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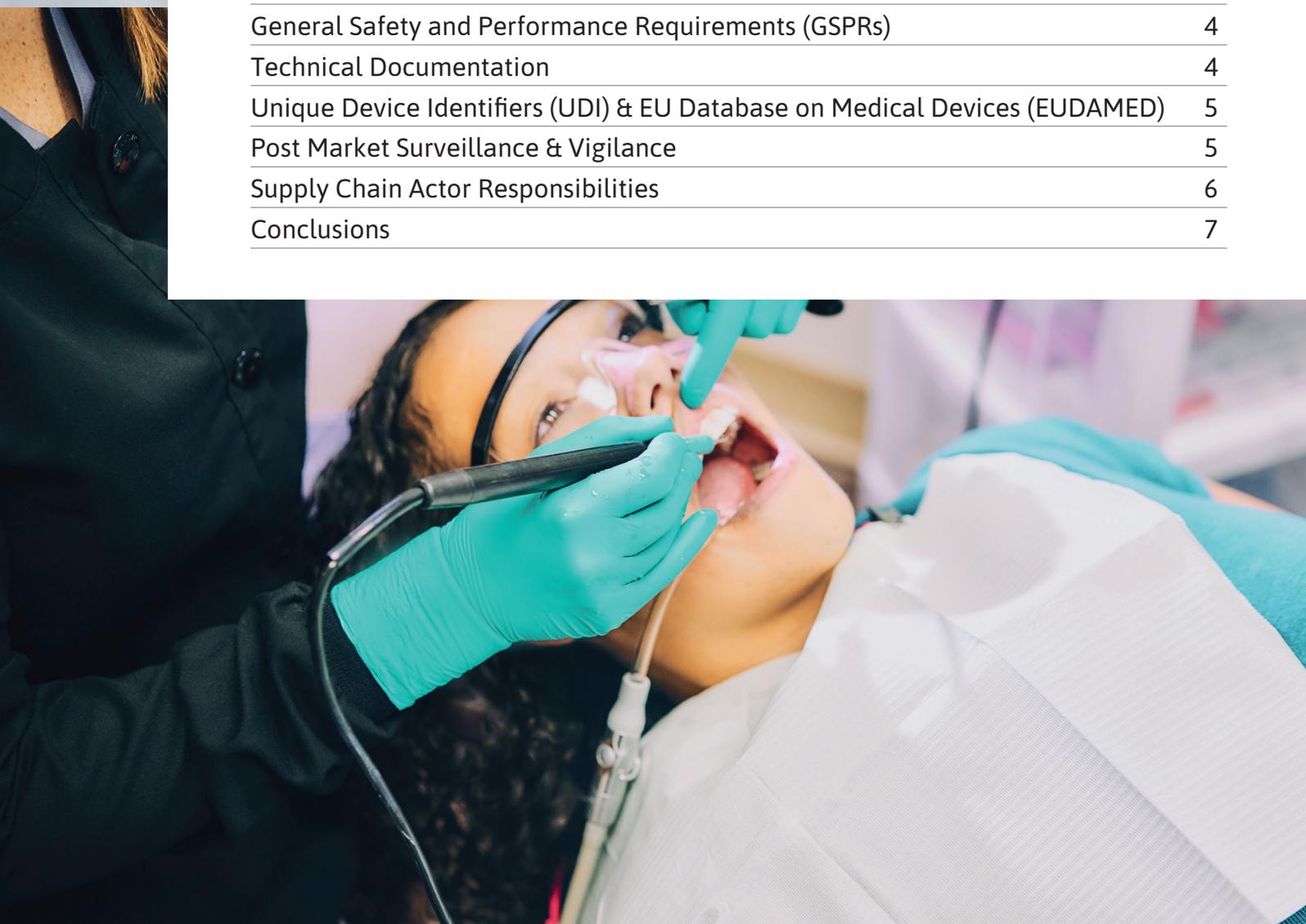
**A GUIDE TO THE NEW EUROPEAN UNION
MEDICAL DEVICE REGULATION (MDR)**

EU-MDR 2017/745



CONTENTS

Overview	1
Timeline	2
Devices Covered by the MDR	3
Device Classification & Conformity Assessment	3
General Safety and Performance Requirements (GSPRs)	4
Technical Documentation	4
Unique Device Identifiers (UDI) & EU Database on Medical Devices (EUDAMED)	5
Post Market Surveillance & Vigilance	5
Supply Chain Actor Responsibilities	6
Conclusions	7





1 Overview

The European medical device industry will experience significant changes in May 2021 as the EU Medical Device Regulation, EU 2017/ 745 (“MDR” for short) comes into immediate effect across all 27 EU countries. The MDR replaces the previous council directive MDD 93/42/ EEC or “MDD”, which contained general rules that EU member states transposed into their national laws in different ways over different time periods. Compliance with the MDR is mandatory for all companies that manufacture, import, and distribute medical devices in Europe, including companies that sell medical gloves and masks.

