involved in the electrotechnical industry, allowing them to assess products for compliance with substance restriction requirements.

ISO/TC 61: this standard provides guidance when dealing with plastics and plastic products, covering various aspects such as terminology, classification, test methods, specifications, and guidelines for the use of plastics in different industries and applications. In particular **ISO/TC 61/SC 11** deals with the standardization of plastics and other polymeric materials used in electrical and electronic equipment. This includes materials used in various components, insulating materials, cable sheaths, and other applications within the electrical and electronics industry. Subsections of this standard provide specific guidance regarding:

- Electrical insulating materials for cables and wires.
- Plastics used in electronic components like connectors, insulators, and enclosures.
- Materials used in printed circuit boards (PCBs) and flexible circuits.
- Flame-retardant plastics for electrical and electronic equipment.
- Environmental aspects of plastics used in electronics, such as recycling and end-of-life considerations.

Although not explicitly tailored for plastic components, the most important standard in this specific subsector is probably **ANSI-UL 62368-1**, specifically designed to address the safety requirements of information technology equipment, covering a wide range of electronic products. The standard is developed by Underwriters Laboratories (UL), a globally recognized organization that conducts safety testing and certification for various industries.

The main objective of ANSI-UL 62368-1is to ensure that information technology equipment is safe to use and does not pose any significant risks to users, operators, or the environment during normal operation and foreseeable misuse. It sets forth requirements related to electrical, mechanical, thermal, and fire safety aspects of electronic devices, including those with plastic components.

Key aspects covered by ANSI-UL 62368-1include:

- Electrical safety: requirements for insulation, electric shock protection, protection against electrical hazards, and proper grounding of the equipment.

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- Fire safety: the standard addresses the flammability and fire resistance properties of materials used in the construction of the equipment, including plastic parts.
- Mechanical safety: requirements for structural integrity, protection against sharp edges, and appropriate marking and labelling are included to ensure the safety of users during handling and operation.
- Energy hazards: ANSI-UL 62368-1 covers potential hazards related to energy sources used in the equipment, such as power supplies and batteries, to prevent injuries or accidents.
- Thermal safety: The standard specifies temperature limits for various parts of the equipment to prevent overheating and potential fire hazards.
- Radiation and emissions: Requirements for electromagnetic radiation and emissions are outlined to ensure compliance with relevant regulations and to prevent interference with other devices.

Compliance with ANSI-UL 62368-1is typically a prerequisite for the manufacturer to obtain the UL safety certification mark, which signifies that the product has been independently tested and meets the safety requirements set forth by the standard. Additionally, UL safety certification is widely recognized and accepted by regulatory authorities and consumers worldwide, enhancing the marketability and trustworthiness of the products.

Medical Industry

Medical Industry makes a large use of injection moulding to produce, for example, beakers, test tubes, surgical tools, syringes and others. The medical device industry has to follow several standards to ensure the patient safety. First of all, the Medical Device Regulation 2017/745 is fundamental to assess the conformity of medical devices with the scope of improve quality, safety and reliability on the European market. Therefore, manufacturers have to follow medical industry standards to ensure quality, performance and safety and also to be able to select the right materials for the production of equipment that are biocompatible or that can withstand a sterilization process. Injection moulders must define stringent processes and procedures during the production to guarantee the compliance with the standards. Therefore, a fast reconfiguration to the medical sector could not be feasible, also because several tests to evaluate the safety of the products are required, as explained in the next paragraphs.

Focusing on the materials, some common injection moulding plastics used for medical devices are listed below:

- PE: Polyethylene is used in the development of medical devices due to its biocompatibility
- Silicone: this material is biocompatible and is particularly useful in moulding processes because the process itself takes place at relatively low pressures
- PP: polypropylene is a material characterized by excellent resistance to humidity, it is biocompatible and can be steam-sterilized due to its high thermal resistance
- PC: polycarbonate is used in the production of materials instead of glass, due to its transparency and high temperature resistance. This last condition also makes it particularly suitable for sterilisation.
- PFA: This material is particularly performing at high temperatures, has relevant creep resistance and chemical resistance.
- PEEK: due to its performance in terms of chemical, heat and radiation resistance

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The selection of the materials is highly regulated by international standards such as the ISO 10993 that sets a series of requirements and procedures to evaluate the biocompatibility of materials or medical devices, facilitating the evaluation of possible alternatives or the choose of reliable suppliers.

Other common standard to consider in the medical device industry are ISO 13485 – Medical Devices and ISO 14644 – Cleanrooms & Associated Controlled Environments that highly affect the manufacturing process, including injection moulding.

In the following sections, more details about the mentioned standards are given.

ISO 10993 – Biological Evaluation of Medical Devices

The manufacturer of medical devices that come into contact with the human body has to test the products following the procedures and the requirements defined in the ISO 10993. The objective of the standard is to reduce the risk of adverse effect on the patients exposed to materials or medical devices. The standard consists of several parts that include animal welfare requirements, tests procedures for genotoxicity, carcinogenicity and reproductive toxicity, in vitro cytotoxicity and various sterilization techniques.

Food and Drug Administration (FDA) developed a guidance document to assist organisations in the evaluation of the biological effect of their products. The FDA defined a possible framework for this evaluation as shown in Table 9 [17]. A first testing step is the definition of nature, degree, duration, frequency and conditions of exposure or contact with the human body, so a categorization of the medical device. The initial categorization allows to understand the tests to carry out.

Table 9: Biocompatibility Evaluation Endpoints

Medical device categorization by			Biological effect											
Nature of Body Contact		Contact Duration	Cytotoxicity	Sterilization	Irritation of Intracutaneous Reactivity	Acute Systemic Toxicity	Material-Mediated Pyrogenicity	Subacute/Subchronic Toxicity	Genotoxicity	Implantation	Hemocompatibility	Chronic Toxicity	Carcinogenicity	Reproductive/Developmental Toxicity	Degradation
Category	Contact	A – limited (≤24 h) B – prolonged (>24h to 30d) C – permanent (> 30d)													
Surface device	Intact skin	A	X	X	X										
		B	X	X	X										
		C	X	X	X										
	Mucosal membrane	A	X	X	X										
		B	X	X	X	O	O	O		O					
		C	X	X	X	O	O	X	X	O		O			
	Breached of compromised surface	A	X	X	X	O	O								
		B	X	X	X	O	O	O		O		O	O		
		C	X	X	X	O	O	X	X	O					

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External communicating device	Blood path indirect	A	X	X	X	X	O				X				
		B	X	X	X	X	O	O			X				
		C	X	X	O	X	O	X	X	O	X	O	O		
	Tissue/ bone/ dentin	A	X	X	X	O	O								
		B	X	X	X	X	O	X	X	X					
		C	X	X	X	X	O	X	X	X		O	O		
	Circular blood	A	X	X	X	X	O		O		X				
		B	X	X	X	X	O	X	X	X	X				
		C	X	X	X	X	O	X	X	X	X	O	O		
Implant device	Tissue/bone	A	X	X	X	O	O								
		B	X	X	X	X	O	X	X	X					
		C	X	X	X	X	O	X	X	X		O	O		
	Blood	A	X	X	X	X	O		O	X	X				
		B	X	X	X	X	O	X	X	X	X				
		C	X	X	X	X	O	X	X	X	X	O	O		

X = ISO 10993-1:2009 recommended endpoints for consideration*
O = Additional FDA recommended endpoints for consideration*

ISO 13485 – Medical Devices

ISO 13485 [18] defines the requirements for a Quality Management System (QMS) for organisations producing medical devices to demonstrate their ability to provide services and products that meet customer and regulatory requirements. The standard is applicable to the organisation involved in one or more stages of the life-cycle of a medical product and can also be used by suppliers or external parties.

ISO 13485 introduces additional requirements to the ISO 9001, on which the standard is based. Therefore, if an organisation has already an ISO 9001 QMS, it should take less effort to implement the changes to obtain the ISO 13485 certification.

There are similarities between the two standards, such as:

- Help the organisation defining the QMS
- Risk assessment and mitigation

For what concerns the differences a high-level summary is shown in Table 10.

Table 10: High Level differences between ISO 9001 and ISO 13485

ISO 9001	ISO 13485
6 Procedures	27 Procedures
Customer satisfaction and continuous improvement are primary objectives	Customer satisfaction and continuous improvement are not primary objectives
General requirements	Specific requirements for different types of products

Some of the additional requirements introduced in ISO 13845 are the following:

- Cleanliness of products

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- Installation activities
- Servicing activities
- Requirements for sterile medical devices

Moreover, ISO 13845 is more demanding in terms of documentation and document control, allowing to produce regulatory documents such as the Device Master Record (DMR), DHF (Design History File) DHR (Design History Record).

Document	DMR	DHF	DHR
Purpose	An instruction manual for manufacturing the medical device	Proof the instruction manual is compiled correctly	Evidence the instructions have been correctly followed
Contents	Includes: • Design specifications • Production Processes • Equipment specifications • Packaging and labelling specifications • Maintenance and servicing procedures	Includes: • Design and development plans • User Requirements • Design inputs • Design outputs • Design review records • Design verification results	Includes: • Acceptance records • Product/component IDs • Material Lots • Production records

Being compliant with ISO 13485 is fundamental for an organisation producing medical devices since it allows to demonstrate the high-quality of the manufacturing process and the continuous attention to the improvement of the production. Moreover, the compliance with the standard increases credibility and profitability of the organisation ensuring a continuous customer satisfaction.

Therefore, obtaining the ISO 13485 certification is a key point. The certification process follows, as usual, these steps:

- Identify the requirements to satisfy with the QMS.
- Conduct a gap analysis.
- First internal audit.
- Corrective actions, implementing processes and procedures required by the standard.
- Perform the certification audit.
- Perform the periodic surveillance audit.
- Perform the certification renewal audit.

