NBOG	Notified Body Operations Group
PMS	Post-Market Surveillance
STED	Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices
TEAM-NB	European Association for Medical Devices of Notified Bodies
UDI	Unique Device Identifier

21.2 European Union: Medical Device Market and Structure

The European Union (EU) as of 2020 comprises 27 countries which represent 447.7 million inhabitants (source Eurostat 2020) (Table 21.1). The United Kingdom (UK) has left the EU on January 31, 2020 (so called Brexit) in accordance with the withdrawal agreement with a transition period until end of 2020. The medical device market is estimated to be of 120 billion Euros total sales amount making up 27% of the world market for medical technologies. It is the second largest medical technology market in the world after the United States (US). The medical device sector is consisting of around 32,000 companies, the majority of them (95%) are small and medium sized enterprises (SMEs). Based on manufacturer prices the largest markets in the EU are Germany (27%), France (14%), the United Kingdom (11%), Italy (10%) followed by Spain (6%), the Netherlands, Sweden, Belgium and Austria (all between 5% and 2% market share) (Source MedTechEurope 2020, the European Medical Technology Industry).

Those countries constitute the EU where the free circulation of goods, services and humans is established. Medical Devices bearing a marking indicating the European Conformity Assessment to regulations the—CE mark—are considered to be cleared in the European Union market. CE marking indicates that a product has been assessed by the manufacturer and deemed to meet EU safety, health and environmental protection requirements hence to be in compliance with the EU conformity assessment regulations.

It is required for products manufactured anywhere in the world that are then marketed in the EU.

Table 21.1 Member states of the European Union (EU)

Date of entry into the EU	EU member states
1958	Belgium, France Germany, Italy, Luxembourg, the Netherlands
1973	Denmark, Ireland, the United Kingdom (Brexit on January 31, 2020)
1981	Greece
1986	Portugal, Spain
1995	Austria, Finland, Sweden
2004	Czech Republic, Cyprus, Estonia Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic, Slovenia
2007	Bulgaria, Romania
2013	Croatia
2020	Withdrawal of the United Kingdom

The European Economic Area (EEA) was established on January 1, 1994, following an agreement between the member states of the European Free Trade Association (EFTA) and the European Community: Iceland, Liechtenstein and Norway are allowed to participate in the EU's Internal Market without a conventional EU membership. In exchange, they are obliged to adopt all EU legislation related to the single market, for Medical Devices for instance. One EFTA member, Switzerland, has not joined the EEA. CE marking of Medical Devices is, however, recognized in Switzerland by means of a Mutual recognition Agreement (MRA) between EU and Switzerland, in which every law specifically needs to be confirmed into the MRA structure.

CE marking is also in place in Turkey, following the Ankara Agreement between EU and Turkey. Mutual acceptance between Turkey and EFTA is arranged in an agreement between these parties based on CE marking. The EU has also signed MRAs to promote trade in goods between the European Union and third countries and facilitate market access outside Europe with Australia and New Zealand (Table 21.2).

Figure 21.1 Structure of the EU institutions.

Table 21.2 Associated states with EU accepting conformity assessment results

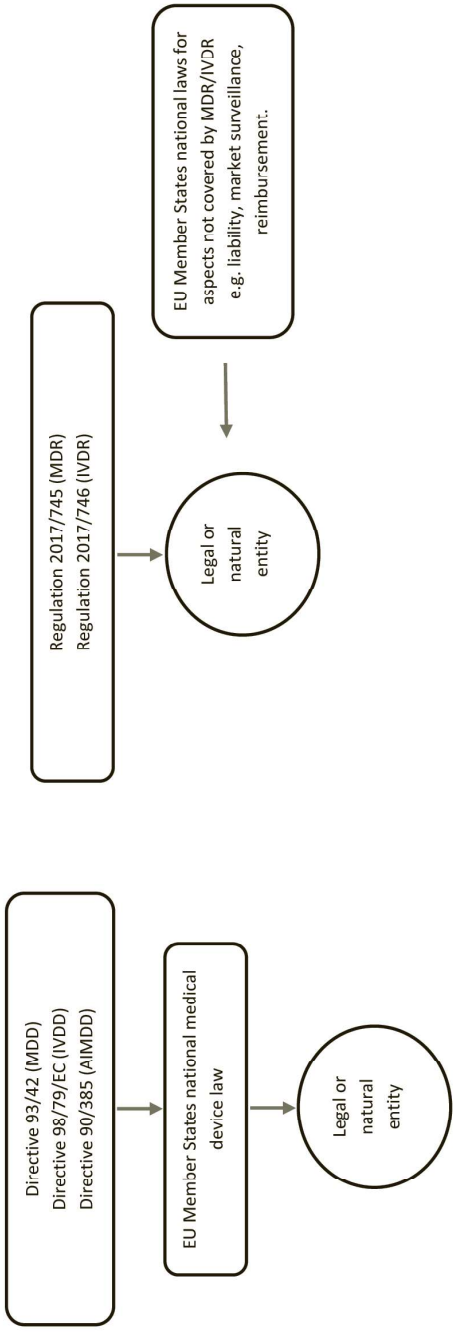
Association	States
EFTA/EEA	Iceland, Lichtenstein, Norway
Mutual Recognition Agreements (MRA)	Switzerland, Turkey, Australia, New Zealand