The European Council introduced the MDR for several reasons. One is a wish to restore confidence in the regulatory oversight system following several scandals involving companies that marketed unsafe medical devices under the MDD. The Council also wanted to create a single approach to medical device regulation that would be common across all EU member states, rather than continue to allow for differences in interpretation and application across Europe. Finally, the Council wanted to keep pace with scientific and technological developments such as modern software or devices that collect health data. The new MDR will ensure high standards of quality and safety for medical devices being produced in or supplied to Europe. It will do this by establishing a robust, transparent, predictable and sustainable regulatory framework that supports innovation while ensuring better protection of public health and patient safety.

Goals of Implementing New MDR



Restore confidence

in the regulatory oversight system following scandals to better protect public health and patient safety

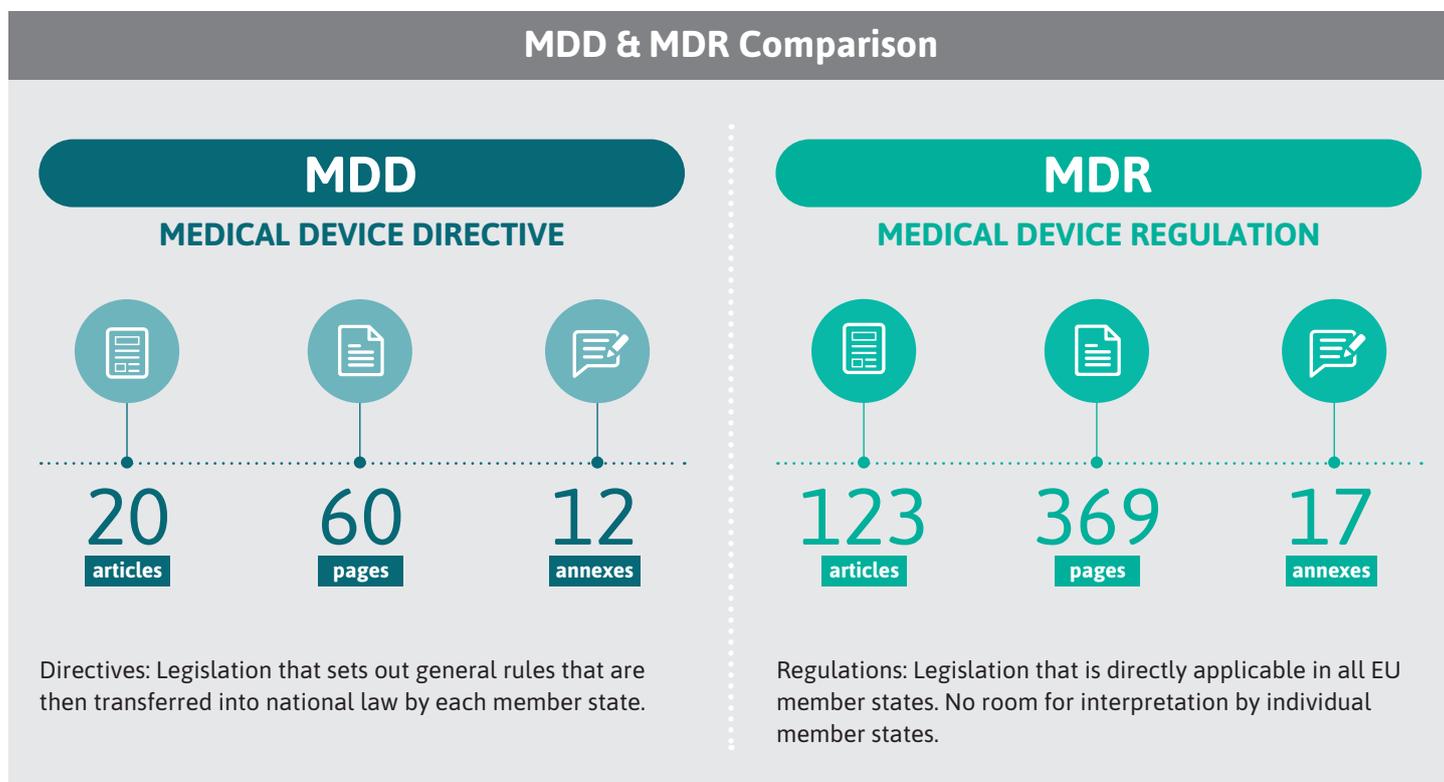
- Strict pre-market control
- Reinforced designation and oversight of Notified Bodies
- Introduction of UDI
- Reinforced PMV obligations and transparency
- New obligations of Manufacturers and Authorised Representatives aimed at protecting Consumers / Patients

