

# POSITION PAPER

## Moving from the MDD to the MDR



### A summary of Key Changes regarding Sterile Packaging and considerations on recommended changes to standards

#### Introduction

EN ISO 11607 “specifies the requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use”. Since 2007 the standard is harmonized with the medical device directives in Europe. It consists of 2 parts:

- EN ISO 11607-1:2009/Amendment 2014 - Packaging for terminally sterilized medical devices - Part 1: *Requirements for materials, sterile barrier systems and packaging systems.*
- EN ISO 11607-2:2006/Amendment 2014 - Packaging for terminally sterilized medical devices – Part 2: *Validation requirements for forming, sealing and assembly processes.*

In these standards four key terms are defined. **Sterile barrier system (SBS)** is defined as “the minimum packaging configuration that provides a microbial barrier and allows aseptic presentation of the product unit at the point of use”. A **preformed sterile barrier system** is a “partially assembled sterile barrier system prior to filling and final closure and sealing”. **Protective packaging** is the “packaging configuration designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use”. **Packaging system** is the “combination of the sterile barrier system and protective packaging” and includes the transit packaging. These definitions have been introduced in 2006 and today the terminology of “sterile barrier system” is also included in EN ISO 13485 since its latest revision published in 2016.

As a harmonized standard, EN ISO 11607 provides partial presumption of conformity with a few relevant essential requirements of directive 93/42/EEC (MDD) as they apply to sterile packaging. Part one of the standard deals with materials and packaging design as well as design validation, while part two covers packaging process design, validation and process controls. The standard is a general, horizontal standard, but also a process standard and covers a wide range of sterile devices.

With the introduction of the new Regulation (EU) 2017/745 (MDR), sterilization equipment is “deemed” to be a medical device, SBS continues to be an accessory in a similar way as with the MDD and sealing equipment is neither an accessory nor a medical device.

The present document compares “General Safety and Performance Requirements” (SPRs) of the MDR that are relevant for packaging with the essential requirements (ERs) of the MDD. The changes are discussed and recommendations are made for compliance and for revisions to EN ISO 11607.

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The SPRs in annex I of the MDR are in general based on the ERs in annex I of the MDD, with a few key changes to be considered by manufacturers and for the revision of EN ISO 11607 as well as its future annex Z on conformity.

This document represents the views of the Sterile Barrier Association based on member's feedback. The purpose is for generating a general discussion, to provide input to CEN TC102 and its working group WG4 for the revision of EN ISO 11607 and serving as input for the future harmonization process of EN ISO 11607. It shall however not substitute or bypass the standard development process of CEN or ISO.

### Current Annex Z of EN ISO 11607

Annex Z has been revised in 2016 by CEN TC102/WG4 to include also the directive for active implantable devices (AIMDD) and the directive for in-vitro diagnostic devices (IVDD). The new version has been adopted by the CEN Technical Board in June 2017. The 2017 version of EN ISO 11607 part 1 and 2 with the new annexes ZA, ZB and ZC has been ratified and published on the 19<sup>th</sup> of July 2017.

Annex ZA of EN ISO 11607 parts 1 and 2 revision 2017 cover the following essential requirements of the MDD where partial compliance can be claimed based on the details provided:

#### Essential Requirements (ERs) of Directive 93/42/EEC included in annex ZA of EN ISO 11607

8.1 The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use

8.3 Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.

8.4 Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.

For simplification, the discussion will only cover the MDD and the MDR. Similar conclusion can be made for the IVDD and the IVDR.

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### Analysis of changes for packaging of Regulation (EU) 2017/745<sup>1</sup> versus the directive 93/42/EEC<sup>2</sup>.