21.3 EU Regulations on Medical Devices

The EU has with 2017 launched new Regulations on Medical devices 2017/745 (MDR) and In vitro Diagnostics Regulation 2017/745 (IVDR) with a transition period of 4 respectively 5 years and Date of Application of May 2021 for MDR and May 2022 for IVDR. These new Regulations will replace the existing Directives. The Directive is addressed to the EU Member States and to be transposed into national law in each country whereas the Regulation is directly applicable in each EU member state without national transposition necessary. Detailed technical requirements and characteristics are further provided by voluntary product standards and guidance document developed by national and international expert groups such as the international standards organization (ISO www.iso.org, e.g. EN ISO 10993 series on biocompatibility, ISO 14155 on clinical investigation of medical devices or ISO 14971 on risk management). The international reference standard for medical device quality systems requirements is ISO 13485 is fully accepted in the EU by competent authorities and notified bodies.

21.4 Harmonized Standards, Presumption of Conformity and State of the Art

A standard stands for an agreed understanding of key words and terminology and methods, which, when applied by the manufacture, ensure a common global level of safety of medical care to patient.


Directive 93/42 (MDD)
Directive 98/79/EC (IVDD)
Directive 90/385 (AIMDD)
EU Member States national medical device law
Legal or natural entity
Regulation 2017/745 (MDR)
Regulation 2017/746 (IVDR)
Legal or natural entity
EU Member States national laws for aspects not covered by MDR/IVDR e.g. liability, market surveillance, reimbursement.

The formal definition of a standard is: standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines or definitions of characteristics, to ensure that materials, products, process are fit for their purpose. Standards can

- provide reference criteria that a product, process or service must meet;
- provide information that enhances safety, reliability and performance of products, processes and services;
- assure consumers about reliability or other characteristics of goods or services provided in the marketplace.

Harmonized standards are European standards prepared in accordance with the General Guidelines agreed between the Commission and the European standards harmonization, and follow a mandate issued by the Commission after consultation with the Member States. Harmonized standards are published in the official journal of the European Union in the framework of the implementation of Council Directive 93/42 or Regulation 2017/745 as new standards are added to the list or revisions are to be applied. In case of revisions, the communication also gives clarity on the transition period until which the new version has to be complied with.

Conformity with harmonized standards as published in the official journal, confers a presumption of conformity with the Essential Requirements of the medical devices directive 93/42/EEC. Doing so harmonized standards become binding with the same legal quality as EU or national medical device laws. In addition to harmonized standards, regulators in the EU request economic operators and especially manufacturers to comply with latest standard versions available from standardization organizations (e.g. www.iso.org) in the context of the state of the art (SOTA) requirements as stipulated by ISO 13485 requirements and national medical device laws. The SOTA benchmark requires the industry to actively and regularly screen latest developments of standards and document gaps and necessary actions to comply with the latest version within due time. Non-compliance to harmonized standard or SOTA standards leads to non-conformity and possibly loss of CE marking for the concerned device.

For getting information about standards under review or creation and for acquisition of the published standard, the manufacturer has to apply and buy them from the standard organizations at the European level (Table 21.3) or at national level.

Table 21.3 List of committees for standardization

Committee name	Scope
CEN	CEN is the European Committee for Standardization. CEN contributes voluntary technical standards which promote free trade, the safety of workers and consumers, environmental protection, exploitation of research and development programs, and public procurement.
CENELEC	CENELEC is the European Committee for Electrotechnical Standardization and is responsible for standardization in the electrotechnical engineering field.
ETSI	The European Telecommunications Standards Institute (ETSI) produces globally applicable standards for Information and Communications Technologies (ICT), including fixed, mobile, radio, converged, broadcast and internet technologies.
IEC	IEC is the International Electrotechnical Commission. IEC is World's leading organization that prepares and publishes International Standards for all electrical, electronic and related technologies.
ISO	ISO is International Standards Organization: it is an international standard-setting body composed of representatives from various national standards bodies.

21.5 European Associations

The European associations which are active in Europe and contribute to shape the regulatory environment and offer platforms for regulators and industry to communicate with each other and work on harmonization. A non-exhaustive list of some organization is listed in Table 21.4.