Overcome divergence

in interpretation and application of one single approach across member states

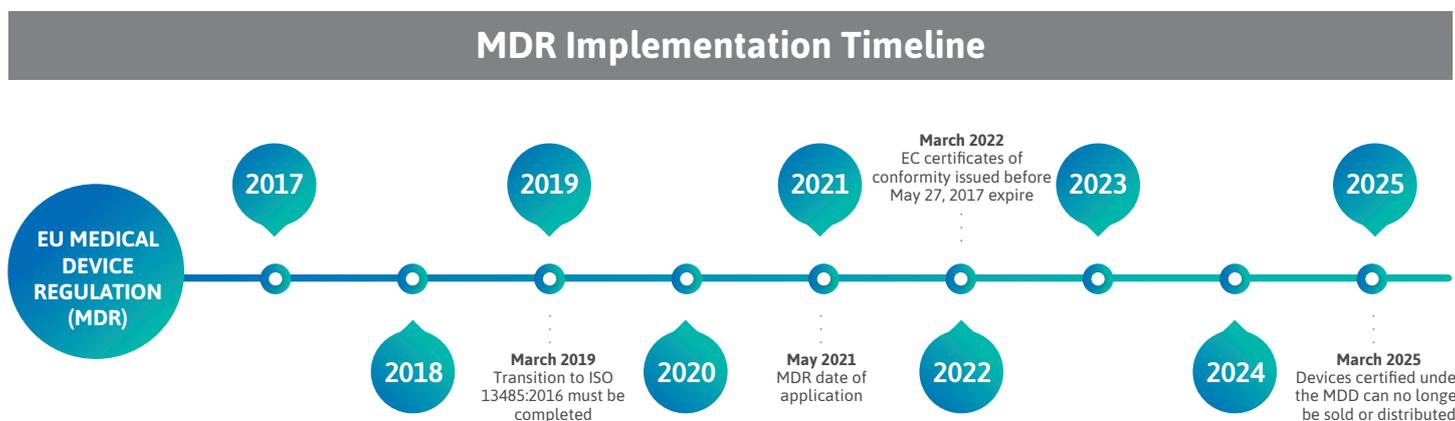
- Registration of Devices and Economic Operators
- Improved Coordination between Member States in the fields of Vigilance and Market Surveillance
- Strengthening EU Joint Assessment procedure for Notified Bodies

While the old MDD was a “directive” that served as a manual for medical device manufacturers who wanted to get a CE marking, the MDR is a “regulation” that more broadly aims to enhance safety for people across Europe. It introduces new responsibilities for economic operators across the medical device supply chain and requires each to verify that a previous operator is compliant. The MDR also introduces new requirements in areas such as clinical evaluation, post-market surveillance, and labelling, as well as new systems that make tracing medical devices easier. **As a regulation, the MDR is legally binding and enforced across all member states with less room for differences in interpretation or enforcement.**



2 Timeline

The final MDR document was published in May 2017, and the regulations will come into force in May 2021. During the transition period, devices may be placed on the market under either AIMDD/MDD or EU MDR. Medical device companies can receive compliance certification from notified bodies up to the effective date of May 26, 2021, and these certificates will remain valid for five years from the date of issuance, allowing for a smooth transition period.