ISO 14644 – Cleanrooms & Associated Controlled Environments

ISO 14644-2015 regulates the use of cleanrooms, defining several classes from Class 1 to Class 9, where the Class 1 has the most stringent cleanliness requirements. This standard is fundamental for medical devices manufacturing since the risk of exposing them to airborne particles has to be reduced. The

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standard is developed not only for medical devices but also for several other fields, such as, aerospace industry, food sector, laboratories.

ISO 14644 is composed by 14 parts and defines specific requirements for designing, manufacturing and maintaining of cleanrooms. The critical parameters of a cleanrooms to consider are the following:

- air cleanliness, exchange rate, volumes
- cleanroom class choice
- clothing in cleanrooms
- air filters
- planning of access areas

For what concerns the injection moulding production of medical devices, the class of the cleanrooms could be from Class 5 to Class 8 to limit the potential contamination of the products. Most injection moulded devices are produced in Class 8 cleanrooms, but sterile devices require a Class 5 cleanroom see Table 2.

2.5. Demonstrator #4: MEN

Menicon is Japan's first and largest contact lenses manufacturer, in particular, the company serves the market for prescription contact lenses (PCL) that are customized and personalized to each individual patient. The lens design is based on optometric measurements and, therefore, it has a high degree of variability and complexity, which make the production of the lenses a very intensive process with the use of multiple specialized machines and manual intervention. The production process of the contact lenses consists of several steps among which the lathing of the lenses is the fundamental one. The usual steps to followed in the manufacturing of the contact lenses are:

1. Raw Material Selection: the possible materials to produce contact lenses are monomers, pigments, and other additives.
2. Monomer Mixture: base polymers are created by a mixture of monomers. Then, a polymerization process is used to create from the mixture the lens material.
3. Polymerization: the chemical process to link the monomers together to form a solid material.
4. Lathing: Lathe cutting is the process of cutting the lens material into the desired shape. A lathe machine specifically designed for contact lens manufacturing is used.
5. Surface Finishing: the lens is subjected to a series of surface finishing processes to improve its surface quality and to ensure its performances. This step may include processes such as polishing, coating, and surface modification.
6. Quality Control: once the lens is manufactured, it is subjected to a series of quality control to ensure the product meet the required specifications (i.e., thickness, curvature, and refractive power).
7. Sterilization: the lens is subjected to a sterilization process to ensure the absence of harmful contaminants.
8. Packaging: the lens packaging is carried out in a sterile environment including information such as the expiration date and recommended care instructions.

The previous steps are basic steps in the manufacturing of contact lenses, but additional ones can be performed such as tinting and colouring or the addition of other features. Menicon does not perform the

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first three steps, it chooses the right base material and starts the process from step 4. In fact, as stated before, Menicon core process is the lathing one, but other methods of manufacture are also possible depending on the type of lens to produce. Table 11 summarises the main methods of manufacture.

Table 11: Contact lenses manufacturing methods comparison

METHODOLOGY	PROS	CONS
Lathe-Cutting	• Cutting of a wide range of materials • Wide range of parameters • Eco-friendly packaging • Reduced waste • Reproducibility • Wide range of design • Wide range of products options • Create unique prescription based lenses	• Cleaning is required • Greater risk of infection • More complex processing
Cast Moulding	• Wide range of modalities • Thinner • Finished product with no need to polish • High quality with lower cost • Consistent edges and smooth surface • Mass production	• Limited parameters • More waste

Menicon demonstrates its quality and attention to the customer by obtaining the following certifications:

- EN ISO 13485 – Medical devices — Quality management systems – Requirements for regulatory purposes
- European Medical Device Directive (MDD) – CE Mark in conformity with MDD (Council Directive 93/42/EEC concerning Medical Devices)

The company is highly involved in research activities too, such as, designing and developing new materials and manufacturing methods, research about the myopia progression and control in children and development of specialty contact lenses to improve the quality of vision and life.

2.5.1. Contact Lenses Standards

The contact lenses production has to follow high standards as medical devices for the material and the manufacturing methods used. Some of the main standards for contact lens manufacturing are:

- ISO 13485 (discussed in Section 2.4.2)
- ISO 14534 – Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements
- ISO 18369 – Ophthalmic optics — Contact lenses

Moreover, manufacturers of medical devices face other requirements defined by the Medical Device Regulation (MDR) 2017/745, that replaced the Medical Device Directive (93/42/EEC) whose certificates will be valid until their expiry date or 26 May 2024. Therefore, the manufacturers of medical devices must

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migrate their products certificates to MDR satisfying the new rules and requirements. The MDR shares the same basic regulatory requirements with the Directives, but MDR brought some changes:

- More information is needed from the technical files.
- Reclassification of certain devices.
- Reinforcement of the requirements for clinical evaluation.
- Substantial changes for the quality management system.

This new Regulation is fundamental to improve clinical safety and takes into account the latest development in the medical devices sector.

Focusing on the ISO 14534:2011, this standard specifies safety and performance requirements for contact lenses, contact lenses care products and other accessories for contact lenses. Several requirements are defined, such as:

- Safety and performance: documented demonstration of the product performances with information about of human use. To assess the safety, information about the microbiological properties, biocompatibility is needed.
- Design and materials: the design of the product has to be carefully documented and the choose of the material has to meet the requirements for safety, performance, manufacture.
- Clinical evaluation: the product should be evaluated by one of the following methods, compilation of relevant literature available, experience during previous use or clinical investigation.

For what concerns ISO 18369, this standard defines the physical, chemical and optical properties, manufacturing and usage of contact lenses. Moreover, it defines a terminology and a classification of contact lenses materials. It consists in 4 parts:

- Part 1: Vocabulary, classification system and recommendations for labelling specifications – it defines the terms, definition and symbols related to contact lenses and contact lenses care products and a classification of contact lenses materials;
- Part 2: Tolerances – it specifies the tolerances limits of the contact lenses optical and physical parameters, such as, radius of curvature, diameter, thickness, surface imperfection;
- Part 3: Measurement methods – it defines the methodologies to measure the parameters specified in part 2;
- Part 4: Physicochemical properties of contact lens materials – it defines the methods of testing the contact lenses materials.

Among the several standard about the contact lenses, particular attention has to be given to a more general one, the ISO 10110:2019. This standard wants to give a general and universal way to represent and understand optical components drawing, to make easier the exchange of information. More details are reported in Section 2.5.1.1.

2.5.1.1. ISO 10110 – Drawings for Optical Elements and Systems

The ISO 10110:2019 has been developed to enable designer and manufacturers to easily share information and understand each other about optical components. The standard full name is ISO

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10110:2019 – "Optics and optical Instruments – Preparation of optical drawings for optical elements and systems". It is composed of the following parts:

- Part 1: General
- Part 5: Surface form tolerances
- Part 6: Centring tolerances
- Part 7: Surface imperfections
- Part 8: Surface texture
- Part 9: Surface treatment and coating
- Part 10: Table representing data of optical elements and cemented assemblies
- Part 11: Non-toleranced data
- Part 12: Aspheric surfaces
- Part 14: Wavefront deformation tolerance
- Part 16: Diffractive surfaces
- Part 17: Laser irradiation damage threshold
- Part 18: Stress birefringence, bubbles and inclusions, homogeneity, and striae
- Part 19: General description of surfaces and components

There are several advantages following this standard, such as, the drawings can be easily interpreted by persons having any language background, indications are alphanumeric symbols, the drawings can be integrated in optical design software and list of tolerances are available.

2.5.2. Adjacent Sectors

An organisation whose core business is the manufacturing of contact lenses and the production of contact lenses care product can be readapted to cover a wider range of Eyewear Industry products (i.e., spectacle frames and lenses, sunglasses, sport goggles). In particular, for what concerns the standardization activities, the compliance with the international standards reported in Table 12 should be ensured depending on the eyewear product considered.

Table 12: Eyewear products standards

Eyewear Product	ISO/EN Standard	Standard Title
Contact Lenses	ISO 14534	Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements
	ISO 18369	Ophthalmic optics — Contact lenses
Spectacle Lenses	ISO 14889	Ophthalmic optics — Spectacle lenses — Fundamental requirements for uncut finished lenses
	ISO 21987	Ophthalmic optics — Mounted spectacle lenses
Spectacle Frames	ISO 12870	Ophthalmic optics — Spectacle frames — Requirements and test methods
Reading Glasses	ISO 16034	Ophthalmic optics — Specifications for single-vision ready-to-wear near- vision spectacles
	EN 14139	Ophthalmic optics – Specifications for ready-to-wear spectacles

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Sunglasses	ISO 12312	Eye and face protection — Sunglasses and related eyewear
Sport Goggles	ISO 18527-1	Eye and face protection for sports use — Part 1: Requirements for downhill skiing and snowboarding goggles
	ISO 18527-2	Eye and face protection for sports use — Part 2: Requirements for eye protectors for squash and eye protectors for racquetball and squash
	ISO 18527-3	Eye and face protection for sports use — Part 3: Requirements and test methods for eyewear intended to be used for surface swimming
	EN 13178	Personal eye-protection - Eye protectors for snowmobile users
	EN 1938	Personal eye protection - Goggles for motorcycle and moped users
Eye Protectors	EN 166	Eye-Protection - Specifications
	EN 167	Personal eye protection - Optical test methods
	EN 168	Personal eye-protection. Non-optical test methods
	EN 172	Personal eye protection - Sunglare filters for industrial use
	EN 1731	Personal eye protection - Mesh eye and face protectors
	ISO 16321-1	Eye and face protection for occupational use — Part 1: General requirements
	ISO 16321-2	Eye and face protection for occupational use — Part 2: Additional requirements for protectors used during welding and related techniques
	ISO 16321-3	Eye and face protection for occupational use — Part 3: Additional requirements for mesh protectors

The adaptation process has to also consider the production chain steps and the raw materials depending on the eyewear product. For example, the manufacturing of spectacle lenses uses different materials such as the one reported in Table 13 [19], therefore new suppliers have to be integrated.