Table 21.4 List of European associations

Association name	Competences/terms of reference	Participants
Medical Device Coordination Group (MDCG)	MDCG provides advice to the Commission and assists the Commission and the Member States in ensuring a harmonized implementation of medical devices Regulations (EU) 2017/745 and 2017/746.	Organization and Member States
Notified Body Operations Group (NBOG)	The Notified Body Operations Group's aim is to contribute to improvement of the overall performance of notified bodies in the medical devices sector by primarily identifying and promulgating examples of best practice to be adopted by both notified bodies and those harmonization responsible for their designation and control. They review the "recommendations" issued by the NB-MED (group where all the EU notified bodies participate) and act as a "Mirror Group" following GHTF work relating to notified bodies.	Competent Authorities/ designating Authorities (experts), COM services (On focal points, a notified body representative can be invited to participate)
TEAM-NB	Team-NB stands for The European Association for Medical Devices of Notified Bodies, a non-profit association of notified bodies under the medical device regulations The Association aims • to actively support the transition to the new medical devices and in vitro diagnostic regulations 2017/745 and 2017/746 and the new regulatory framework; • to promote high technical and ethical standards in the functioning of notified bodies; and • to protect the legal and commercial interests of notified bodies in their vital role in the functioning of the three medical device directives.	Medical device notified bodies

Association name	Competences/terms of reference	Participants
MedTech Europe **Medical Devices Technology Industry Association** MedTech Europe from diagnosis to cure	MedTech Europe represents the medical technology industry in Europe. MedTech Europe members include both national and pan-European trade and product associations as well as medical technology manufacturers, representing around 22,500 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability.	Industry re presentatives
EDMA **European Diagnostic Manufacturers Association** 	EDMA is the trade association that represents the In Vitro Diagnostic (IVD) industry active in Europe. EDMA membership brings together 22 National Associations in European countries and 43 major companies engaged in the research, development, manufacture or distribution of IVD products. Through its affiliated National Associations, EDMA represents in total more than 500 companies across Europe. Since its establishment in 1979, EDMA acts in co-operation with other European and international trade associations representing medical devices, pharmaceuticals and biotechnology in general, as well as with scientific societies and patients organizations to make a real difference in health and life quality.	Industry representatives
COCIR 	European Radiological, Electromedical and Healthcare IT Industry non-profit trade association founded in 1959, representing the medical technology industry in Europe. COCIR's aim is to represent the interests and activities of its members and act as a communication channel between its members and the European institutions and other regulatory bodies. It also cooperates with other organizations on issues of common interest.	Industry representatives

(*Continued*)

Table 21.4 (*Continued*)

Association name	Competences/terms of reference	Participants
	COCIR seeks to promote the development of harmonized international standards and regulatory control which respect the quality and effectiveness of the medical devices and healthcare IT systems without compromising the safety of patients and users and promote the free worldwide trade of these products. COCIR encourages the use of technology in delivering cost-efficient and state of the art healthcare systems.	
EUROM VI-Medical Technology	European small and medium enterprises involved in medical devices for: –surgery (including dental), anesthesia, respiration and inhalation, operating theatre, gas supply, sterilization, disinfection, internal and external orthopedics, opto-medical and ophthalmology area, rehabilitation and handicaps fields, infusion and transfusion. Its objectives are to represent European Medical Technology Industry to promote cooperation between members but also with other European organizations; to encourage worldwide trade by being involved in harmonization of legislation, standardization, mutual recognition and certification procedures, to be a partner on works with UE Commission and Standardization Bodies; to defend European Industry views on international activities.	Industry representatives

21.6 Overview of New Medical Devices Regulations

The EU has revised its laws governing medical devices and in vitro diagnostics to align with the developments of the sector. The priority was to ensure a robust, transparent and sustainable regulatory framework and maintain a high level of safety, while supporting innovation. Two new regulations on medical devices and in vitro diagnostic medical devices entered into force in May 2017 and are progressively replacing the existing directives after a transition period. The existing directives on medical devices and in vitro diagnostics are currently replaced by new regulations with their date of application (DOA) (Table 21.5).

Table 21.5 List of applicable regulations to medical devices

Repealed directives	Scope	New EU Regulations	Date of application (DOA)	Examples
AIMDD 90/385/EEC	Active Implantable Medical Devices	**Regulation 2017/745/EU (MDR)**	**26.05.2021**	Cardiac pacemaker, defibrillator Sutures, syringes, implants, software, ophthalmic or orthopedic devices, devices without medical purpose
MDD 93/42/EEC	Medical Devices			
IVD 98/79/EC	In Vitro Diagnostics Medical Devices	**Regulation 2017/746/EU (IVDR)**	**26.05.2022**	Cancer diagnostics, self-tests, immunoassays, glucose monitors

Other products which do not fall under the scope of Medical Devices are regulated by different Directives and Regulations such as

- Biocides Directive 98/8/EC;
- Directive for Medicinal Products 2001/83/EC, applicable to medicinal products/drugs;
- Regulation 1223/2009 establishing the safety and efficacy requirements for cosmetic products in the EU applicable to cosmetic products.