3 Devices Covered by the MDR

Under the MDR, “medical device” is broadly defined as any instrument, apparatus, appliance, software, implant, reagent, material or other article designed 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 mean of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations

Devices for the control or support of conception, and other products intended for the cleaning, disinfection or sterilisation of medical devices are also themselves considered “medical devices” under the MDR. The MDR also covers some groups of products that do not have an intended medical purpose such as non-corrective contact lenses, equipment for liposuction and equipment intended for brain stimulation.

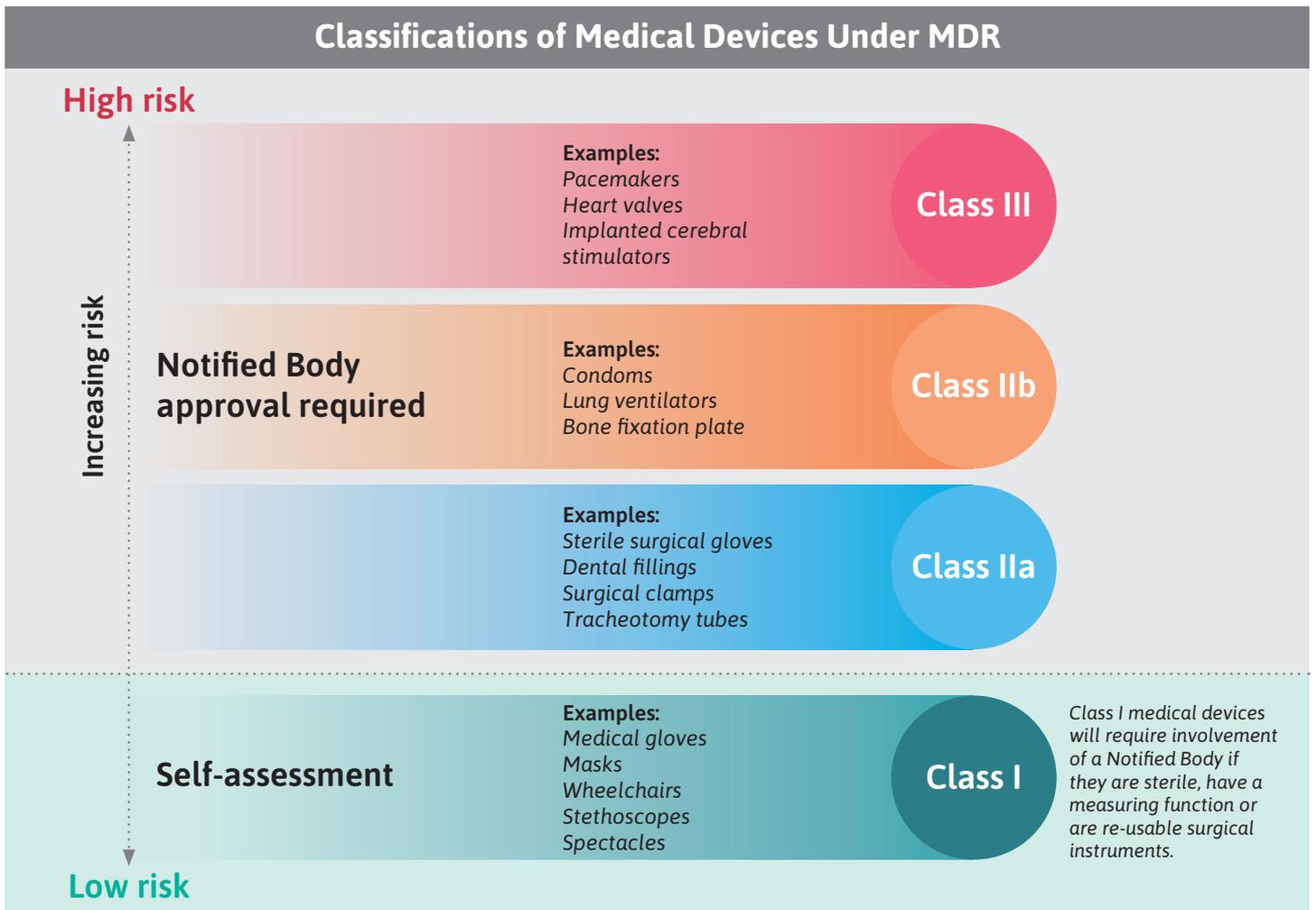
Medical exam gloves and masks are considered Class I medical devices under the MDR, and sterile surgical gloves are considered Class IIa medical devices.