Table 13: Characteristics of lens materials

Material	Refractive Index	Abbe Number	Density [g/cm^3]
CR-39	1.499	58	1.32
Crown Glass	1.523	58	2.54
Spectralite	1.537	47	1.21
Polycarbonate	1.586	30	1.20
RLX Lite	1.555	36	1.24
Ormex	1.558	37	1.23
Finalite	1.600	42	1.22
1.60 MR-6	1.597	36	1.34

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1.66 MR-7	1.660	32	1.35
1.6 Index Glass	1.601	40	2.62
1.7 Index Glass	1.701	30	2.93
1.8 Index Glass	1.805	24	3.37

The production of spectacle lenses generally follows the listed steps:

- If the lenses are prescription lenses, the optical prescription is given as input to manufacture a high-quality product.
- **Preparation:** based on the customer's specific needs, the parameters of the lenses are calculated, and, based on the results, semi-finished raw materials are selected from an inventory.
- **Lathing step 1**: the raw material is loaded into a lathe to shape the back (inner surface) of the lens into the final shape.
- **Blocking**: in this phase, an adhesive is applied to inner surface of the lens, and glued onto a mounting base, necessary to properly clamp the lens for further machining.
- **Lathing step 2**: The front surface of the lens, resting on the mounting base, is machined to obtain the final shape, according to the customer's requirements. For machining, automated methods based on CNC are typically used.
- **Polishing and engraving**: a polishing process is performed to ensure that the final product has the desired characteristics. In the engraving process the product will be engraved with a unique identification for traceability.
- **De-blocking and cleaning**: the manufacture process then proceed with the separation of the lens from the mounting base (de-blocking). After this operation, the lens is carefully washed to avoid the presence of debris deriving from the previous phases of the manufacturing process.
- **Tinting:** in this phase, if required, the process foresees the tint of the lenses. This process is carried out with particular attention to the aspects relating to safety and human health.
- **Coating:** the coating stage is extremely important because it is the phase in which it's performed the creation of a shielding capable of avoiding the formation of scratches, providing a crystalline vision and being adaptable to atmospheric situations of different nature.
- **Quality assurance:** Once the product has been processed, a meticulous inspection is carried out to determine possible imperfections, the presence of debris deriving from processing or inconsistency with the geometric requirements. Only once this inspection has been passed the product can be considered marketable.
- **Packaging**: In the packaging process step, the lens is placed in a container filled with fluid.
- **Sorting**: Containers are sorted to complete a customer order (e.g. a left and right lens) and delivered to the customer.

Readapting the production to manufacture spectacle lenses, the production of spectacles frames could be another business opportunity. For the frames, there are several different materials to consider depending on the desired durability, flexibility and affordability of the final product. Some of the materials used are:

- Nylon: durable and lightweight plastic often used for sport frames

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- Aluminium: light metal with anti-corrosion properties
- Stainless Steel: durable and lightweight metal frames
- Cellulose Acetate: hypoallergenic plastic affordable and customizable

The frames are usually produced with a die-cutting process, followed by a series of steps (i.e., curving, polishing) to cut and smooth the material into the final product.

The reconfiguration to an adjacent sector is possible, integrating new suppliers and machineries and training the employees. In this case the reconfiguration does not need a specific certification since the ISO 13485 is already obtained. The standards previously reported could be followed to assure and prove the quality of the production and the products. Therefore, the times for the reconfiguration are linked to the new suppliers, machineries and training due to change sector. These actions if carefully planned in advance could allow a fast reconfiguration to the adjacent sector.

3. Relevant Standards for RaRe^2 Activities

One of the RaRe^2 Work Package 1 objectives is to give a state-of-the-art of the standard framework for the industrial automation and interoperability of product data. In particular, the attention is focused on the work of the ISO/TC184/SC4 "Industrial Data". This technical committee, active since the '80s, is continuously searching to update itself on the basis of the most relevant innovation and development of the industries and categories. The following standards have been considered the core of the Task 1.1 activities:

- Interoperability of product data definitions (ISO 10303 and ISO 15926);
- Manufacturing (ISO 15531, ISO 18629, ISO 18828 and ISO 18876);
- Visualization (ISO 14306 and ISO/PAS 17506).

These standards represent a great effort of the ISO/TC184/SC4 and give lots of inputs to understand the evolution and the progresses in the manufacturing systems. In a world more and more connected and digitalized, an efficient exchange of information is necessary, searching to support the different industries in overcome the limitations and the issues due to the use of different applications and resources. Moreover, the ISO/TC184/SC4 work could be an additional boost to the development of new technologies and ways to collaborate among different enterprises. Further standards are also discussed for the development of the digital twin and the artificial intelligence.

3.1. Electronic Exchange of Data

The International Organization for Standardization (ISO) is constantly working on the development of standards for the electronic exchange of product data. Today, the information related to product design, prototyping, manufacturing, testing and so on are computer-based. Therefore, the ability to share product data information quickly and efficiently is a key to let the world move towards a constant growth and progress based on a collaborative effort of the companies. The ISO 10303 and ISO 15926 have been developed with this aim.

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3.1.1. ISO 10303 – Product Data Representation and Exchange

The ISO 10303 standard [20],[21], informally known as STEP (Standard for the Exchange of Product data), has been developed thanks large efforts of ISO TC184/SC4 and it is still expanding. It is an International Standard for computer-interpretable representation of product information and for the exchange of product data. Thanks to its support, the organizations are able to represent the information in a neutral computer-interpretable form, complete and consistent when exchanged among different computer systems.

The transition from engineering paper drawings to drawings created with Computer-Aided Design (CAD) tools brought great productivity and new opportunities, facilitating the realization of complex products and the automatic definition of manufacturing instructions. Despite these improvements, the new various CAD and Computer-Aided Manufacturing (CAM) tools were related to different data formats to capture and store product data. Without the right tools the products models were useless. Moreover, companies could not often use a common set of CAD/CAM tools among joint venture partners. Therefore, the need of a common format for neutral information exchange rose up, leading to the definition of the ISO 10303. In fact, this Standard is mostly recognized by organizations for exchanging data between different CAD tools/systems.

STEP supports:

- Product data exchange: STEP defines the form of the product data to be exchanged between two different applications. Each application holds its own form of the product data since STEP is just transitory and defined for the exchange.
- Product data sharing: STEP is designed to support the interfaces between a single copy of a product data and the applications that share it. The applications do not hold their own form for the product data.
- Product data archiving: STEP could be used to storage product data. The architectural elements of STEP can be used to support the development of the archived product data.

Today different product types (e.g., electronic, mechanical, architectural) and life cycle stages (e.g., design, analysis, planning, manufacturing) are covered by ISO 10303. The covered information is continuously expanding since new parts (referred as ISO 10303-xxx) of the standard are issued.

The STEP is divided into many parts that cover topics such as methods to represent the standard, implementation architectures, conformance testing methodology and frameworks and others. A high-level structure of STEP is shown in *Figure 9*.

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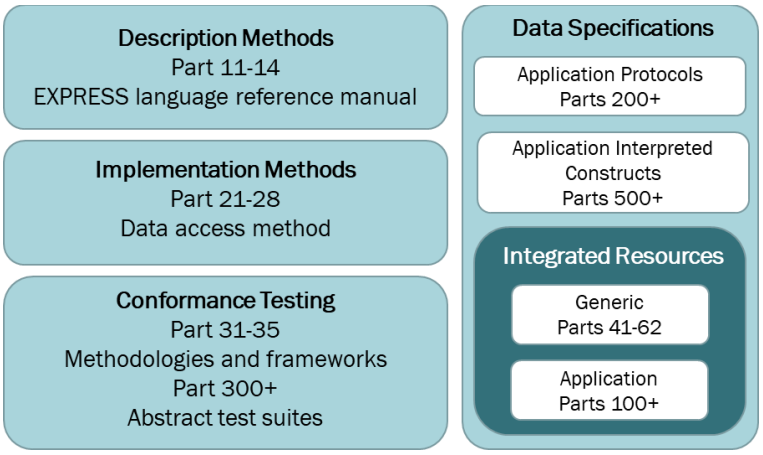

Figure 9: STEP structure

The numbering of the parts of the International Standard reflects its structure:

- Parts 11 to 14 specify the description methods,
- Parts 21 to 28 specify the implementation methods,
- Parts 31 to 35 specify the conformance testing methodology and framework,
- Parts 41 to 62 specify the integrated generic resources,
- Parts 101 to 113 specify the integrated application resources,
- Parts 201 to 242 specify the application protocols,
- Parts 301 to 332 specify the abstract test suites,
- Parts 401 to 442 specify the application protocol modules,
- Parts 501 to 523 specify the application interpreted constructs, and
- Parts 1001 to 1999 specify the application modules.
- Parts 3001 to 3099 specify business object models,
- Parts 4401 to 4499 specify domain models.

The complete list of parts is reported here: https://standards.iso.org/iso/10303/tech/step_titles.htm.

The description methods are mechanisms to specify the data construct of STEP. For example, they include: the formal data specification language, known as **EXPRESS**, specially developed for the Standard; the graphical form of EXPRESS, a mapping language for EXPRESS etc. EXPRESS is a language for communicating information about data that has a lot in common with some database definition and programming languages. EXPRESS provides several advantages:

- Eliminates ambiguity.
- Assists in Validating Information Models.
- Can be used to generate STEP-capable software.
- Supports STEP architecture.
- Is user-friendly.