21.7 Guidelines MEDDEV/NB-MED

The interpretation of the medical device laws is supported by the elaboration of guidelines entitled "MEDDEV" and issued within the Medical Device Experts Group: they are elaborated through a process of consultation with Competent Authorities and Commission representatives, notified bodies, industry and other interested parties in the medical devices sector. They remain voluntary; however, it is anticipated that the guidelines will be followed within the Member States and, therefore, ensure uniform application of relevant Directive provisions. Guidelines are subject of a regular updating process. The MEDDEVs are primarily applicable for devices under the Directive (MDD 93/42) but are also applicable for MDR 2017/745 devices as long as no new guidance exist. MEDDEVs will consecutively be amended and replaced by MDCG Guidance documents under the new Regulation (MDR 2017/745) as described below. In addition, the European Association for Medical Devices Notified Bodies (TEAM NB) has issued several guidance documents in order to facilitate the implementation of the medical devices regulations (NB-MED recommendations) (Table 21.6). Please note NB-MED is changing its name to NBCG (Notified Body Coordination Group).

Table 21.6 Examples of MEDDEV and NB-MED guidance (the exhaustive list in their latest revision is available on line on the MEDDEV and NBMED website)

Scope	Title	MEDDEV/NBMED reference
MDD Scope, filed of application, Definitions	Borderline products, drug-delivery products and medical devices incorporating, as integral part, an ancillary medicinal substance or an ancillary human blood derivative	MEDDEV 2.1/3 rev 3
MDD Classification of devices	Guidelines to the classification of medical devices	MEDDEV 2.4/1 rev.9
	Manual Borderline Classification Medical Devices	Version 1.22 (05-2019)
Technical Dossier, life cycle	Technical documentation	NB-MED/2.5.1/Rec5
	Reporting of design changes and of changes of the quality system	NB-MED/2.5.2/Rec2

Scope	Title	MEDDEV/NBMED reference
Clinical investigation, clinical evaluation	Clinical evaluation: Guide for manufacturers and notified bodies	MEDDEV 2.7.1 Rev4
	Guidelines for Competent Authorities for making a validation/assessment of a clinical investigation application under directives 90/385/EEC and 93/42/EC	MEDDEV 2.7/2 rev. 2
		MEDDEV 2.7/3 rev.3
		MEDDEV 2.7/4
	Clinical investigations: Serous adverse event reporting	
	Guidelines on Clinical investigations: a guide for manufacturers and notified bodies	
Market surveillance and vigilance	Medical Devices Vigilance System	MEDDEV 2.12/1 rev.8
	Clinical Evaluation–Post Market Clinical Follow-up	MEDDEV 2.12/2 rev.2
	Post-Marketing Surveillance (PMS) post market/production	MEDDEV 2.12/Rec1
	Manufacturer Incident Report (MIR) Form	Version 2020

21.8 Guidelines MDCG and Common Specifications

Under the new Regulations, the European Commission provides a range of guidance documents to assist stakeholders in implementing the medical devices Regulations. Legally non-binding guidance documents, adopted by the medical device coordination group (MDCG) these documents pursue the objective of ensuring uniform application of the relevant provisions of the regulations within the EU. The scope of these guidance documents provide details in line with the new requirements of the MDR and IVDR with regards to Unique Device Identifier (UDI), the new EUDAMED database, requirements for notified bodies and transition period as well as clinical evaluation and investigation and the new person responsible for regulatory compliance (PRRC).

Table 21.7 Examples of MDCG Guidelines and Common Specifications (the exhaustive list in their latest revision is available online on the European Commission website)

Scope	Title	Reference
UDI	Guidance on UDI for systems and procedure pack	MDCG 2018-3
	Guidance on basic UDI-DI and changes to UDI-DI	MDCG 2018-1
	Clarifications of UDI related responsibilities in relation to article 16 MDR	MDCG 2018-6
EUDAMED	Timelines for registration of device data elements in EUDAMED	MDCG 2019-4
	Registration of legacy devices in EUDAMED use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States	MDCG 2019-5 MDCG 2020-15
Notified bodies and transition	Significant changes regarding the transitional provision regarding to devices covered by MDD or AIMDD certificates	MDCG 2020-3 MDCG 2019-13
	Guidance on sampling of devices for the assessment of the technical documentation	MDCG 2019-10 MDCG 2020-2
	Transitional provisions concerning validity of certificates issued in accordance to the directives	
	Class I transitional provisions under Article 120 (3 and 4)—(MDR)	
Clinical investigation and evaluation	Clinical evaluation assessment report template	MDCG 2020-13
	Guidance on sufficient clinical evidence for legacy devices	MDCG 2020-6 MDCG 2020-5
	Guidance on clinical evaluation—Equivalence	MDCG 2019-9
	Summary of safety and clinical performance (SSCP)	
Person Responsible for Regulatory compliance	Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a "person responsible for regulatory compliance" (PRRC)	MDCG 2019-7
Reprocessing of single-use devices.	Commission Implementing Regulation (EU) 2020/1207 of 19 August 2020 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards common specifications for the reprocessing of single-use devices	Regulation (EU) 2020/1207