4 Device Classification & Conformity Assessment

Chapter V, Section 1, Article 51 of the MDR defines 4 main categories for medical devices by factoring in the intended purpose of the device, as well as the inherent risk to a person’s health associated with using it. Class I devices present the lowest risk while Class III products present the highest risk.

Before placing a medical device onto the market, manufacturers must undertake a conformity assessment of the device. This assessment must be done in accordance with the applicable

conformity assessment route outlined under the MDR, based on the product classification. Once this assessment has been completed, manufacturers can place a CE mark on the product to show that the medical device has met the requirements and is therefore compliant with MDR. Class II, Class III and some Class I devices will require the approval of a Notified Body. A list of active Notified Bodies recognised under the new MDR can be found on the European Commission New Approach Notified and Designated Organisations (NANDO) database.



5 General Safety and Performance Requirements (GSPRs)

Annex I of the EU MDR details the specific requirements of the General Safety and Performance Requirements (GSPRs). These are broken down into three chapters:

- **Chapter 1 - General Requirements**
- **Chapter 2 - Requirements Regarding Design and Manufacture**
- **Chapter 3 - Requirements Regarding the Information Supplied with the Device**

5.1. Chapter 1 – General Requirements

General requirements outlined in the new MDR include that:

- Devices must perform in a way that aligns with the intended design.
- Devices must not compromise the health or safety of a patient, user, or any other person associated with the device.
- Risks must be reduced as much as possible, but not so much that they negatively affect the ratio of benefit to risk.
- Manufacturers must implement and maintain a thorough, well-documented, and evaluative risk management system that continues to be updated throughout the life cycle of a device.
- Manufacturers must include any necessary measures for protecting users in cases where risks cannot be eliminated.
- Manufacturers must provide users with information about any potential risks that remain. This information must be clear, easy to understand, and considerate of the users' technical knowledge level, use environment, and any applicable medical conditions.
- Devices must withstand the stresses of normal use for the duration of their lifecycle.
- Devices must be designed, manufactured, and packaged in a way that protects them from damage during transport and storage.
- When it comes to risks and negative side effects that are known and foreseeable, designers and manufacturers must make every effort to minimise negative outcomes. They must also ensure that potential risks are acceptable when compared to the potential benefits of a device to its users.

5.2. Chapter 2 – Requirements Regarding Design and Manufacture

The GSPRs also require that manufacturers provide detailed information about medical devices, specifically:

- Chemical, physical and biological properties
- Potential for infection or microbial contamination
- Use of substances that are considered to be a medicinal product or that the human body otherwise absorbs or disperses
- Incorporation of biological materials
- Interaction with its environment
- Ability to diagnose or provide measurements
- Radioactive properties
- Systems that are electronically programmable
- Capability for being active and connected to other devices
- Capability for being active and implantable
- Ability to withstand mechanical and thermal risks
- Ability to safely supply energy or substances to the user or patient
- Ability to be used by lay persons

Within each of these line items, the GSPRs outline details that manufacturers must adhere to in situations where the requirements are applicable.

5.3. Chapter 3 – Requirements Regarding the Information Supplied with the Device

The final key area of governance within the GSPRs relates to specific information a manufacturer must supply with a device. The general requirements for this information state that, "Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information relevant to the user, or any other person, as appropriate." The requirements further state information must be provided on:

- The device label
- The user instructions
- The packaging of a device that is intended to maintain its sterile condition

6 Technical Documentation

Annex II of the EU MDR identifies additional requirements pertaining to the information that manufacturers must supply with a device. Section 4 – General Safety and Performance Requirements states that documentation must contain information that clearly demonstrates conformity, specifically:

- (a) The GSPR's that apply to the device and an explanation as to why others do not apply
- (b) The method or methods used to demonstrate conformity with each applicable GSPR
- (c) The harmonised standards, CS or other solutions applied
- (d) The precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the GSPR. A cross reference indicating where the location of the

information referred to under this point shall incorporate a cross reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.

6.1. Part (a) regarding GSPR requirements that apply / don't apply

To ensure compliance with part (a), manufacturers must assess each GSPR to determine how to best meet each requirement. When a requirement applies, a simple statement may be made that the requirement applies to the device. When a requirement is not applicable, a statement must be made to that effect. In addition, companies must provide justification as to why the requirement does not apply.