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The implementation methods are protocols that are driven by the EXPRESS language: STEP-file, STEP-XML, SDAI (Standard Data Access Interface). They include the physical file exchange structure, the data access interface, the language bindings.

The conformance testing provides a framework for conformance and methodologies that describe how the implementation of STEP parts are successfully tested. Moreover, a set of abstract test cases necessary for conformance testing is defined in an abstract test suite to give all the inputs to the implementation under test.

The data specifications are conceptually of three types (integrated resources, application protocols and application interpreted constructs) and are documented using the description methods.

- The **integrated resources** are the basic semantic elements to describe any product at any stage of the product life cycle. They define the resource construct for a particular application protocol.
- The **application protocols** (AP) specify a subset of data structures for a particular industrial application, and they include:
    - application activity model: to describe the activities and processes of a defined application context domain;
    - application reference model: to describe the information requirements and constraints;
    - application interpreted model: to describe the STEP data structures;
    - conformance class: to describe the valid population of the file.
- The **application interpreted constructs** satisfy a specific product data need in more than one application context. They specify the data structures and semantics used to exchange product data among two or more application protocols.

3.1.2. ISO 15926 – Integration of Life-cycle Data

ISO 15926 [22],[22],[24] is an International Standards for the representation and the exchange of life cycle data of industrial plants. The full title is “Industrial automation systems and integration – Integration of life cycle data for process plants including oil and gas production facilities”, but despite it refers directly to oil and gas industry, the standards is applicable to various domains thanks to the definition of general concepts. The ISO 15926 defines a generic data model and reference data library for process plants that can be used to model any state information. This standard was developed as a companion to STEP, with the objective to define a standard for a process plant data warehouse (outside the scope of STEP), which can contain:

- Requirements for a process plants.
- Design of a process plants.
- Physical objects in a process plants.

Since through the life cycle the industrial plants are affected by different changes, the ISO 15926 implements the four-dimensional (4D) approach for the representation of life cycle data. The approach is related to the fact that physical objects can have spatial (3D) and temporal (1D) decomposition. Therefore, the approach considers the definition in space and time, for example, places and time for usage, storage or maintenance, of physical objects.

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The current ISO 15926 consists of the following parts:

- Part 1 – Overview and fundamental principles
- Part 2 – Data model
- Part 3 – Reference data for geometry and topology
- Part 4 – Initial reference data
- Part 5 – Procedures for registration and maintenance of reference data
- Part 6 – Methodology for the development and validation of reference data
- Part 7 – Implementation methods for the integration of distributed systems: Template methodology
- Part 8 – Implementation methods for the integration of distributed systems: Web Ontology Language (OWL) implementation
- Part 9 – Implementation standards, with the focus on standard web servers, web services, and security
- Part 10 – Conformance testing
- Part 11 – Methodology for simplified industrial usage of reference data
- Part 12 – Life cycle integration ontology represented in Web Ontology Language (OWL)
- Part 13 – Integrated life cycle asset planning life cycle
- Part 14 – Data model adapted for OWL2 Direct Semantics (under development)

Focusing on some parts of the ISO 15926 help to understand better its utility. Part 2 contains the data model written using EXPRESS language (from STEP) and its objectives are to give:

- generic concepts associated with set theory and functions;
- concepts and relationships for the implementation of the "4D approach" for the physical objects changes previously described;
- generic information and relationships to engineering (specification and selection of materials, information about plant equipment, production and process operations. Maintenance and replacement of equipment).

Therefore, Part 2 allows to define and easily manage the life cycle information in a process plant supporting the process engineer, operators, maintenance engineer etc. in their work.

Part 4 contains the initial set of core reference data items used within the process industries. Basic classes and properties are contained in the library that is continually revised and extended as an ISO register, following the methodologies reported in Part 5 and Part 6.

With the availability of Web Ontology Language (OWL), from Part 7 the translation of the ISO 15926 to the OWL started.

3.1.3. Other Standards for Information Exchange

The secure and standardized acquisition and transfer of data are two of the key pillars of RaRe^2 – Project. The development of the digital twin can be successful if and only if internal and external data are available and manageable. In fact, these data allow to constantly analyse the processes of the production chain as

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well as external factors, for example economic and ecological factors, in order to be able to simulate and finally indicate which are the best reconfiguration possibilities for the production chain itself.

Therefore, an overview of the standards for information exchange and data formats mainly used by European industries is a first fundamental step to efficiently proceed with the next Project activities. By collecting information from the RaRe² beneficiaries and external stakeholders, a preliminary list of relevant standards and data formats has been developed in Table 14.

Table 14: Overview of standards and data formats for information exchange.

Standards/Data Formats	Description
ISO/IEC 21778:2017 – JSON	JSON (JavaScript Object Notation) is a lightweight test-based syntax that facilitates the data exchange between all programming languages. JSON defines a small set of rules to structure data. It is a common data formats used in electronic and web applications data exchange.
HDF5	HDF5 (Hierarchical Data Format) is a data model, library and file format designed to store and manage large amounts of data. It is very flexible since it supports an unlimited variety of datatypes and is portable and extensible.
XML	XML (Extensible Markup Language) is a markup language and file format for storing and transporting data. XML standardizes the information exchange between two systems. It has been used to develop COLLADA described in Section 3.3.2.
ISO/IEC 15445:2000 – HTML	HTML (HyperText Markup Language) is a markup language to display information in a web browser. HTML defines how to structure a web page and its content.
ISO/IEC 15948:2004 – PNG	PNG (Portable Network Graphics) is a bitmap file format for a lossless, portable, compressed individual computer graphics image transmitted across the Internet.
JPEG	JPEG (Joint Photographic Experts Group) is a file format for digital images common for photo storage and web development.
ISO/IEC 20922:2016 – MQTT	MQTT (Message Queuing Telemetry Transport) is a lightweight, open and simple messaging transport protocol. MQTT is commonly used for communication in Machine to Machine (M2M) and Internet of Things (IoT) context.
IEC 62541 – OPC-UA	OPC-UA (OPC Unified Architecture) is a standard for data exchange from sensors to cloud application. OPC-UA is open source with data models freely available for several types of industrial equipment.
IEC 61784 – Modbus	Modbus is an open-source data communication protocol developed for industrial application for connecting electronic devices. Modbus is simple and easy to deploy, placing few restrictions on the data format to be transferred.
ISO 10303-21 – STEP or STP	STEP is a file format developed to easy represent and exchange 3D object in computer-aided design with the related information. STEP

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	is defined in ISO 10303-21 described in Section 3.1.1. The standard is not freely available.
STL	STL is the most common file format for 3D object. STL is simple and storage-efficient and can be easily imported and managed by different CAD software and 3D printing software.
DWG	DWG is a binary file format used to store 2D and 3D design. DWG is the native format for AutoCAD and is widely used for CAD drawings.

3.2. Manufacturing

Manufacturing could be defined as the transformation of raw material to products or goods. The information about the manufacturing process is crucial for the life cycle of a product, so being able to correctly handle and exchange them is a key in a context of sustainable development. A manufacturing management system should be capable of identify, model and represent all this information through the whole production chain, from suppliers to distributors and customer. Organisations and enterprises that collaborate should be capable of communicate with a common terminology without chances for misunderstandings. For the previous reasons, the standards reported in this section have been developed.

3.2.1. ISO 15531 – Industrial Manufacturing Management Data

ISO 15531 [25],[26],[27], also known as MANDATE (MANufacturing management DATa Exchange), is an International Standard for the computer interpretable representation and exchange of industrial manufacturing management data. This International Standard is associated with STEP and other SC4 standards and it is intended to facilitate the exchange of information between software applications, manufacturing management software, maintenance management software, quotation software etc.

Whitin the supplier plants, the production planning functions should constantly exchange information with the responsible of the scheduling of the main plant about future demands to allow the suppliers to plan their production. The suppliers should receive orders from the main plant to ensure the availability of components and resources needed to the manufacturing and assembly process. Therefore, MANDATE addresses three main categories of data:

- Information related to the management of resources (Resource model);
- Information related to the management of time (Time model);
- Information related to the manufacturing flows (Flow management model).

The aim is to provide standardised data models for the previous three categories of manufacturing management data, to facilitate the integration and exchange of information between industrial applications during the entire production life cycle.

MANDATE is so structured in three series of parts:

- **Production data for external exchanges (Parts 15531-2x series)**: for the representation and modelling of production and product information to be exchanged with the industrial companies and external environment (customers and suppliers), to improve exchanges and integration through the use of Electronic Data Interchange (EDI) protocols.

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- **Manufacturing resource usage management data (Parts 15531-3x series)**: information related to the management of the resources' usage, such as hierarchy (generic, specific, individual resource), characteristics, administration, status (availability or not of the resource), resource view (specific aggregation of resources), resource representation (physical values), resource configuration.
- **Manufacturing flow management data (Parts 15531-4x series)**: for the representation of the data and elements supporting the control and monitoring of the flow of materials in manufacturing processes.

3.2.2. ISO 18629 – Process Specification Language

ISO 18629 [28],[29],[30], also known as PSL (Process Specification Language), is an International Standard developed to provide a common language to support interoperability for industrial data integration of processes and products in industrial applications. "Interoperability" stands for the ability to share technical and business data, information and knowledge between two or more software tool or application systems in an error-free manner with minimum manual interventions [31].

PSL is a generic language applicable to process in manufacturing and other application and is based on first order logic, on mathematical set theory and situation calculus. Each concept is specified with a set of definitions, relations (that specify the links between definitions or elements of definitions), and axioms (that constraint the use of elements), expressed in Knowledge Interchange Format (KIF). The language can describe processes throughout the entire production in the same or across several companies.