The MDR also foresees a new set of requirements in the form of common specifications (CS) (Table 21.7), which means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device. According to where no harmonized standards exist or where relevant harmonized standards are not sufficient, or where there is a need to address public health concerns, the European Commission, after having consulted the MDCG, may, by means of implementing acts, adopt CS in respect of the general safety and performance requirements set out in MDR Annex I, the technical documentation set out in MDR Annexes II and III, the clinical evaluation and post-market clinical follow-up set out in MDR Annex XIV or the requirements regarding clinical investigation set out in MDR Annex XV. It is also foreseen that specific product groups such as the MDR Annex XVI devices without medical purpose are subject to CS. As of October 2020 the Commission has published one set of CS via Implementing Regulation (EU) 2020/1207 of 19 August 2020. This CS is laying down rules for the reprocessing of single-use devices.

21.9 Definitions

21.9.1 Medical Device

A "medical device" according to MDR EU 2017/745 Art. 2 means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the

human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- Devices for the control or support of conception
- Products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) MDR and of those referred to in the first paragraph of this point

21.9.2 Devices without Medical Purpose

According to Art.1 (2) MDR the Regulation shall also apply, as from the date of application of common specifications adopted pursuant to Article 9 MDR, to the groups of products without an intended medical purpose that are listed in MDR Annex XVI, so called non-medical purpose devices. These group of products enters into the scope of the MDR in line with the common specifications to be adopted by the end of 2020. The MDR is regulating these devices having no intended medical purpose such as non-medical contact lenses, product modifying the anatomy, substances for dermal implantation, equipment to modify adipose tissue and others listed in MDR Annex XVI.

21.9.3 CE Mark

The CE Mark is the proof from the manufacturer that the product is in conformity with the Regulations.

CE Marking attests that the products are in conformity with the General Safety and Performance Requirements (GSPR) of the MDR and IVDR and that the products were subjected to the procedure of conformity assessment envisioned in the directives.

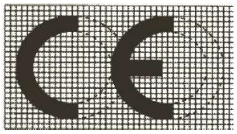
CE Marking is affixed before marketing the product and releasing it to the EU market for distribution or use.

CE Marking allows freedom of movement of the medical device in the territory of the European Union (EU) and EFTA/EEA.

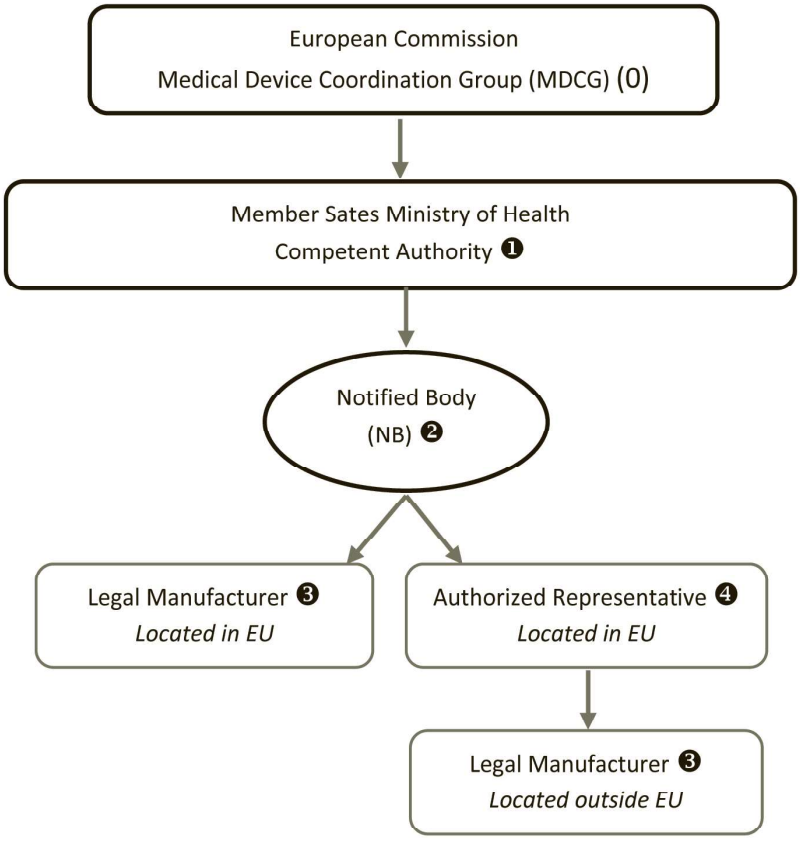
It engages the responsibility of the legal manufacturer, on all aspects relative to the products safety and efficacy as the legal (CE) manufacturer being the EU market authorization holder centrally responsible for the safety and efficacy of the product and all related activities such as design, manufacturing, sterilization and labeling.

