MDR Guidance document – Questions and Answers

Forewords

The purpose of the document is to give the overall understanding if and how requirements of the European Medical Device Regulation (MDR, Regulation (EU) 2017/745) apply to sterile barrier systems, packaging systems and packaging materials, and how to find specific related information.

Definition(s)

For the purposes of this document, the following definitions apply.

A sterile barrier system (SBS) is defined as *"minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use"*.
A sterile barrier system material is defined as material that suitable and intended for the manufacturing of sterile barrier systems.
A **preformed sterile barrier system** is a sterile barrier system that is supplied partially assembled for filling and final closure or sealing.

The packaging system is the *"combination of the sterile barrier system and protective packaging"* and may include the transport packaging.

Introduction

Sterile medical devices are manufactured and/or processed by Medical Device Manufacturers (MDM's) and in healthcare or reprocessing facilities. Depending on the situation, they will be packaged in at least one SBS or in a packaging system designed to maintain sterility through exposure to expected conditions and hazards during the specified processing, storage, handling, and distribution. The sterility must be maintained until that SBS is opened at the point of use or until the expiry date. Preformed sterile barrier system and sterile barrier system materials are supplied by their manufacturers for filling and final closure or sealing. Such materials will be covered by the MDR under two different scenarios (a or b):

a. If SBS are used in healthcare facilities, during the re-processing of medical devices, they are considered an “accessory” to a specific medical device. However, an accessory to a medical device is treated like a medical device itself, and thus, SBS are to be classified as Class I and must be CE marked as such. Although SBSs are intended to be used during sterilisation, they are provided to healthcare facilities in a non-sterile condition, and thus, correct classification is Class I unsterile. The MDR does not include precise language on the classification of SBS, but the approach is generally accepted as such by the industry and by competent authorities. The manufacturer of SBS is responsible for meeting the applicable MDR requirements and for the CE marking.

b. If SBS is an integral part of a medical device that is placed on the market in sterile condition, then it is not appropriate to classify the SBS. In this case, the packaging is not classified on its own, but it will constitute an integral part of the medical device that will be classified according to its specific risk class. Preformed SBS and SBS materials will be supplied by their manufacturer under the supplier controls established by the QMS of the manufacturer of the medical device.

Questions and answers presented in this document are mainly applicable for SBS’s used in healthcare facilities (scenario a. above). Only question 15.3 concerns SBS’s as an integral part of medical device.

Question:		Answer:
1. General Questions		
1.1	Should SBS be classified as medical devices?	Yes, if scenario a. applies. No, if scenario b. applies. See Introduction, 2. Paragraph.
1.2	How should product classification of SBS be done?	Corresponding with scenario a., classification of SBS applies if SBS are used as accessory to other medical devices during the processing and re-processing of these medical devices. Then, SBS are always treated as medical devices of **Class I, unsterile**. The classification follows Annex VIII, Chapter III, rule 1 of MDR.
2. Making available on the market and putting into service of devices / Obligations of Economic Operators		
2.1	What do I need to do before I can make an SBS classified as medical device available on the market and put it into service?	SBS classified as Class 1 unsterile device shall meet the general safety and performance requirements asset out in Annex I of MD-Regulation, including clinical evaluation in accordance to article 61. Note: named aspects are crucial for patient safety, but more aspects need to be respected to fully comply with Medical Device Regulation. E.g., Declaration of Conformity shall be issued.
2.2	What type of marketing or other claims can I give for my products (SBS)?	Marketing rules are presented in Article 7. Information shall not be misleading nor create a false impression related to the impressions or properties of the device. All risks associated with use of the device shall be informed.