ISO 18629 is constituted by parts, independent of any specific processes representation or model used in a given application, that provide a structural framework for interoperability. The series of parts are numbered in a way consistent with the other standards developed within ISO TC184/SC4:

- Core theories (Parts 18629-1x)
- External mappings (Parts 18629-2x)
- Definitional extensions (Parts 18629-4x)

Parts 1x are the basis of the PSL ontology. Parts 4x define concepts for modelling applications and are utilized by the applications to specify and exchange the processes.

PSL can be used to exchange only one or a set of processes between two different applications, since it is not necessary to exchange all their processes for interoperability. The exchange is performed in three steps:

1. Syntactic translation of the native syntax of an application to the PSL syntax (KIF).
2. Semantic translation to PSL by using the definitions for the considered application.
3. Semantic translation from one application to another, by mapping the source application to the target application through PSL (intermediate language)

Therefore, the data for the relevant processes can be exchanged.

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3.2.3. ISO 18828 – Standardized Procedures for Production

ISO 18828 [32],[33], *Standardised procedures for production systems engineering*, is an International Standard to provide reference planning process between the product design and production processes. This Standard deals with production processes, information flows, key performance indicators (KPIs) and manufacturing changes, that are useful aspects for production planner.

At this time, ISO 18828 is composed by the following 5 parts: Part 1 – *Overview*; Part 2 – *Reference process for seamless production planning*; Part 3 – *Information flows in production planning processes*; Part 4 – *Key performance indicators (KPIs) in production planning processes*; Part 5 – *Manufacturing change management*. Each part is a single document, but Part 2, Part 3 and Part 4 are strictly linked. Planning processes are the main outcome form Part 2 and can be seen as input to information flows (Part 3) and KPIs (Part 4). Moreover, planning process information and statistical data can be input to manufacturing change (Part 5). The interrelations between the different part of the ISO 18828 are shown in Figure 10.

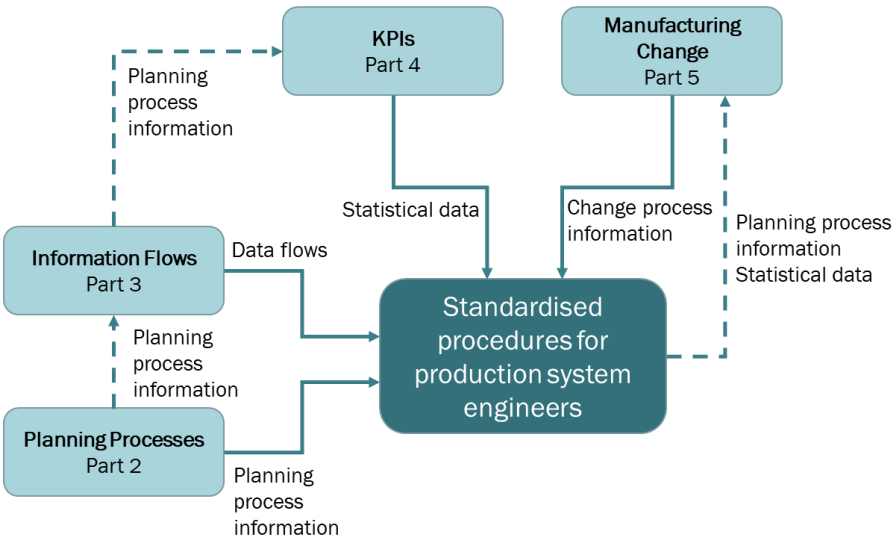

Figure 10: Interrelations between ISO 18828 Parts

3.2.4. ISO 18876 – Integration of Industrial Data

ISO 18876 [34], *Integration of industrial data for exchange access and sharing*, is an International Standard to provide architecture, methodology and other specifications for integrating industrial data for exchange, access and sharing.

The ISO 18876 allows to:

- integrate data from different sources or contexts, data described by different models or defined in different modelling languages;
- share data among applications;
- resolve conflicts between models;
- translate data and models between different encodings and modelling languages.

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3.3. Visualization

Digital Engineering Visualization gives the possibility to have access to 3D data without using traditional CAD system, allowing a higher number of people to just view information without being necessarily the creators. This is fundamental since the visualization of information is mostly related to people who did not create them such as customers, partner organizations etc.

3.3.1. ISO 14306 – JT File Format

ISO 14306 [35] is an International Standard that defines the syntax and semantic of the JT (Jupiter Tessellation) format for product 3D visualization, interrogation of geometry and manufacturing information, collaboration, digital mock-up and other purposes. JT format is an openly published data format developed by Siemens Digital Industries Software that was officially published as ISO 14306 in 2012.

The JT format is mainly linked to the following use cases:

- Viewing: the first objective of the JT format development, includes high end visualization, bidding processes, material specification etc too.
- Digital Mock-Up (DMU): to define processes for tolerance studies and analysis, manufacturing, supplier integration etc.
- Design in Context: to define the more advanced processes, such as hybrid design in context, simulation activities etc.

JT data model includes geometry information offering the possibility to displaying the models in various degrees of precision. It supports visual attributes such as lights, textures and materials, boundary and configuration representations too. The success of this format is not only linked to the possibility to display the 3D geometry, but to the additional possibility to display the product manufacturing information such as dimensions, tolerances, surface properties and other attributes, with the 3D model. Moreover, the JT files are “lightweight”, since they weight about the 10% of the size of a CAD file, so they are ideal for sharing information with supplier and partners on-line too.

3.3.2. ISO 17506 – COLLADA

ISO 17506 [36],[37],[38] is an International Standard that describes the COLLADA (COLLAborative Design Activity) schema, an open XML-based schema to freely exchange digital assets among 3D software applications, tool chains, prototyping tools, real-time visualization applications without losing information. COLLADA is managed by Khronos Group and was published as ISO 17506 in 2012.

COLLADA schema has been developed following these goals:

- To provide an open-standard, royalty-free format liberating digital assets from proprietary binary formats.
- To provide a standard common language usable in existing content tool-chains.
- To provide an easy mechanism to make all the data available.
- To be used as basis for data exchange among 3D applications.

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- To be a catalyst for digital-asset schema design among developers and Digital Content Creation (DCC), hardware, and middleware vendors

COLLADA uses XML that provides a well-defined framework for structured content and is easy to understand given only a sample instance document and no documentation. A document describing the COLLADA scheme is available to enable software developer to create tools to process COLLADA resources. [38]

3.4. Digital Twin

Methodologies based on the Digital Twins paradigm are absolutely topical, representing a fundamental enabling technologies for a series of opportunities and applications that are contextualized in the technological macro trends of the coming years, such as for example the massive development of Artificial Intelligence.

More specifically to the case study, this technology can above all be applied in manufacturing processes with the aim of optimizing their effectiveness. Digital Twins can be used, as an example among all, to be able to create digital copies, completely virtualized, which can be exploited to carry out preliminary validations on changes to existing production processes or to study innovative production processes.

The exploitation of these technologies, in fact, allows to carry out extensive tests in a much more effective and faster way, without the need to directly exploit the existing structures, thus avoiding the need to interrupt the production cycles and effectively eliminating the risk of possible problems which slow it down or prevent it from restarting.

3.4.1. ISO 23247 – Digital Twin Framework for Manufacturing

The ISO/DIS 23247 [39] standard series introduces a generic development framework for digital twins in manufacturing. It consists of four parts: overview and general principles, reference architecture, digital representation, and information exchange. Each part provides guidelines and procedures for defining scope and objectives, analysing modelling requirements, promoting common terminology usage, and supporting information synchronization between a digital twin and its physical system, the Observable Manufacturing Element (OME)

ISO 23247 Part 1: Overview and General Principles This part establishes general principles and requirements for developing digital twins in manufacturing. It defines terminologies used throughout the standard and emphasizes the importance of modelling OMEs using available standards and technologies. Synchronization between a digital twin and its OME ensures the twin remains updated with real-time data, optimizing both the twin and the physical system.

ISO 23247 Part 2: Reference Architecture Part 2 presents a reference architecture for digital twins in manufacturing. It comprises four domains: the observable manufacturing domain, data collection and device control domain, core domain, and user domain. Each domain performs specific tasks and functions through functional entities (Fes). The reference model illustrates the relationships and interactions among these entities.

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ISO 23247 Part 3: Digital Representation Part 3 describes the basic information attributes for typical OMEs. It emphasizes the use of existing standards, such as IEC 62264-2, to represent OME information. The selection of appropriate information models is crucial for each use case, and the enterprise unique identifier is recommended whenever possible.

ISO 23247 Part 4: Information Exchange Part 4 presents technical requirements for information exchange within the digital twin framework. It identifies different networks for communication, including user networks, service networks, access networks, and proximity networks. This part also provides example use cases and suggests standards and technologies for information exchange.

According to the ISO 23247 standard, the procedures to apply the framework to a digital twin use case in the implementation of a digital twin framework, the following high-level procedure is recommended:

1. Select relevant standards and technologies for data collection from OMEs and data processing.
2. Choose appropriate methods and tools for OME control, including interface development and command translation.
3. Determine communication standards and technologies between the data collection and device control entity and the core entity.
4. Select applicable functional entities and develop them using selected standards and technologies for digital twin development.
5. Integrate completed functional entities using modular interfaces or service networks.
6. Establish communication standards and technologies between digital twins and users, including human users and enterprise applications.
7. Develop graphical user interfaces and integrate digital twins with existing enterprise applications.

3.4.2. IEC 62832 – Digital Factory Framework

The IEC 62832 is an international standard to provide a reference model for the representation of production systems. A digital representation of a production system allows to manage and support the whole life cycle, providing a consistent information exchange and making this information understandable, reusable and changeable.

