

MDR requirements for labelling of Sterile Medical Products:

‘Sterile Barrier System Indication’ and ‘Check the IFU’

Results from the survey on proposals for new symbols

Survey closed 31.03.2018

Scope of the survey

The Medical Device Regulation 2017/745 (MDR) establishes a new requirement for labelling the sterile barrier systems (SBS) of medical devices to be recognized as such. This shall assist end-users to unwrap respectively open the sterile packaging in an aseptic manner.

The MDR introduces also another new labelling requirement to refer to instructions for use in case of damage to the sterile packaging:

‘MDR, Annex I, Article 23.3.:

23.3. Information on the packaging which maintains the sterile condition of a device ('sterile packaging')

The following particulars shall appear on the sterile packaging:

(a) an indication permitting the sterile packaging to be recognized as such

...

(j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use.

The MDR sets high standards of quality and safety for medical devices, and (sterile) Medical Products which will be placed on the market under the rules of the MDR have to be labelled with the information required in Article 23.3.

The above cited labelling requirements are new, and no symbols exist yet to fulfill this clause of the Medical Device Regulation.

The **Sterile Barrier Association (SBA)** developed alternative proposals for appropriate symbols to comply with the new EU Medical Device Regulation (MDR) and conducted a survey to collect stakeholder feedback on various proposals for an applicable symbol that identifies the sterile barrier system (SBS) that maintains sterility until the point of use and for a symbol to check the instruction for use (IFU) in case a sterile packaging is damaged prior to use.

The **Sterile Barrier Association** is the European trade association for companies who produce Sterile Barrier Systems (SBS) and associated equipment and accessories for the healthcare industry. SBS materials and equipment are sophisticated and allow single use and reusable medical devices to be sterilised after manufacture or after reprocessing.

Design and Concept of the Survey

The survey presents 3 alternative proposals for new symbols on Sterile Barrier System (SBS) configurations and 2 alternative proposals for a symbol to check the instruction for use (IFU) in case the sterile barrier system is damaged or unintentionally opened prior to use.

Questions address aspects of intuitive understandability, printability and supportiveness for aseptic presentation.

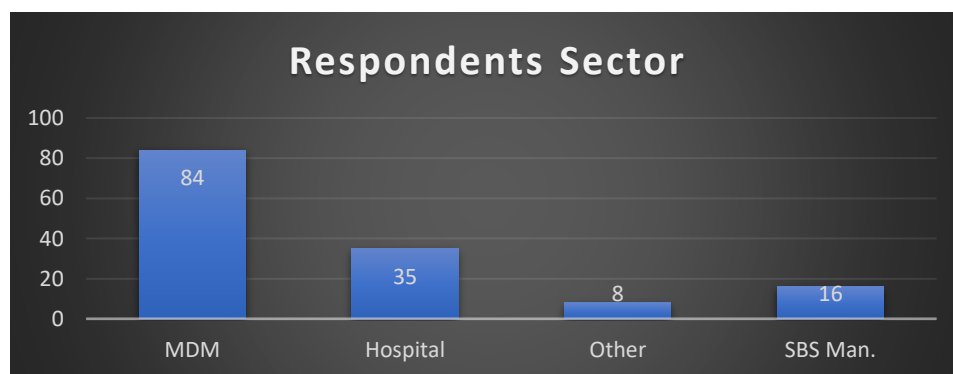
The survey has been distributed by SBA member companies and through social media to stakeholders within the healthcare sectors, i.e. healthcare professionals in hospitals and practitioners, medical device manufacturers and manufacturers of sterile barrier systems.

The survey has been published in 4 languages, i.e. English, German, French and Dutch and is available as a hard copy form to be filled in manually as well as an online survey on Google forms.

The survey was published first in November 2017 and was closed on March 31, 2018.

- 152 responses in total
- 122 respondents used Google forms
- 21 respondents used the manual format
- 9 persons had been interviewed and a summary had been entered into the categories where applicable
- Not all respondents filled in all categories
- 134 respondents entered their countries:

FR France	10	IT Italy	1
AT Austria	7	LU Luxembourg	2
BE Belgium	24	NL Netherlands	6
CH Switzerland	8	PT Portugal	1
CZ Czechia	1	RU Russia	1
DE Germany	19	SE Sweden	4
DK Denmark	1	TR Turkey	2
ES Spain	1	UK United Kingdom	8
IE Ireland	2	US United States of America	34
IN India	1	country not entered:	18





















Summary of the most important and remarkable results from the survey:

1. The drafted proposals for symbols on sterile barrier system configurations seem to be suitable, nevertheless there is no absolute majority for one of the proposals 1) or 3), whereas proposal 2) receives least acceptance.
MDM votes are very close to the overall result, not surprisingly, as they represent 55% of all respondents.
Healthcare Professionals are voting with an absolute majority of 72% in favor of symbols 2) and 3) which represent the shape of commonly used SBS. Within this peer group symbol 3) finds a significant majority over symbol 2)
2. An absolute majority of 69% considers the distinction between sterile barrier layer indicated by solid lines, and protective packaging layer, indicated by dotted lines, as clearly understandable. If responses are filtered by sector, 77% of healthcare professionals agreed with this concept.
3. A big majority of 76% confirms that the symbols help to ensure that effective aseptic presentation is carried out.
The group of healthcare professionals confirms with an even larger majority of 85%.
4. Comments have been made by approx. 23% of all respondents. Most of these comments expressed concerns about introducing new or additional symbols. This might be related to unawareness that the necessity for this additional labelling is deriving from legal requirements.
5. Several comments confirm that training and education on understanding and use of these new symbols will be essential. There seems to be a need for general training on aseptic presentation as well.
6. Proposal 4) for 'check the IFU' is clearly seen as better readable compared to proposal 5) by 72% of respondents, while 62% consider these symbols as intuitively understandable.

The SBA forwards the results of this survey to standardization bodies (ISO TC 198 WG7, CEN TC 102 WG4 and ISO TC 210 WG 3) for consideration and inclusion in future standardization works and commits to further support stakeholders in this regulatory topic.

Results of the Survey

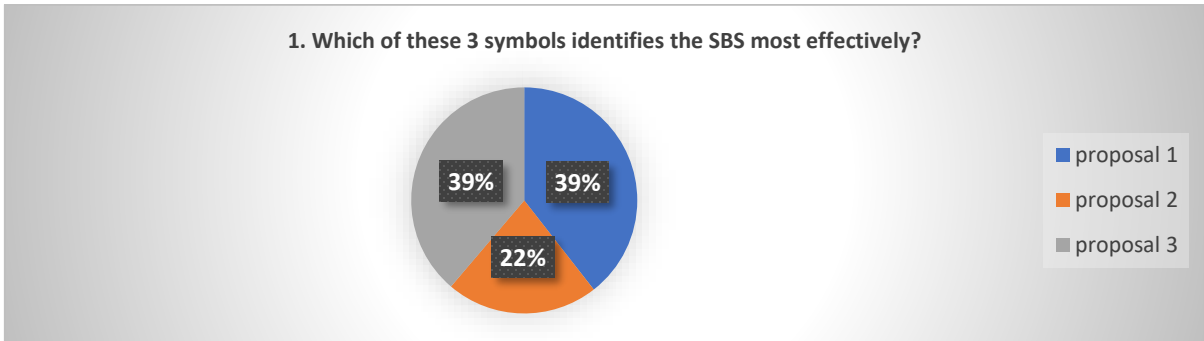
Symbols for SBS: three alternative proposals 1 – 2 – 3

	Proposal 1 Use the abbreviation 'SBS' to indicate the sterile barrier system configuration	Proposal 2 Use the form of a blister to indicate the sterile barrier system configuration	Proposal 3 Use the form of a pouch to indicate the sterile barrier system configuration
Solid line indicates sterile barrier material			
Dotted line indicates an additional inner packaging layer (without microbial barrier) to minimize the risk of contamination during aseptic presentation or indicates an outer protective packaging layer			
Configuration A: Sterile barrier system /sterile packaging			
Configuration B: Sterile barrier system with an additional packaging layer inside to minimize the risk of contamination during aseptic presentation			
Configuration C: Non-sterile protective packaging with sterile barrier system inside			
Configuration E: Double sterile barrier system		 2=2 sterile barrier systems	 2=2 sterile barrier systems