<i>Medical Device Regulation (SPR)</i>	<i>Medical Device Directive (ER)</i>	<i>Comments</i>
7. Devices shall be designed, manufactured and <b>packaged</b> in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.	5. The devices must be designed, manufactured and <b>packed</b> in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	<b>Adding example of</b> fluctuations of temperature and humidity during transport and storage

EN ISO 11607 requires manufacturers to validate their packaging designs by doing performance testing to demonstrate that the packaging system provides an “adequate protection to the product through the hazards of handling, distribution and storage” with the objective to show that integrity of the sterile barrier system is maintained to ensure sterility. It is best practice to use standards as ASTM 4169, ISTA 1, 2 and 3 series or ISO 4180-1 to define test cycles based on the distribution cycle defined by the manufacturer that will also include environmental challenges like fluctuations of temperature and humidity. These standards are listed in annex B of EN ISO 11607-1.

**SBA Proposal:** The SBA recommends that SPR 7 will be considered for inclusion into the future annex Z-MDR<sup>3</sup> of EN ISO 11607 with the comment that the SPR is partly covered for the function of maintenance of sterility assuming that the manufacturer has included environmental challenges in their test program.

<sup>1</sup> [Regulation \(EU\) 2017/745](#) of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

<sup>2</sup> [Council Directive 93/42/EEC on Medical Devices \(MDD\) \(1993\)](#)

<sup>3</sup> Currently there is no naming convention yet for annexes indicating relationships with the MDR/IVDR.

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<i>Medical Device Regulation</i>	<i>Medical Device Directive</i>	<i>Comments</i>
<p><b>11. Infection and microbial contamination</b></p> <p>11.1. Devices and manufacturing processes shall be designed in such a way as to <b>eliminate or to reduce as far as possible the risk of infection</b> to patients, users and, where applicable, other persons. The design shall:</p> <p>(a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries,</p> <p>(b) <b>allow easy and safe handling,</b></p> <p>(c) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and</p> <p>(d) <b>prevent microbial contamination of the device or its content such as specimens or fluids.</b></p>	<p><b>8. Infection and microbial contamination</b></p> <p>8.1. The devices and manufacturing processes must be designed in such a way as to <b>eliminate or reduce as far as possible the risk of infection</b> to the patient, user and third parties.</p> <p>The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use.</p>	<p><b>Added requirements a, b, c, d,</b></p> <p><b>New Requirement:</b></p> <p>b) easy <b>and safe</b> handling</p> <p>(d) prevent microbial contamination of the device or its <b>content such as specimens or fluids.</b></p>

A sterile barrier system is an essential part of a sterile medical device and plays an essential role in the fight against health care associated infections. Sterile barrier systems in their function to maintain sterility and to allow for aseptic presentation are one of the elements contributing to the elimination or to the reduction of the risk of patient infections. SPR 11.1 takes over the idea of ER 8.1 and extends it with further specific requirements for the design. Applying this requirement to sterile packaging is straightforward. Presenting a product in an aseptic manner requires the application of proper **Aseptic Technique** adapted to the specific design of the sterile barrier system. The current draft EN ISO DIS 11607 includes a proposal introducing a normative usability evaluation to assess the ability of proper aseptic technique in the intended clinical environment. This usability evaluation will allow for confirmation that 11.1, 11.1a) and 11.1d) are fulfilled for the packaging function.

**SBA proposal:** The SBA supports the inclusion of a usability evaluation of aseptic presentation in the future revision of EN ISO 11607 as it is currently proposed in the EN ISO DIS 11607-1. The SBA has developed a guidance document for usability of sterile barrier systems that can be used as supporting documentation for such evaluation. ([link](#))

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<i>Medical Device Regulation</i>	<i>Medical Device Directive</i>	<i>Comments</i>
<p>11.4. Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened <b>at the point of use.</b></p> <p><b>It shall be ensured that the integrity of that packaging is clearly evident to the final user.</b></p>	<p>8.3. Devices delivered in a sterile state must be designed, manufactured and <b>packed</b> in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.</p>	<p><b>Deleted</b> “non-reusable pack”</p> <p><b>Added</b> “at the point of use”</p> <p><b>Added requirement:</b> “It shall be ensured that the integrity of that packaging is clearly evident to the final user.”</p>

The current EN ISO DIS 11607-1 proposes a requirement for SBS to be visually inspected prior to use. If instructions for use are required, they shall include instructions for visual inspection of integrity.