The standard defines a framework that helps at reducing the interoperability barriers for exchange of information that are described in a standardized manner. The framework defines models of production assets and relationships between different production system assets, the flow of information about the production system. It can be applied for continuous control, batch control or discrete control production processes in any industrial sector.

The IEC 62832 consists of the following three parts:

- IEC 62832-1: General principles – it introduces models and principal of the Digital Factory (DF) framework
- IEC 62832-2: Model elements – it details the data model for all the elements of the DF framework
- IEC 62832-3: Application of Digital Factory for lifecycle management of production systems – it describes how to apply the DF framework to manage the life cycle of the production system

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3.5. Artificial Intelligence

The rapid advancement of Artificial Intelligence (AI) technology has revolutionized various industries, including manufacturing, by enhancing data analysis methods and enabling automation. AI has also been integrated with Big Data, significantly improving data analysis methods by reducing the need for manual sorting and interpretation, quickly delivering insights, time-saving automations, and increasing overall efficiency. With the rapid evolution of AI algorithms' complexity, understanding the reasons behind some results and decisions can become almost impossible, making AI systems very useful tools but not completely trustworthy. Despite having already proved its capacity, AI is not exempt from making errors. Moreover, the scientific community has already demonstrated that Artificial Intelligence systems are only as good as the data that is put into them. The main way to mitigate the risk of having biases in AI algorithms is to post-process them after the AI has been trained. This means altering some of the predictions of the algorithm so that it will satisfy an arbitrary fairness constant. These considerations lead to the conclusion that developing AI algorithms that can be easily explained is of fundamental importance.

In general, this technological progress comes with several concerns related to security, ethics, and the trustworthiness of AI systems. These challenges need to be addressed with effective standards, regulations, recommendations, and reference architectures. Creating open AI platforms and resources for AI standards can foster global cooperation, but careful timing in developing standards must be achieved in order to ensure they align with the current state of technology and support innovation.

The European Commission (EC) has been at the forefront of creating trustworthy AI guidelines, emphasizing the need for lawful, ethical, and robust AI systems. One of the highly relevant developments in the AI regulatory landscape is the proposed Artificial Intelligence Act. Born out of years of discussions and research on an EU framework for AI regulation, this Act aims to address the risks associated with AI use and establish guidelines for its responsible deployment. The proposed EC Act aims to provide developers and deployers with clear requirements and obligations for AI use while reducing burdens on businesses, especially SMEs. Several Standard Development Organizations (SDOs) have also been active in the AI field by supporting AI policy goals, facilitating trust among states and researchers, and encouraging efficient development. International standards also mitigate risks, having an essential role in guiding the AI community through the responsible development and deployment of AI solutions and applications in various industry sectors.

Hereafter, a list of the standards currently published by the ISO/IEC JTC 1/SC 42 [40] that could be taken as references for the development of the early detection and reconfiguration tool:

- ISO/IEC TS 4213:2022 – Information technology — Artificial intelligence — Assessment of machine learning classification performance
- ISO/IEC 8183:2023 – Information technology — Artificial intelligence — Data life cycle framework
- ISO/IEC 20546:2019 – Information technology — Big data — Overview and vocabulary
- ISO/IEC TR 20547-1:2020 – Information technology — Big data reference architecture — Part 1: Framework and application process
- ISO/IEC TR 20547-2:2018 – Information technology — Big data reference architecture — Part 2: Use cases and derived requirements

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- ISO/IEC 20547-3:2020 – Information technology — Big data reference architecture — Part 3: Reference architecture
- ISO/IEC TR 20547-5:2018 – Information technology — Big data reference architecture — Part 5: Standards roadmap
- ISO/IEC 22989:2022 – Information technology — Artificial intelligence — Artificial intelligence concepts and terminology
- ISO/IEC 23053:2022 – Framework for Artificial Intelligence (AI) Systems Using Machine Learning (ML)
- ISO/IEC 23894:2023 – Information technology — Artificial intelligence — Guidance on risk management
- ISO/IEC TR 24027:2021- Information technology — Artificial intelligence (AI) — Bias in AI systems and AI aided decision making
- ISO/IEC TR 24028:2020 – Information technology — Artificial intelligence — Overview of trustworthiness in artificial intelligence
- ISO/IEC TR 24029-1:2021 – Artificial Intelligence (AI) — Assessment of the robustness of neural networks — Part 1: Overview
- ISO/IEC TR 24030:2021 – Information technology — Artificial intelligence (AI) — Use cases
- ISO/IEC TR 24368:2022 – Information technology — Artificial intelligence — Overview of ethical and societal concerns
- ISO/IEC TR 24372:2021 – Information technology — Artificial intelligence (AI) — Overview of computational approaches for AI systems
- ISO/IEC 24668:2022 – Information technology — Artificial intelligence — Process management framework for big data analytics
- ISO/IEC 25059:2023 – Software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Quality model for AI systems
- ISO/IEC 38507:2022 – Information technology — Governance of IT — Governance implications of the use of artificial intelligence by organizations

Since AI has been growing exponentially during the recent years, there are several standards under development that have to be duly taken into account in the next future, such as:

- ISO/IEC FDIS 42001 – Information technology — Artificial intelligence — Management system
- ISO/IEC DIS 5259 – Artificial intelligence — Data quality for analytics and machine learning (ML)
- ISO/IEC FDIS 5338 – Information technology — Artificial intelligence — AI system life cycle processes
- ISO/IEC DTR 5469 – Artificial intelligence — Functional safety and AI systems

In the following sections, a brief description of some relevant standards (ISO/IEC TR 20547 family, ISO/IEC TR 24027) is reported.

3.5.1. ISO/IEC 23894 – AI Guidance on Risk Management

The ISO/IEC 23894 [41] is an international standard providing guidelines to organisations on how manage risk specifically related to Artificial Intelligence when develop, produce and use product, systems and

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services that utilize AI. The standard provides guidance for the integration of the risk management in their AI-driven activities.

ISO/IEC 23984 has as baseline the ISO 31000 in terms of principles, framework and processes, extending the ISO 31000 guidance specifically for AI systems. Therefore, it is divided into three main parts:

- Clause 4: Principles – the principles of the risk management are described with specific consideration of the use of AI.
- Clause 5: Framework – it defines the risk management framework, underlying specific aspects to the development, provisioning or use of AI systems.
- Clause 6: Processes – it provides a specific description of the processes for AI involving the systematic application of policies, procedures and practices to the activities of communicating and consulting.

3.5.2. ISO/IEC TR 20547 – Big Data Reference Architecture

Industries, and not only, are facing an explosive growth in the sizes of the generated data. Two main issues raise dealing with big data:

1. Lack of standard definitions for terms related to the concept of big data
2. There is no consistent approach to implement and describe big data architecture

The ISO/IEC TR 20547 family has the objective to solve the second issue, providing a framework and reference architecture to organisations to effectively and consistently develop and describe their technologies. For the sake of completeness, the first issue is solved by the standard ISO/IEC 20546.

ISO/IEC TR 20547 is composed by 5 parts:

- Part 1: Framework and application process – it describes the framework of the big data reference architecture and the process to apply it in developing a user problem.
- Part 2: Use cases and derived requirements – it provides use cases examples with related technical considerations useful for big data architects.
- Part 3: Reference architecture – it describes the big data reference architecture (BDRA).
- Part 4: Reference architecture – it describes the security and privacy aspects to big data.
- Part 5: Standards roadmap – it provides a list of published standards and standards under development related to big data, specifying their relationships with the reference architecture.

The BDRA, described in terms of User and Functional views, is intended to provide a common language, encourage the application of the standard, facilitate the understanding of the big data components, processes and systems and the analysis of standard for interoperability.

3.5.3. ISO/IEC TR 24027 – Bias in AI

Bias in AI system can be introduced by deficiencies in system design due to human bias. Developing an AI without unwanted bias is challenging and is an active area of research. ISO/IEC TR 24027 addresses bias in AI systems and provides methods and processes to detect and treat bias in AI.

This standard includes:

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- an overview of bias and fairness;
- potential sources of unwanted bias and terms to specify the nature of potential bias;
- assessing bias and fairness through metrics;
- addressing unwanted bias through treatment strategies.

4. Development Possibilities and Limitations

The Chapter 4 reports an overview of the limitations and possibilities for the RaRe^2 Digital Twin to efficiently carry out the dynamic process of adaptation of the production chain. An analysis of the European organisation production management facing different changes factors is carried out through a specific survey. The responses are useful to give an overview of the possible choices and decisions, involved departments in the context of several changing scenarios.

4.1. Digital Twin for Use Cases Optimization

The creation of the Digital Twin (DT) within the RaRe^2 project is a very challenging goal that offers the possibility to have a versatile solution to the multifaceted challenges posed by the four distinct use cases. This dynamic effort encapsulates a diverse spectrum of requirements, perspectives, and expectations from stakeholders, collectively shaping the future trajectory of the DT. As the pivotal driving force behind the project's concept, the DT aims to overcome conventional boundaries in the reconfiguration capabilities of most companies, paving the way for a new era of manufacturing processes optimization and adaptability.

Implicit in this approach is the need for meticulously curated data inputs, the true foundation upon which the DT's decision-making capabilities rest. In fact, this endeavor is fundamentally contingent on the DT's capacity to interact with, interpret, and leverage data in a digital format. It is of course highly impractical to feed the DT decision making algorithm with paper documents, underscoring the indispensability of electronic file formats for facilitating efficient interactions and analyses. Unavailability of digital data can be compensated by the possibility to manually insert missing information. Nevertheless, this last option should be utilized as less as possible in order to not collide with the DT’s intrinsic automatic nature.