6.2. Part (b) regarding methods of use

Part (b) relates to the way a company complies with that GSPR. Historically, this would be listed as a standard or other documentation reference that a company has applied to demonstrate compliance. The question of 'method or methods used', however, is new to the MDR and it is expected that a verbal description be provided.

6.3. Part (c) regarding common specifications, harmonised standards or other solutions applied

Below are definitions of common specifications, harmonised standards and "other solutions":

- **Common Specifications (CS)** are a new concept in the MDR that allows the EU to bring in additional requirements that must be met in order to claim compliance. Common specifications are defined as "A set of technical and/or clinical requirements, other than a standard, that provide a means of complying with the legal obligations applicable to a device, process or system." Common specifications can be introduced in areas where no harmonised standards exist, where they are insufficient, or where there is a public health threat that needs to be addressed. Devices that meet the requirements of a common specification are presumed to be in conformity with the GSPRs of the MDR. Manufacturers must comply with the common specifications unless they can justify that they have adopted solutions that ensure a level of safety and performance that is at least equivalent.
- **Harmonised Standards** are standards that have been specifically developed and assessed for compliance to a regulation or directive. They are published in the Official Journal of the European Union and if a company complies, there is a 'presumption of conformity' with that directive or regulation to which they have been harmonised. These harmonised standards can only be created by a recognised European Standard Organisation. When a standard is harmonised, an annex is added that describes how the standard conforms to the directive or regulation.

- **Other Solutions** are simply alternative mechanisms that companies use to demonstrate conformity with the GSPRs. These can be things such as other international standards and manufacturers' own documentation.

6.4. Part (d) regarding the cross-references and summary technical documents

Part (d) states that manufacturers must demonstrate conformity with regards to "the precise identity of the controlled documents offering evidence of conformity with each harmonised standard, CS or other method applied to demonstrate conformity with the general safety and performance requirements. The information referred to under this point shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation."

This means that someone looking at the document should be able to easily identify exactly where in the technical documentation the evidence of compliance can be found.

6.5. Archiving Periods for Technical Documentation

Technical documentation should be stored safely, protected from unauthorised access and alteration. Under the legislation of the MDD, manufacturers were obliged to keep technical documentation for a period of at least 5 years (15 years for implants) after the last device has been placed on the market. Under the MDR, manufacturers now need to keep documentation available to CAs for 10 years after the last device has been placed on the market (15 years for implants). In the case of manufacturers whose place of business is outside the EU (+ EEA, Switzerland, Turkey) the authorised representative must share this obligation, meaning they need to have a full and up-to-date copy of the technical documentation available for CA consultation for the same periods as manufacturers.

7 Unique Device Identifiers (UDI) & EU Database on Medical Devices (EUDAMED)

Under the MDR, all devices will be required to have a Unique Device Identifier (UDI) on their label and packaging, and for certain devices, on the product itself. The UDI is intended to improve the traceability of medical devices throughout the supply chain by connecting all the information about each medical device through a digital information repository called EUDAMED. MDR requires that a UDI label be directly attached to a medical device or to its packaging.

8 Post Market Surveillance & Vigilance

Chapter VII, Sections 1 and 2 of the MDR state that manufacturers are responsible for conducting "post-market surveillance" and being "vigilant". "Post-market surveillance" includes all activities carried out by manufacturers in cooperation with other supply chain operators to collect and review information for the purpose of identifying possible needs to correct or prevent safety issues. This means supply chain operators must ensure the ongoing safety of the device; inform healthcare providers, users and other relevant parties about device changes; and conduct field safety corrective actions (FSCA's) for the purpose of preventing or reducing the risk of problems. Manufacturers, importers and sellers must be "vigilant" by ensuring that they report serious incidents and injury trends they become aware of that are related to the device. "Serious incidents" are defined as incidents that directly or indirectly led, might have led or in the future may lead to the death of a patient, user or other person; or to the deterioration of their health.

9 Supply Chain Actor Responsibilities

Under MDR, there are new requirements related to importation and distribution activities of medical devices – including medical gloves and masks. MDR states that each economic operator in the supply chain must verify that a previous economic operator has complied with the EU MDR requirements. This means that importers and distributors must ensure that, prior to placing medical devices such as gloves or masks on the market, the manufacturer, importer and the device itself are all compliant with EU MDR requirements. The device labelling must include the importer's name and address and they need to be registered on EUDAMED.