**SBA comments:** The requirement to protect until the point of use adds clarity in that sense that SBS have to be protected against loss of packaging integrity until they are opened at the point of use where healthcare is provided. Manufacturers have to consider this new requirement and need to provide guidance on how to handle units of products in the hospital environment as well as test for it. The SBA supports the clarity that is provided by adding the “point of use” and recommends upgrading EN ISO 11607 in that sense.

Visual inspection of packaging prior to use is important, however the user will have only a short time to do this and the ability to detect small breaches of integrity is limited. This visual inspection will never be a 100% verification and should be considered an additional control rather than claiming it as only a risk mitigation measure. For these reasons a strong focus should be on design control and subsequent design validation. The SBA recommends to manufacturers to consider the usability evaluation of packaging as an opportunity to seek feedback from users on their ability to assess integrity of specific packaging designs. This step will allow to confirm that the design ensures that “*the integrity of that packaging is clearly evident to the final user*”.

The new legislation refers to sterile barrier systems as “the packaging which is intended to maintain their sterile condition”. The SBA would welcome if the EU commission could clarify the use of such language used in the MDR in one of their future guidance documents referring to term “sterile barrier system”. The SBA believes that use of this term adds significant clarity to requirements.

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Medical Device Regulation	Medical Device Directive	Comments
11.5. Devices labelled as sterile shall be processed, manufactured, <b>packaged</b> and, sterilised by means of appropriate, validated methods.	8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an appropriate, validated method.	<b>“packaged” has been added</b>

**SBA comments:** The SBA welcomes that more clarity has been added to this SPR by explicitly adding packaging. The ER 8.4 is among those listed in the current annex ZA of EN ISO 11607. Packaging is to be considered part of “manufactured”, adding “packaged” to the new SPR of the MDR leaves no room for interpretation. There are no further changes to be made since this has already been considered in EN ISO 11607 and EN ISO 13485.

Medical Device Regulation	Medical Device Directive	Comments
11.6. Devices intended to be sterilised <b>shall</b> be manufactured and <b>packaged</b> in appropriate and controlled conditions <b>and facilities</b> .	8.5. Devices intended to be sterilized must be manufactured and <b>packaged</b> in appropriately controlled (e. g. environmental) conditions.	<b>“facilities” added</b>

In the 2016 revision of EN ISO 13485, the requirements on the control of the work environment have been strengthened. In particular, clause 6.3 covers the infrastructure and clause 6.4 the work environment and contamination control. These requirements are not part of the EN ISO 11607 series.

**SBA comments:** More clarity has been added to this SPR by explicitly adding the word “*facilities*”. There is no recommendation for revision of EN ISO 11607. Adding new requirements for work environment and facilities would be redundant with quality management system requirements.

Medical Device Regulation	Medical Device Directive	Comments
11.8. The labelling of the device shall distinguish between identical or similar devices placed on the market in both a sterile and a non-sterile condition <b>additional to the symbol used</b> to indicate that devices are sterile.	8.7. The packaging and/or label of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition.	<b>Added requirement to include symbol and specific label</b>

**SBA comments:** The current symbol 5.2.7 defined in EN ISO 15223-1 can continue to be used (see appendix). Medical device manufacturers will need to find ways to add the required information in addition to the symbol to their label in order to comply with this SPR. The SBA will support proposals clarifying this situation and standardizing the approach taken by manufacturers.

### Note:

EN ISO 11607 addresses labelling requirements for materials and preformed sterile barrier systems. EN ISO 15223-1 addresses labelling requirements for medical devices.