The manufacturer must maintain the technical documentation of the device and supply it to the regulatory authorities in case of quality audits or inspections at any time.

Devices other than custom made devices and those intended for clinical investigations, that are put on the market or brought into service in Europe must be CE Marking according to the provisions of the MDR Annex V.



The manufacturer chooses a procedure for CE Marking, whether or not to utilize a notified body, in particular according to the class of the medical device.



21.9.4 European Commission and MDCG (0)

The European Commission helps to shape the EU's overall strategy, proposes new EU laws and policies such as the MDR and IVDR regulations, monitors their implementation and manages the EU budget. Within the European Commission, there are several Directorate Generals (DGs) that are in charge for the different policies. The DG internal market and DG health are responsible for the implementation and supervision of the EU MDR and IVDR regulations as the medical devices and IVD sector are essential to the provision of healthcare to citizens and is an important player in both the European and global economy.

The Medical Device Coordination Group (MDCG) provides advice to the Commission and assists the Commission and the Member States in ensuring a harmonized implementation of medical devices Regulations (EU) 2017/745 and 2017/746. The MDCG consists of Member States and Organizations involved in MD and IVD policy and consists of the following working groups involved in the implementation of the regulations and advocacy and guidance (e.g. MDCG guidance documents):

- Notified Bodies Oversight (NBO) Working Group
- Standards Working Group
- Clinical Investigation and Evaluation (CIE) Working Group
- Post-Market Surveillance and Vigilance (PMSV) Working Group
- Market Surveillance Working Group
- Borderline and Classification (B&C) Working Group
- New Technologies Working Group
- EUDAMED Working Group
- Unique Device Identification (UDI) Working Group
- International Matters Working Group
- In vitro Diagnostic Medical Devices (IVD) Working Group
- Nomenclature Working Group
- Annex XVI MDR devices Working Group

21.9.5 Competent Authority ❶

The Competent Authority is a government agency or other entity in an EU Member Sate that exercises a legal right to control the use or sale of medical devices within its jurisdiction respectively territory. It has the ability to take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements.

Its roles and responsibilities are as follows:

- Accreditation and inspection of the notified bodies
- Supervises the market
- Centralizes and evaluates the vigilance data until EUDAMED is operational
- Takes suitable enforcement measures in case of violation of the laws.

Examples of Competent Authority:

- UK: MHRA (Medicines and Healthcare products Regulatory Agency)
- France: ANSM (Agence Nationale de Sécurité du Médicament et des produits de Santé)
- Ireland: IMB (Irish Medicines Board)
- Germany: BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte)
- Spain: AEMPS (Spanish Agency of Medicines and Medical Devices)

21.9.6 Notified Body—Conformity Assessment Body ❷

A notified body or Conformity Assessment Body (as per MDR terminology) is a certification organization authorized by the relevant Member State's Competent Authority to perform conformity assessment tasks specified in the Regulation. As per Art. 38 MDR Conformity assessment bodies shall submit an application for designation to the authority responsible for notified bodies (ARN).

The assessment of the application is further described in Art 39ff MDR and involves the ARN, European Commission, the MDCG and a joint assessment team including an onsite audit of the applicant. After assessment of the application, the audit and corrective measure completion, the ARN shall submit its final assessment report and the NB designation to the Commission, the MDCG and the joint assessment team. After a final positive opinion, the ARN is responsible for the designation decision.

The notified body is responsible to evaluate the conformity of the product with the General Safety and Performance Requirements (GSPRS) and issues the CE mark certificate and quality management certifications. The notified body is an organization indicated and supervised by the proper authority of the Member State and must meet the criteria of Annex VII of MDR 2017/745. Notified bodies have to undergo designation until May 2021, date of Application (DOA) of the MDR in order to be able to continue their activities under the new Regulation.

The manufacturer calls upon the notified body of his choice: among the 56 (out of the original 87) registered notified bodies designated under the medical devices directive 93/42/EEC only 44 applications have been submitted for designation under the MDR. The number of accredited notified bodies has decreased in the past year and will continue to do as quality requirements for the NB designation are increasing in the EU.