The core of the DT's efficiency should lie on its ability to seamlessly accommodate quantitative parameters, with a correct characterization of which can be considered variable and which should be considered constants, creating an accurate description of the manufacturing landscape. While the digital segment catalyzes these interactions, it is the human factor that should deal with the pragmatic manifestation of these processes. A keen understanding of the roles and competencies required for each process allows the DT to craft a meticulous digital map, seamlessly connecting roles to actionable tasks within specific operational zones. This orchestration forms the fundaments of this optimized problem-solving platform, simplifying the convergence of human versatility and digital precision.

Yet, the DT's scope should extend well beyond individual processes. The project's framework is linked with diverse threads, each representing distinct processes in distinct sectors, spanning constructions, injection molding, assembly and many more. It is the responsibility of the DT to consolidate this heterogeneous mosaic into a coherent macrosystem, meticulously cataloging information pertinent to each sector's demands. The challenge is of great difficulty as the DT should interface with machinery of disparate

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natures, each governed by unique protocols, control mechanisms, and operational aspects. The DT's true value depends then upon its ability to interface with a multitude of machines, each a vital gear in the intricate manufacturing ecosystem.

A corollary to this principle emerges in the case of MMM, where the field's interface with the DT becomes a critical key point. As an intermediary, a dedicated employee could assume the role of ensuring unceasing data connectivity, affording real-time insights that act as a bridge between the real construction site and the DT. This is vital as the availability of materials in the field is analyzed. Using a comprehensive database, the DT can make real-time decisions based on real-world data.

However, connectivity is not the only challenge for the creation of the DT. The various components like machinery, software, databases, and human expertise need to work together, to create a seamless process guided by the DT which should act like a conductor, coordinating interactions among different systems with unique running environments and protocols. As just shown, different realities may have different priorities and different aspects that may be more troublesome to address during DT implementation.

For example, from the vantage point of Karwala, the central constraint should center around the imperative to effectuate a seamless transition towards the production of alternative devices. In this context, the DT assumes a role of paramount significance with its primary functions set to provide a comprehensive roadmap for transitioning materials, suggest potential new suppliers, orchestrate the integration of specific machinery, or delineate requisite modifications such as the introduction of new moulds or equipment specifications. The DT could also analyse machinery intrinsic characteristics and suggest an optimized usage optimization by allowing the user to indirectly communicate through the DT itself.

Regarding current production processes, a sufficient understanding of Fontana’s high aesthetic standards may be too challenging in the implementation phase of the DT. As a consequence, the DT could focus on transition toward other sectors, analysing materials in stock, new materials, potential new suppliers, available personnel and their unique skills, market status, new sector requirements and many other factors. Ideally, the DT should then suggest a list of actions to perform to successfully transition into the sector evaluated to be the most profitable relatively to the current company status.

For Menicon, it is suspected that the high precision and accuracy need for their specific products will be challenging factors in the development of the DT. An interesting feature that could be evaluated in the implementation phase, which would have positive effects also on the other companies and sectors, could be the addition of an analysis tool able to analyse the technical specifications of machinery and materials in order to determine if a machine that, for example, now produces contact lens, could be converted to produce, for example, lens for glasses.

Certainly, the challenges and opportunities go beyond individual use cases. In a world where seamless connectivity is vital, standardizing processes is important for smooth communication between different entities. The DT's usefulness wouldn’t be confined to the digital world; it would be about bringing together the physical and virtual.

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Precision is crucial in this context, and it goes hand in hand with adaptability, efficiency, and economic implications. Unfortunately, these factors require a lot of effort in the development phase, and their implementation is yet to be confirmed. In this view the DT should work like a compass, balancing precision with practicality, guiding the manufacturing process through changes.

Another predictable problem, related to the DT's potential, is closely tied to human experience. Managing change, training, and cultural acceptance all play a role in the success of DT projects. A successful outcome depends on an environment ready for change, where technology and human collaboration come together. It can easily be predicted that a lot of effort will have to be placed in the training, both from a practical point of view (i.e., operators will need time to understand how to efficiently use and interface with the DT) and from a psychological point of view. Historically, new technologies come with a certain level of distrust among the operators which could feel threatened by the automatization the DT would introduce and scared by the possibility of being replaced. That could lead to a conscious or unconscious sabotage of the system. It must then be correctly explained how this kind of instrument will interface with short and long-term activities in the company environment.

Looking ahead, the DT will play a central role in steering industries toward a digital future. It's built on data, but its importance lies in optimizing for humans, making real-time decisions, and coordinating different processes smoothly. The DT's limitations push for innovation, promoting collaboration and standardization. Its potential depends on what the manufacturing landscape will focus on, hopefully leading to an adaptive, efficient, and digitized future. As the project continues, the DT will evolve, shaped by the contributions, challenges, and successes of those involved.

4.2. Change Factors and Reconfiguration Possibilities

In today's rapidly evolving business landscape, companies must proactively adapt to potential changes to ensure their competitiveness and long-term sustainability. One way that manufacturers can become more agile is to be prepared to adapt to change. This means being able to respond to changes quickly and effectively in market demand, product design, supply chain structure, or regulatory requirements. The RaRe^2 project focuses on exploring reconfigurability strategies for companies facing various disruptions, including economic shifts, environmental factors, and changes in suppliers. The survey conducted as part of the project provided valuable insights into the potential challenges and actions that companies can consider to navigate these changes effectively.

- **Market Demand**: To successfully navigate fluctuations in market demand, companies have shown general interest in implementing robust demand forecasting tools and techniques. Leveraging advanced data analysis and predictive modelling can enable businesses to anticipate demand patterns more accurately and as such they can align production levels with projected demand. Companies can also optimize their operations to avoid excessive inventory or stockouts, and their transportation schedules and routes to allow a quick adjustment to changing customer needs, improving overall responsiveness. Another interesting result that has emerged within the survey, is that there is a general feeling that more could be done regarding R&D activities, developing new products, services, and solutions that can satisfy evolving market demands, providing competitive edge changes. In general, by correctly reading data-driven market signals,

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streamlining logistics operations, and pursuing a culture of innovation, companies can proactively respond to changing market dynamics and exploit emerging opportunities.

- **Shifts in Supply Chain Structure**: Maintaining operational efficiency and resilience requires companies to adapt to shifts in the structure of the supply chain, which in an increasingly interconnected and globalized business landscape, constantly evolves due to factors such as changing market conditions, emerging technologies, and geopolitical developments. To effectively navigate these shifts, companies expressed the need to employ strategic foresight and proactive measures like integrating new suppliers into existing logistics networks and enhancing supply chain flexibility. By forging relationships with new suppliers, companies can face with additional expertise, resources, and geographic reach, reducing dependence on a single source. Furthermore, revaluating transportation routes and carriers allows companies to identify cost-efficient and sustainable alternatives. Good strategies include exploring alternative modes of transportation, optimizing routing algorithms, or leveraging digital platforms that facilitate collaboration and data-sharing among multiple stakeholders. Moreover, implementing supply chain risk management strategies, such as diversifying sourcing locations and establishing backup plans, helps ensure continuity of operations and mitigate potential disruptions that could occur when the production process relies on a single source. Embracing advanced analytics and predictive modelling can further enhance the ability to identify potential disruptions and take pre-emptive actions.
- **Introduction of New Products or Product Lines**: The introduction of new products or the expansion of existing product lines necessitates careful planning and adjustment across various aspects of the business. It is crucial, for example, to optimize warehouse layout and storage systems to accommodate the unique characteristics of new products. This may involve reconfiguring shelving arrangements, implementing specialized storage equipment, or adopting innovative inventory management solutions. Furthermore, introducing new products often requires an expansion of distribution channels or routes to effectively reach target markets and expand the customer base. These requirements could be achieved by partnering with additional distributors, exploring e-commerce platforms, or establishing strategic alliances to leverage existing distribution networks. By diversifying sales channels, companies can discover new customer segments, increase market penetration, and increase overall revenue. Additionally, upgrading inventory management systems to accurately track and manage new product lines is of fundamental importance. Practical actions could be the implementation of advanced inventory tracking technologies, such as RFID tagging, barcode scanning, or real-time monitoring. The use of data analytics and demand forecasting models could also help determining optimal stocking levels, anticipate demand patterns, and optimize inventory replenishment strategies. By embracing these measures, companies can successfully navigate the complexities associated with introducing new products or expanding existing product lines, ensuring a seamless transition.
- **Regulatory Changes**: Staying informed and compliant with regulatory changes is vital for businesses operating in dynamic environments. As regulatory frameworks evolve, companies must remain vigilant and proactive in adjusting their logistics and supply chain practices to meet new requirements. Adapting logistics procedures to meet new regulations, such as documentation or labelling requirements, ensures compliance and helps avoiding penalties.

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Furthermore, as regulations often aim to enhance product safety, companies can implement additional quality control measures in warehousing, transportation and production process to safeguard product integrity and enhance customer satisfaction. For example, routine inspections could be conducted, temperature-controlled storage facilities could be implemented, or product packaging could be enhanced in order to meet stringent safety standards. But continuous training for employees on updated regulatory requirements is surely the most crucial activity in mitigating risks and ensuring adherence to evolving standards. Investing in ongoing education and training programs, companies empower their workforce with the knowledge and skills necessary to navigate complex regulatory landscapes confidently. Furthermore, following a culture of compliance and establishing robust monitoring and auditing mechanisms further strengthens regulatory compliance efforts. Another wise action companies should do, is staying ahead of regulatory changes, thus maintaining a competitive edge, building trust with stakeholders, and ensuring their operations align with legal requirements.

4.3. Sector Transition Results

One of the objectives of RaRe^2 Project is to enable the European organizations to reconfigure their production depending on internal and external factors duly taken into account to develop and follow the best and most efficient strategy for readaptation. In particular, a first analysis has been carried out related to the use-case providers sectors to understand the possibilities of reconfiguration and entrance in adjacent sectors.