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<i>Medical Device Regulation</i>	MDD	Comments
<p><b>23.3. Information on the packaging which maintains the sterile condition of a device ('sterile packaging')</b>            The following particulars shall appear on the sterile packaging:            (a) <b>an indication permitting the sterile packaging to be recognized as such,</b>            (b) a declaration that the device is in a sterile condition,            (c) the method of sterilization,            (d) the name and address of the manufacturer,            (e) a description of the device,            (f) if the device is intended for clinical investigations, the words: 'exclusively for clinical investigations',            (g) if the device is custom-made, the words 'custom-made device',            (h) <b>the month and year of manufacture,</b>            (i) an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and,            (j) <b>an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.</b></p>	<p>(b) → 13.3 (c)            (c) → 13.3 (m)            (d) → 13.3 (a)            (e) → 13.3 (b) but changes to language            (f) → 13.3 (h)            (g) → 13.3 (g)            (h) → 13.3 (l) only for active devices            (i) → 13.3 (f) but changes to language</p>	<p><b>Modified text and new specific requirement for sterile packaging labelling (a), (h), (j)</b></p>

**SBA comments and proposals:** The SBA welcomes the added requirement to provide an indication permitting the sterile packaging to be recognized as such. Indeed, there is a potential risk of confusion when additional packaging layers are used in order to reduce the risk of loss of sterility during aseptic presentation or in case of double sterile barrier systems.

The SBA developed a proposal for such labelling in the annex of this document to be considered for inclusion into EN ISO 15223-1.

The SBA also recommends that ISO TC198/WG7 and CEN TC102/WG4 addresses the situation of double sterile barrier systems and additional layers of packaging that are part of the design in order to reduce the risk of loss of sterility during aseptic presentation.

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<i>Medical Device Regulation</i>	<i>Medical Device Directive</i>	<i>Comments</i>
<p><b>23.4. Information in the instructions for use</b></p> <p>(l) If the device is supplied sterile, instructions in the event of the <b>sterile packaging being damaged or unintentionally opened</b> before use.</p> <p>(m) If the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation.</p> <p>(n) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, <b>packaging</b> and, where appropriate, the validated method of re-sterilisation <b>appropriate to the Member State(s) where the device is placed on the market</b>. Information <b>shall</b> be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.</p>	<p><b>13.6. Where appropriate, the instructions for use must contain the following particulars:</b></p> <p>(g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;</p> <p>h) if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, <b>packaging</b> and, where appropriate, the method of sterilization of the device to be resterilized, and any restriction on the number of reuses.</p>	<p>Adding case of “unintentionally opened sterile packaging”</p> <p><b>Extended requirements in case device is supplied non-sterile for sterilization or for reusable devices</b></p>

EN ISO 11607-1:2009/Amendment 2014 includes a list of requirements for reusable containers and fabrics including the requirement to establish processing procedures and acceptance criteria for inspection prior to reuse.

**SBA comment and proposal:** The SBA welcomes that information on appropriate processes for reuse include the aspects of packaging. This is in line with the concept of EN ISO 11607-1 since packaging designs have to be validated with the device and sterilisation has to be validated with its specific sterile barrier system.

It is recommended to consider this aspect for inclusion into ISO WD 20417 *Medical Devices — Information to be provided by the manufacturer*.



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### The Sterile Barrier Association (SBA) - about us

The SBA is the European trade association for companies who produce Sterile Barrier Systems (SBS) and associated equipment and accessories for the healthcare industry. Sterile barrier systems are made from sophisticated materials and allow single use and reusable medical devices to be sterilised after manufacture or after reprocessing. Sterilisation may take place at a medical device manufacturer or in the Central Sterile Supply Department (CSSD) of a hospital. In both cases the critical function of the SBS is to maintain product sterility up to the point of use.

Our mission: To be the recognised expert association in the healthcare industry, promoting the use of and providing education on the most suitable single use sterile barrier systems to ensure patient safety

The Association represents its members in promoting this very important sector of the healthcare industry, creating a positive environment to drive innovation in the technology associated with the production of sterile barrier systems and in setting the highest standards in product and manufacturing excellence.

SBA members account for over 75% of the European sterile barrier industry and SBA members' products are sold all over the world. The current list of member companies is available [here](#). Representatives of the companies meet twice a year to review the ever-changing regulations surrounding both medical devices and the components of SBS. These meetings take place all around Europe and members are updated on the situation in each of the countries they visit by local medical market experts.

The SBA is a non-profit making organisation.