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<tr><td></td><td></td><td></td></tr>
<tr><td>2.3</td><td>Is my company an economic operator? If yes, what does it mean?</td><td>There are four economic operator roles, and your company may have several roles, if scenario a. applies and SBS are classified as a medical device:

<table><tr><th>Role</th><th>Description</th></tr><tr><td>Manufacturer</td><td>Operator responsible for design, development, manufacturing and post-market activities of the device</td></tr><tr><td>Authorized Representative</td><td>Operator acting on behalf non-EU manufacturer in relation to manufacturers MDR obligations</td></tr><tr><td>Importer</td><td>Operator placing non-EU devices to EU market</td></tr><tr><td>Distributor</td><td>Operator providing devices on the market</td></tr></table>
Symbols for economic operators: ISO ISO 15223-1

Each role has responsibilities under MDR, which are presented later in this document.</td></tr>
<tr><td colspan="3">3. General obligations for Manufacturers</td></tr>
<tr><td>3.1</td><td>Where can I find the general obligations for the manufacturer?</td><td>General obligations of the manufacturer are presented in Article 10. Some of the obligations have separate articles and/or annexes in regulation. More information about these obligations is presented in the following sections of this document.
One of the obligations is to establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with MDR. Quality management standard ISO 13485 has several additional requirements which are critical for product safety, such as traceability requirements for raw materials.

There is also a separate MDCG -guidance for class I manufacturers (MDCG 2019-15, “Guidance notes for manufacturers of class I medical devices”).</td></tr>
<tr><td colspan="3">4. Requirements for Economic Operators / Authorized representative</td></tr>
<tr><td>4.1</td><td>Who is authorized representative and what does it mean?</td><td>Authorized representative applies only if a manufacturer is not located in the European Union. A Manufacturer must designate a sole authorised representative in order to place the products to Union market, and this shall be based on a written mandate that meets the minimum requirements of Article 11(3) of the Regulations.
The authorized representative has to register in Eudamed, has to responsibly check the compliance of medical devices with European Regulation, by e.g. checking the declaration of</td></tr>
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		conformity and the technical documentation, and serves as the contact for European Authorities. There is a separate MDCG 2022-16 Guidance for authorized representative.
5. Requirements for Economic Operators / Importer		
5.1	Who is importer and what does it mean?	Importer applies only if a manufacturer is located outside of European Union. The Importer (article 13) is responsible for entry of medical devices that are manufactured outside of the European Union into the European Union. Importers are – like AR – obliged to register in Eudamed and may serve as contact for European Authorities. For practical information, there is a separate guidance document, MDCG 2021-27: questions and answers on requirements related to importers and distributors under MDR.
6. Requirements for Economic Operators / Distributor		
6.1	Are there requirements for the distributor?	Distributors have responsibilities (article 14) such as obligation to check declaration of conformity and to control the correct labelling of products. For the distributors, it is not necessary to register in Eudamed, but there might be national registration requirements. For practical information, there is a separate guidance document, MDCG 2021-27: questions and answers on requirements related to importers and distributors under MDR.
7. **Risk Management**		
7.1	How do I comply with risk management requirement?	It is possible to comply with risk management requirements of the MDR with any suitable approach . However, any own approach needs justification, and thus it is easier to follow the common understanding of appropriate risk management. One accepted standard is ISO 14971, which is also – at least partially - implemented within quality management standard ISO 13485 and relevant product standards such as ISO 11607-1:2019/Amd 1:2023.
8. Person responsible for regulatory compliance (PRRC)		
8.1	Do I need a PRRC and are there competence requirements for this role?	Provided that scenario a. applies, as of economic operators, manufacturer and authorized representative shall have PRRC. Competence requirements are presented in article 15. In case of uncertainty whether the PRRC has adequate training and/or experience, it's recommended to confirm the competence from national authority. Additional information can be found from MDCG 2019-7 *"Guidance on Article 15 of the Medical Device Regulation (MDR) and in vitro Diagnostic Device Regulation (IVDR) regarding a 'person responsible for regulatory compliance' (PRRC)".*