First, to make the reconfiguration “easier”, the organisation should be certified for three relevant standards, the ISO 9001, ISO 14001 and ISO 45001. These standards allow the organisation to have a well-established management system to prove the quality of their production, the attention to the environmental sustainability and the health and safety of their employee and customers. These certifications are fundamental to be trusted and to open lots of possibilities of business for the organisations. With a well-planned strategy, the three certifications can be obtained (if not obtained yet) with less than 6 months for sure. It could be even possible to be certified in 2 months. This is possible if the organisation has already established a good enough management system that has only to be certified after the implementation of possible small changes. The three standards have several requirements in common and this similarity helps in quickly obtaining the certifications. RaRe^2 Project could help in this way, helping the organisations to well-define their processes and management system, to understand the needs and supporting them in fundamental decisions.

Focusing on the use-case providers sectors, the possibilities and needs for the reconfigurations have been studied with particular attention to the required certifications for the adjacent sector of interest.

MMM, a leader in manufacturing of RUMED, could be interested not precisely in a sector transition, but in different applications in the same sector that is modular building. In this case, the production line and processes are almost the same for different healthcare applications, but also for the other applications such as educational buildings and offices. The expertise of an organization like MMM in the production of modular building, allows to adapt the design phase and production depending on the considered application. For different types of application, new designs of the modular building are needed. The integration of new suppliers could be possible, but modular buildings are made mostly of the same

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materials. Also the production line is almost the same. Therefore, in terms of supplier and production, a transition to other modular building applications can be fast. The main limitation is related to the possibility to join different country markets, since the requirements for the building technical setup could be very different from country to country. This consideration brings the need to have a parametrized design for the modular building sizes and systems (HVAC, electrical, plumbing). The issue is not directly related to the design phase, but to the huge amount of information to gather depending on the country where the modular building has to be installed. In Europe the requirements don't vary much, for example several countries follow the ISO 14644 for the HVAC systems and the same guidelines for the healthcare centres. However, outside Europe obtaining the needed information to correctly design the modular unit could be quite tricky.

Fontana Group has a strong expertise in aluminium shaping and manufacturing of dies for the automotive industry. Therefore, possible adjacent sectors are the rail and aerospace industries whose production is also related to the expertise of an organization like Fontana. For what concerns the rail sector, the main limitation to the transition is linked to the IRIS certification that is mandatory for sales in Europe of rolling stocks and related equipment and components. In order to obtain such certification, the average time is about 12 months. However, with the RaRe^2 development, since the IRIS is based on ISO 9001 with the addition of requirements specific for the rail sector, an organization could plan in advance a perfect and customized strategy to obtain the certification faster than 12 months. The minimum needed time to obtain the certification is related to the required 6 months of records to monitor and evaluate the management of the production line and the satisfaction of the requirements reported in the IRIS standard. Therefore, a reconfiguration to the rail sector could be possible with less than 6 months integrating possibly other suppliers and with the need to define new products. To make the transition more efficient the new products, Fontana would have to consider the current production line of the organization, trying to limit the changes to new dies designs. Focusing on the aerospace sector, the similarities with the automotive sector make the fast transition and reconfiguration more feasible. Both automotive and aerospace sectors show advanced engineering in aerodynamics and lightweight material design, efficient production processes to meet market demands and capacity to integrate multiple systems and technologies. Moreover, there are not mandatory certifications to join the aerospace market even if following EN 9100 standard is of fundamental importance to prove quality and be trustworthy. Therefore, considering the integration of potential new suppliers, a fast reconfiguration to the aerospace sector could be feasible even without the EN 9100 certification. The certification should still be obtained afterwards (at least 3 months are needed for the certification process) to enlarge and improve the organisation business.

Karwala main production process is injection moulding, and the analysed adjacent sector and possible products of interest are strictly linked to this process. The transition to the automotive sector is only linked to the IATF certification that is required as minimum requirement by car manufacturers. However, opportunities to join the automotive market are possible even without the IATF certification so a fast transition is considered feasible. This is not true for the rail sector where the IRIS certification is fundamental. For Karwala there are several adjacent sector possibilities due to the versatility of their main production process, the injection moulding. A great opportunity for such type of organisation is the possibility to join the food and beverage packaging industry. To join this market is necessary to integrate

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suppliers that provide materials in line with several standards and regulations to guarantee the safety of food. Therefore, careful research for certified suppliers has to be carried out. Moreover, the production chain for food packaging application has to follow and be compliant with these quality and safety standards too, such as the BRCGS Packaging Materials. 12 months are generally needed to obtain the certification due to the necessity of records and well-defined documentation. As a consequence, even if the sector could be a great opportunity a fast reconfiguration is not considered feasible. Another possibility is the consumer product sector, where the production of toys and components of electronic devices has been studied. The toys production requires the compliance with the European Toy Safety Directive 2009/48/EC that formulated the EN 71 standard to ensure the safety of the toys in the European market. The compliance with this standard requires to execute several tests on the toys to evaluate its safety. The transition to toys production requires the design of new parts and products and moulds, the training of the employees, the execution of tests according to the EN 71 standard and as a result a fast transition is not retained feasible. The fast transition to the production of components for electronic devices is suggested if the production is limited to parts with no advanced electronic components since there are not stringent standards for their manufacturing. Despite this consideration, following the standards for safety and quality is fundamental to be trustworthy and enlarge the number of customers. Lastly, joining the medical industry could also be possible, producing products such as beakers, test tubes, surgical tools. However, the transition to this sector is the most complex since it requires the compliance with high standards for medical industry. For example, the production of medical devices requires a cleanroom with high performances and its implementation could be long in time and high in costs.

Menicon has great expertise in the production of prescription contact lenses that are customized and personalized to each individual patient. Therefore, organisations like Menicon already satisfy standards for medical industry and are compliant with high quality standard for the production of lenses. The adjacent sector taken into account is the one related to eyewear products manufacturing. With a well-planned strategy a transition could be feasible since the basic technology to produce the contact lenses has similarities with the production of other kind of lenses. New suppliers and machineries would have to be integrated in the production chain depending on the product to manufacture. Moreover, a reconfiguration of the production process would be needed. In terms of certification a fast reconfiguration could be feasible, but the reconfiguration of the production line could require more time and efforts.

To conclude, fast reconfiguration is sometimes feasible with less than 6 months. However, this could be possible with the help of a well-designed RaRe^2 dynamic process of adaptation. The bases for the change are the production processes of the sector to join, the suppliers to be integrated and the needed training for the employees. If these factors are carefully studied and planned in advance, together with the attention of the compliance with the relevant standards of the sectors, the transition will proceed quickly and efficiently thanks to the RaRe^2 Project developments, allowing the organisation to implement the right strategy minimizing the waste of time and resources.

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5. Conclusions

In this document, with the goal of fostering operational excellence and adaptability across diverse industrial sectors, a comprehensive analysis and strategic overview of the standards used in the industrial landscape has been conducted and critical pathways for achieving dynamic process adaptation and transformation have been highlighted. The work was based on meticulous studies and insightful interviews and surveys with both internal beneficiaries and external stakeholders, with the objective to comprehend the intricate mixture of challenges, opportunities, and potential accelerators that can support the evolution of industrial automation, production chain management, and change management. The information received from the internal beneficiaries and the external stakeholder served as an input for a better understanding of the existing interconnections between the operational processes that are the ultimate focus of optimization of the project. In particular, a fundamental concept has been the recognition of shared elements between different sectors and manufacturing chains. These similarities not only did underscore the significance of coordination in approaching the different change factors that may disrupt a company core business but will also serve as drivers for improving efficiency.

Particular attention has been paid to the use case providers operational context. An overview on the standards currently in use within their companies has been provided and intensive effort has been put in the detailed analysis of standards, regulations, and certifications commonly used in adjacent sectors considered as best candidates for fast transitioning. The selection of these adjacent sectors has been guided by both suggestions received within the interviews and surveys with partners and stakeholders and by evidences obtained during the analysis of the industrial landscape those companies operate within. For each use case provider several adjacent have been determined and sector specific standards have been analysed in order to characterize as well as possible the legal and practical background the reconfiguration process will eventually be handled. The sector specific standard analysis has not been limited to adjacent sector transitioning. In fact, special needs coming from the use case providers have also been taken into account, and when required, specific indications have been offered. For example, MMM expressed their interest in expanding their market in other countries and as such, an overview of their operational sector status and legislative environment has been provided.

As described in Chapter 4, one of the main challenges that will have to be faced in the development of the Digital Twin objective of this project will be the interoperability between different equipment interfaces and the capability to maintain a seamless connectivity. For this purpose, a detailed description of standards related to these problems has been redacted. In particular, effort has been spent trying to give a complete overview on the different formats of electronic data exchange and the ways to harmonize data standardization between the practicality of the manufacturing processes and the digital aspects of the future work to be performed. These standards not only reflect the evolution of the industrial world but also provide a framework for achieving the ambitious targets of interoperability, data exchange, and streamlined business procedures that stand at the heart of effective change.

Finally, the factors identified as critical causes for the need for production chains reconfiguration have been examined, thus giving the possibility to indicate a way to achieve convergence between the digital and physical aspects of the problem. A roadmap for the development of the Digital Twin has been developed, dealing with the possibilities that this solution offers but also with its boundaries, limits and predictable implementation challenges.

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With a final reflection on the path undertaken in this phase of the project, it is evident that the road ahead is both promising and challenging. The roadmap that has come from this endeavour lays the baseline for the development of an innovative solution that has the potential to redefine the landscape of industrial processes. The pursuit of dynamic adaptation and change is an iterative process, that demands the willingness to engage with evolving standards and with the intense dynamism of the industrial sector.

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