- To maintain, promote and seek to improve the product quality and quality standards relating to the manufacture and supply of single use sterilisation barrier systems to the healthcare industry.
- To provide a forum within which manufacturers of such products and services can discuss issues relevant to the industry.
- To consider all legislative measures and proposals that may affect the industry, and agree proposals to address.
- To establish and maintain links with for example European and non-European legislative and regulatory bodies, related trade associations, and users, and to cooperate with such organisations as necessary on any matter which may affect the industry.
- To promote and influence the harmonisation of standards, practices and procedures within our industry in Europe, and to endeavour to extend that influence into other non-European regions.
- To act as the European industry voice for Sterile Barrier Systems on all relevant matters and at all levels.

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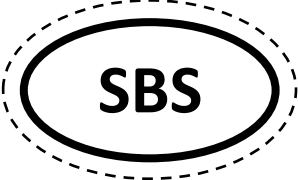

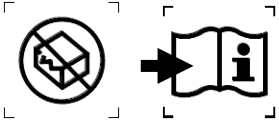

### Appendix: Current and Proposed Symbols for Sterile Products

Current symbols according to EN ISO 15223-1

Description	Symbol	Title of Symbol
<b>5.2.3</b> Indicates a medical device that has been sterilized using ethylene oxide "single sterile barrier system"		Sterilized using ethylene oxide
<b>5.2.8</b> Indicates a medical device that should not be used if the package has been damaged or opened. NOTE This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised".		Do not use if package is damaged
<b>5.2.7</b> Indicates a medical device that has <b>not</b> been subjected to a sterilization process. This symbol should only be used to distinguish between identical or similar medical devices sold in both sterile and non-sterile conditions.		Non-sterile
<b>5.2.9</b> Indicates the presence of a sterile fluid path within the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile.		Sterile Fluid Path

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Description	Symbol	Title of Symbol
<p><b>NEW PROPOSAL 1a:</b> to be printed only on SBS; Allows SBS to be recognized as such, in the case of double layers combination of text and symbol, closed oval indicates a Sterile barrier system with validated protection against microbial contamination. SBS works in multiple languages like English, French, German, Dutch, Swedish, Danish, Italian... Spanish: "Sistema de barrera estéril" is very similar and so is Portuguese... and Polish.</p>		Sterile barrier system
<p><b>NEW PROPOSAL 1b:</b> ... packaged in a double entry package which consists of a "single sterile barrier system" with inside an additional packaging layer (f. ex. wrapping, lidded tray etc) to minimize the risk of contamination during aseptic presentation. Note: the additional packaging layer is not validated as a sterile barrier system although it may look like one, it may be sealed or not. Further protective packaging may be used like carton boxes which may be indicated as an additional dotted line.</p>		double entry package with single sterile barrier system outside
<p><b>NEW PROPOSAL 1c:</b> ... packaged in a double entry package which consists of a "single sterile barrier system" within an additional packaging layer removed before entering into the clean environment to minimize the risk of contamination of this environment. This symbol would be applied on the additional packaging layer while symbol 1a would be applied on the SBS. Note: the additional packaging layer is not validated as a sterile barrier system although it may look like one and is actually formally a protective packaging. Further protective packaging may be used like carton boxes which may be indicated as an additional dotted line.</p>		double entry package with single sterile barrier system inside
<p><b>NEW PROPOSAL 1d:</b> ... packaged in a "double sterile barrier system" to minimize the risk of contamination during aseptic presentation. Note: both packaging layers are validated as sterile barrier systems. Symbol may be combined with an additional dotted line in case of further protective packaging.</p>		double entry package with two sterile barrier systems
<p><b>NEW PROPOSAL 2a:</b> Check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use. Note: only if IFU available, otherwise symbol 2b may be used.</p>		Do not use if package is damaged and check IFU
<p><b>NEW PROPOSAL 2b:</b> Check web based instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use. Note: according to MDR 23.1.d) IFUs shall not be required for class I and class IIa devices if use is evident. If an electronic IFU (f. ex. for a family of devices) is available, this symbol can be used.</p>		Do not use if package is damaged and check electronic IFU