Nando Information System

Notification is an act whereby a Member State informs the Commission and the other Member States that a body, which fulfils the relevant requirements, has been designated to carry out conformity assessment according to a directive. Notification of notified bodies and their withdrawal are the responsibility of the notifying Member State (Table 21.8). The lists of notified bodies can be searched on the NANDO web site. The lists include the Regulation under which the NB is designated (e.g. MDR EU 2017/745 or IVDR EU 2017/746), the identification number of each notified body as well as the tasks for which it has been notified, and are subject to regular update.

Table 21.8 Examples of notified body

Notified body, country		Identification number
GMED, France	GMED	0459
British Standards Institution, the United Kingdom	BSI	0086
National Standards Authority of Ireland, Ireland	NSAI	0050
TÜV SÜD Product Service GmbH, Germany	TÜV	0123

21.9.7 The Manufacturer ❸

The Manufacturer or legal manufacturer means the natural or legal person with responsibility for the design, manufacturing, packaging and labeling of a device before it is placed on the market under his own trademark, regardless of whether these operations are carried out by that person himself or on his behalf by a third party, as defined in each relevant section of the Regulations.

The manufacturer must ensure that it is manufactured to meet or exceed the required standards of safety and performance. This includes the three phases (design/development/testing, manufacturing, packaging and labeling) that lead to a product being ready for the market. The Legal Manufacturer is responsible of all the operations necessary to design, manufacture, label and package the product throughout its lifecycle from design to distribution to the final customer. The Legal Manufacturer is responsible to choose the notified body and affixing the CE Mark on the product once it is obtained. Depending on the organization, the Legal Manufacturer can be the Design Centre but not necessarily.

The manufacturer has an obligation to ensure that a product intended to be placed on the Community market is designed and manufactured, and its conformity assessed, to the GSPRS in accordance with the provisions of the applicable Regulations.

The manufacturer may use finished products, ready-made parts or components, or may subcontract these tasks. However, he must always retain the overall control and have the necessary competence to take the responsibility and liability for the product according to Art. 10 MDR.

The Manufacturers shall also, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under EU law and national law.

The Manufacturer has to establish a person responsible for regulatory compliance (PRRC) in his organization according to Art 15 MDR.

21.9.8 Authorized Representative ❹

The authorized representative means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation. According to Art. 11 MDR where the manufacturer of a device is not established in an EU Member State, the device may only be placed on the Union market if the manufacturer designates a sole authorized representative. This representative must fulfill at least the tasks as described in the Regulation such as the following:

- Verification that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer
- Keeping available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, at the disposal of competent authorities
- Complying with the registration obligations and verify that the manufacturer has complied with the registration obligations in EUDAMED
- Responding to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned
- Forwarding to the manufacturer any request by a competent authority of the Member State in which the authorized

representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device

- Cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices

The authorized representative is explicitly designated by the manufacturer, and he may be addressed by the authorities of the Member States instead of the manufacturer with regard to the latter's obligations under the Regulations.

21.10 Classification

21.10.1 Medical Devices

The EU Classification of Medical Devices is based on the risk of the device and follows the GHTF classification. The classification is made based on the rules laid down in Annex VIII of the MDR EU 2017/745. The classification is based on a risk assessment of the product, when used as intended. The "risk" is composed of the duration of use and the level of invasiveness, as defined by the intended purpose stated by the manufacturer. The "Intended purpose" means the use for which the device is intended according to the data supplied by the manufacturer on the labeling, in the instructions and/or in promotional materials.

Medical devices are divided into four classes named **Class I (s/r), Class IIa, Class IIb, and Class III** according to the level of risk the device as based on the following criteria (Table 21.9):

- Duration of use (transient, short-term, long-term)
- Invasiveness (invasive devices, body orifice, surgically invasive device)
- Active/non-active
- Implantable
- Specific hazards (e.g. contact with the Central Nervous System, animal tissues, absorbable material, ionizing radiation, Medical device with ancillary pharmaceutical substance)

Table 21.9 Examples of medical devices per class

Class	Risk	Examples
Class I	Moderate Risk	Surgical instruments Non-invasive tubing to evacuate body liquids Examination gloves Hospital beds Dental curing lights
Class Is	Moderate Risk (Sterile)	Sterile body liquid collection devices Sterile absorbent pads
Class Im	Moderate Risk (with a measuring function)	Syringe without needle (graduated barrel) Device for measuring body temperature Non-active device for measuring intra-ocular pressure
Class IIa	Moderate—Average Risk	Syringe with needle Tubing intended for use with an infusion pump Non-medicated impregnated gauze dressings Short term corrective contact lenses
Class IIb	Average—Elevated Risk	Hemodialysers Long term corrective contact lenses Urinary catheters intended for long term use Insulin pens Intraocular lenses (IOL)
Class III	Elevated Risk	Neurological catheters Prosthetic heart valves Aneurysm clips Pre-filled syringe for vascular access device flushing Spinal needle Absorbable sutures

21.10.2 Active Implantable Medical Devices

The active implantable medical devices are at maximum risk according to MDR EU 2017/745: by definition they are any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

Following are the examples of active implantable medical devices:

- Implantable cardiac pacemakers
- Implantable defibrillators
- Leads, electrodes, adaptors for above examples
- Implantable nerve stimulators
- Bladder stimulators
- Sphincter stimulators
- Diaphragm stimulators
- Implantable active drug administration device

By default, all accessories to AIMDs are covered under AIMD themselves. They cannot be classified separately under the MDD.