8.2	Is the PRRC the same as the Quality Manager?	PRRC and quality manager can be (if defined in organization) the same person. In many cases this is practical as responsibilities can be the same depending on the roles in the organization. The role of PRRC can also be split or be a separate role.
8.3	Can the PRRC be outsourced?	Only micro or small enterprises can subcontract the PRRC if other criteria are fulfilled. See MDCG 2019-7 Guidance for details.
8.4	Does PRRC need a separate contract? If yes, what it should contain?	. eMDR does not require separate contract, but it is highly recommended that separate contract (different from job contract) is made. Contract should describe the responsibilities and how, in practice, the PRRC is managing different tasks. In some cases, it would be good to define the responsibilities/duties between manufacturer and PRRC, as depending on the structure of the organization, this may be unclear. Organization should also consider separate liability insurance for PRRC.
9. Declaration of conformity (DoC) and CE marking		
9.1	What is the content of DoC, and when it can be signed and by whom?	The minimum content of the DoC is presented in Annex IV of MDR. It shall be drawn up by the manufacturer when compliance with applicable requirements, including conformity assessment, has been demonstrated. DoC is an official and legally binding document, that should be signed by a senior officer authorized by the manufacturer.
9.2	How to use the CE marking and where it should be put?	For SBS used as packaging in a Healthcare facility (scenario a.), the individual packaging should not be CE marked. CE-marking is usually affixed to the transport or sales packaging of SBS (instead of product). It shall also appear in any instructions for use, or in any sales packaging as well as in marketing materials.
10. Traceability of products (SBS's in scenario a)		
10.1	How do I meet the traceability requirements of products?	Traceability requirements for each economic operator are explained in article 25. Requirement is simple: each economic operator needs to record what products (medical devices) are delivered to whom.
11. Unique Device Identification System (UDI)		
11.1	Do I need the UDI for my product and where UDI is used for?	The purpose of UDI -system is to ensure the traceability of the products. UDI is needed for all CE-marked medical devices (SBS's in scenario a.). Basic-UDI-DI is needed for Declaration of Conformity, as well as for EUDAMED to do the device registrations. Each device must also have UDI-DI for EUDAMED registration purposes and traceability.

11.2	How do I get UDI for my product?	At first, a manufacturer has to choose a UDI issuing entity (such as HIBCC, ICCBBA, IFA, GS1) and get a company prefix number. When a prefix number exists, then it is possible to get Basic-UDI-DI for the product group and UDI-DIs for the products. Issuing entities provide information and support for getting the codes.
12. EUDAMED		
12.1	What is EUDAMED?	Eudamed is the European database for medical devices. Its functionality includes registration of economic operators and registration of medical devices themselves, but also the vigilance modules where e.g. serious incidents will be reported between economic operators, authorities, and the public.
12.2	How can I start to use EUDAMED?	To register to EUDAMED, you need to create an EU login account. When you have your EU logins, you can register to EUDAMED. You need to have two users in the system. It is highly advised to read the related guidance from EUDAMED information centre before you start. When you proceed to registrations of economic operators and devices, there are step by step instructions for each action.
13. Registration of devices and economic operators		
13.1	Does our company need to register?	Registration requirement depends on the role of your company as an economic operator. If your company is manufacturer, authorized representative, or an importer, you must register. For each role, you need to do separate registration to Eudamed. Single registration number (SRN) is given for each role.
13.1	Do I need to register my products (SBS)?	As a manufacturer of SBS's in scenario a., you need to register your products. Due to the transition period, and depending on your country, device registration is done either to Eudamed, or to national register. As per timeline given by EU commission, devices should be registered to Eudamed in 2026.
13.2	How will I register my products to EUDAMED?	To register your devices, you need to have the following: - actor registration must be done - Basic-UDI-DI for devices shall exist - UDI-DI's for devices shall exist There are several data fields in the system to be filled for devices. Before starting the registration, it is good to review the EUDAMED user guide to understand what data you need to have available. The latest guide for UDI Devices is v. 2.14 (2024) and it is available on the European Commission EUDAMED user guide (europa.eu)
13.3	Are there registration fees?	There is no direct fee for using EUDAMED, but EU countries have different policies about the fees. . Check from your national authority.