9.1. Definition of Economic Operators

Under the new MDR, economic operators in the supply chain are defined as follows.



Manufacturer

A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.



Importer

Any natural or legal person established within the Union that places a device from a third country on the EU market.



Authorised Representative

Any natural or legal person established within the EU who has received and accepted a written mandate from a manufacturer, located outside the EU, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's MDR obligation.



Distributor

Any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.

9.2. Summary of Supply Chain Actor Responsibilities

Below is a brief summary of manufacturer, authorised representative, importer and distributor responsibilities under the new MDR.

Examples of Responsibilities for Economic Operators under MDR

				
Responsibility	Manufacturer	Authorised Representative	Importer	Distributor
EUDAMED Registration	○	○	○	
Product Compliance	●	●	○	○
Conformity after Handling, Storage & Distribution	●		○	○
Management of Nonconformities	●	●	○	○
Vigilance Reporting, Including Recalls	●	●	○	○
Correct Labelling / Unique Device Identification	○	●	○	○
Complaint Management	●	●	○	○
Post Market Surveillance	●	●		○
Person Responsible for Regulatory Compliance	○	○		
Sufficient Financial Coverage in Case of Liability	○	○		

○ = New Responsibility Under MDR

● = Previous Responsibility Under MDD That Continues

9.3. Impact on Private Label Manufacturers

Under the previous MDD requirements, many small, private label manufacturers were not required to have technical documentation available in their facilities, so long as it was available at the original equipment manufacturer (OEM). Under the new MDR, however, all private label manufacturers will be known as “Virtual Manufacturers” and therefore will have the same responsibilities as stipulated for OEM’s. These include a full quality management system, including risk management and clinical evaluation, full technical files, apply the conformity assessment as applicable for the risk class of the device, including conformity assessment by a Notified Body, if required. In addition, they must comply with all registration, have a Declaration of Conformity (DOC), operate a post market surveillance and vigilance system, hold product liability insurance, have a person responsible for Regulatory Compliance, keep registrations up-to-date and observe all record retention obligations under MDR.

9.4. Impact on Fulfillments Partners

Under the previous MDD, fulfilment partners had very few regulatory responsibilities. Under MDR, fulfilment partners that do anything beyond simple clearance, sorting, transportation or delivery of devices will be considered a distributor. For example, fulfilment partners that store products, package products, relabel packages, handle customer returns or perform similar tasks will be considered distributors under MDR and must therefore meet all obligations of that role. They must be compliant with MDR as of May 2021.

9.5. Penalties for Non-Compliance

To ensure that economic operators across the medical device chain comply with the new MDR, Competent Authorities will continuously conduct market surveillance. They will be monitoring products on the market to ensure proper labeling and auditing supply chain operators to confirm that they have the proper processes, systems and documentation in place. If an economic operator is found not to be in compliance with MDR requirements, possible penalties include:

- Market recall of products and issuance of a Field Safety Notice
- Cancellation of CE Certificate – prohibiting future sales
- Ban of all goods in the EU supplied from the manufacturer
- Prosecution, unlimited fines and imprisonment

Because it is the responsibility of each economic operator in the supply chain to ensure the previous operator is compliant, all are at risk and liable if Competent Authorities find that a product has been placed on the market improperly.

10 Conclusions

All companies that manufacture, import or sell medical devices – including medical gloves and masks – must ensure compliance with the new EU MDR. This will be a challenge for many companies who may distribute medical gloves and masks as part of a broader portfolio of many other products. Effective processes must be established to properly document conformance to GSPR’s and avoid regulatory audits.

Private label manufacturers and distributors must have the ability to store and track all technical documentation regarding relevant medical devices themselves. This includes both production and market-related documentation they previously may not have been responsible for managing. In addition, the legal manufacturer of private label products must have the ability to assess a product’s conformity, keep information up-to-date and observe all record retention obligations under MDR.

Ansell is eager to help companies ensure compliance with the new MDR. If your company is unable to manage MDR requirements regarding quality management, complaint or financial coverage in the event of liability, let us help. We have a sophisticated quality management system, an advanced system for tracking complaints, and a strong financial position as a global leader in health and safety solutions. Contact info@ansell.eu or call +32 2 528 74 00 to discuss how we can put our expertise to work for you.