21.10.3 In Vitro and Diagnostics Medical Devices

The classification of in vitro and diagnostics medical devices is based on the risk of usage in line with IVDR EU 2017/746 (Table 21.10). The new rule-based risk classification system is more flexible than the list-based system from the IVDD that it replaces. Instead of naming specific IVD devices or medical conditions, the risk classification of a device is determined by its intended purpose and takes into consideration not only the risk to the individual but also the risk to public health. To classify their device, manufacturers should consult the rules listed Annex VIII of the IVD Regulation. If more than one rule applies, the rule resulting in the highest classification should be followed. In line with the international principles of classification, the four classes are:

Table 21.10 In vitro diagnostic medical devices risk class

Class	Risk	Conformity assessment
A	Low individual risk and low public health risk	Self-certified by their manufacturers (if non-sterile)
B	Moderate individual risk and/or low public health risk	Conformity assessment by a notified body
C	High individual risk and/or moderate public health risk	
D	High individual risk and high public health risk	

21.11 Conformity Assessment Procedures

Figure 21.2 shows the different steps a manufacturer has to go through from the device classification through the notified body selection to the final CE mark certificate and Declaration of Conformity issuance.

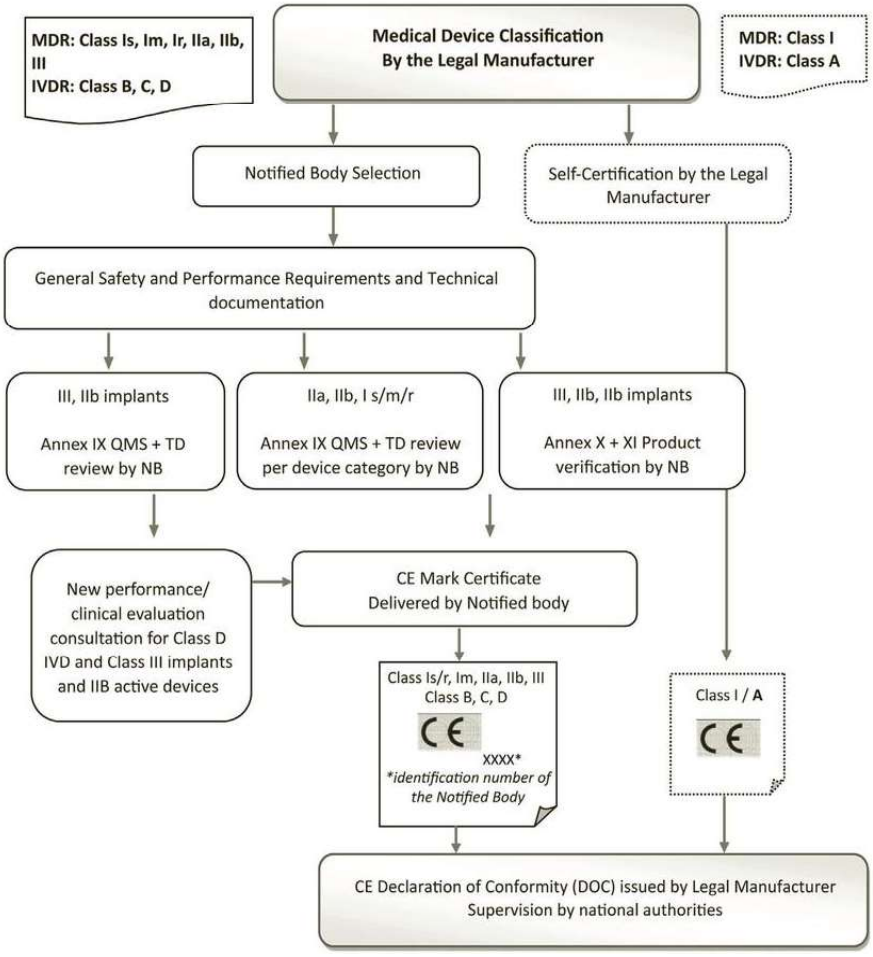


Figure 21.2 Flow chart representing steps to be followed for CE Marking under MDR/IVDR.

The Conformity Assessment Procedures correspond to modules described in the Regulations, which the manufacturer has to