14. Conformity assessment of the product		
	How do I assess the conformity of class I product?	Conformity assessment is well and simply explained in MDCG 2019-15 (Guidance notes for manufacturers of class I medical devices). The document describes all the needed procedures before placing the product on the market - relating to general requirements for the company and to product-related requirements. This document provides help for the implementation of these requirements.
15. General safety and performance requirements (GSPR)		
15.1	How do I comply with GSPR?	Whenever possible, it is recommended to verify the compliance against most recent relevant standards, such as ISO 11607-1 and EN 868 -series. Harmonized standards give the presumption of conformity for some extent, but as long as MDR harmonization work is still in progress, you should use the latest, publicly available version.
15.2	Does my product (SBS) need to comply with every requirement mentioned among the GSPR?	Most simple way to document the compliance against the GSPR's, is to create a checklist of requirements as presented in Annex I. According to each requirement, you can explain how the requirement is met, and refer to test reports or other relevant data for verification. If the requirement is not applicable for your device (for example requirements relating to electricity), you can simply mark N/A and write a (short but valid) justification.
15.3	Our company manufactures SBS materials/ SBS components for packaging of medical devices (scenario b.). Is there something in GSPR considered as requirement for our named products?	Section 10.4 of Annex I lists the requirements concerning the substances of the materials. You need to make sure that your materials, intended to become a part of medical device described in section 10.4.1, do not contain hazardous substances mentioned in section 10.4.
15.4	Labelling of the product	Requirements for labelling are presented in Annex I, Chapter III. It is recommended to present as much information as possible as standardized symbols (ISO 15223) to avoid the national translation requirements as far as possible.
16. Clinical evaluation of the product		
16.1	Is clinical evaluation mandatory for Class I product?	Clinical evaluation is mandatory for all medical devices regardless of their risk classification.
16.2	How to conduct a clinical evaluation?	For clinical evaluation, there are several existing MDCG useful guidance. In the evaluation, you need to specify and justify the level of clinical evidence needed to demonstrate the conformity with the GSPR -requirements.
17. Content of the Technical Documentation (Technical File, TF)		

17.1	What is meant by Technical Documentation?	Technical documentation is all the information that allows the conformity of the device with the requirements of MDR to be assessed. It shall include the elements set out in annexes II and III of the regulation. You should organize this data in a way that it is clear, organized and readily searchable. You may want to consider documenting your company's interpretation of the content of TF.
18. Post market surveillance (PMS)		
18.1	Post market surveillance is a new requirement. What are the mandatory documents to have regarding PMS?	You need to create a Post Market Surveillance system according to Article 83. This system shall be based on the Post Market Surveillance plan (Article 84). The content of the plan is in Annex III. As outcome for PMS, you need to create Post Market Report (Article 85). Documents related to PMS are part of the Technical File. ISO published a technical report (guidance) for Post Market Surveillance: ISO/TR 20416:2020, Medical devices – post market surveillance for manufacturers.
18.2	Is Post Market Clinical follow-up (PMCF) required for SBS?	PMCF is required unless you have justification that it is not applicable to your devices (classified SBS). When applicable, you need to create a PMCF plan, and include that in the PMS plan. Based on your PMCF plan, after conducting the evaluation, you need to create an evaluation report, which is part of the Technical File. PMFC in general is explained in Annex XIV, part B.
18.3	Is Periodic Safety Update Report (PSUR) required for SBS?	PSUR is not required, as it only concerns manufacturers of class IIa, class IIb and class III devices.
19. Vigilance		
19.1	How to manage vigilance reporting requirements?	Requirements relating to vigilance are in article 87. Serious incidents and field safety corrective actions shall be reported to the relevant competent authorities according to timelines presented in Article 87. The European commission has published the forms that must be used for this purpose. In order to manage these requirements, quality system should have vigilance procedure, either as a part of PMS process or separate one.
19.2	How to recognize reportable event?	Guideline MDCG 2023-3 *"Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 on medical devices"* provides information how to recognize different type of incidents and reportability under the MDR.

19.3	What in practice is trend reporting (Chapter VII, Section 2, Article 88)?	A Post-market surveillance plan should include the methods to be used to assess the statistically significant increase in the frequency or severity of incidents and the period during which monitoring will be carried out. If monitoring reveals a statistically significant increase in the frequency or severity of incidents, it shall be reported.