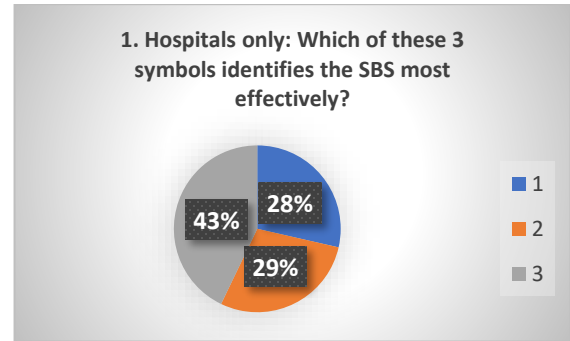
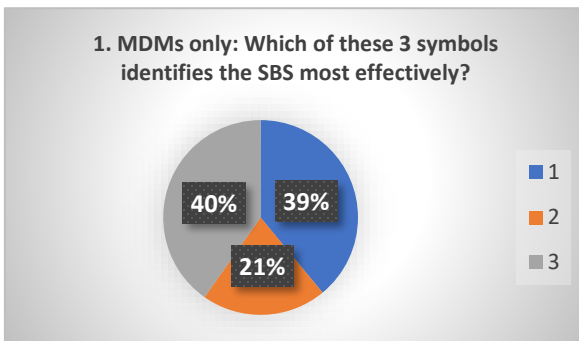
Proposal 1 is using a symbol of higher abstraction instead of the typical shapes of blisters (proposal 2) or pouches (proposal 3). Proposal 1), once introduced, would probably better represent all types of sterile barrier systems, i.e. also header bags, paper bags, flexible sheet wrapping and rigid containers. Proposal 1) would have better readability when printed in small resolution.

Proposals 2) and 3) avoid the use of an acronym. The shape of the symbols is complex and needs higher resolution for printing. Use of numbers potentially may conflict with the symbol for single use. The symbols need further design optimization.

Question 1:



When data are filtered by respondent sectors, the results differ significantly:

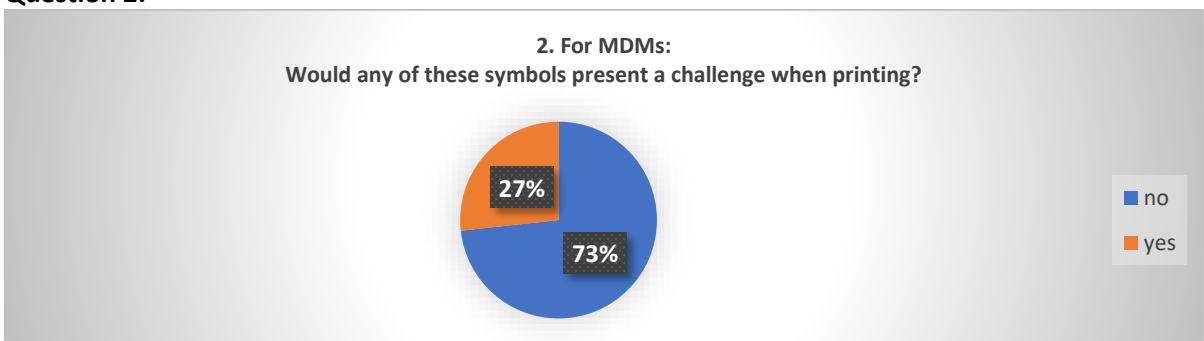


The drafted proposals for symbols on sterile barrier system configurations seem to be suitable, nevertheless there is no absolute majority for one of the proposals 1) or 3), whereas proposal 2) receives least acceptance.

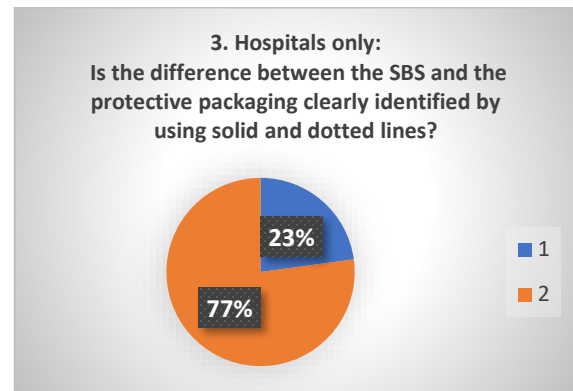
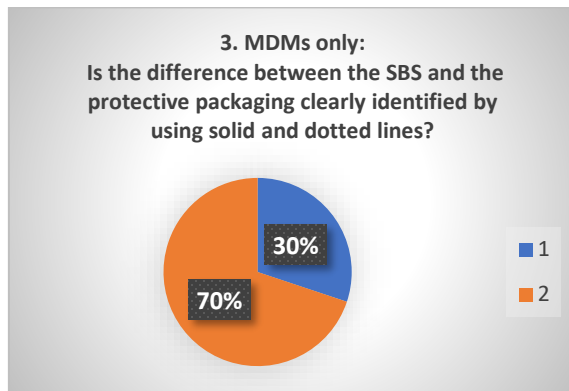
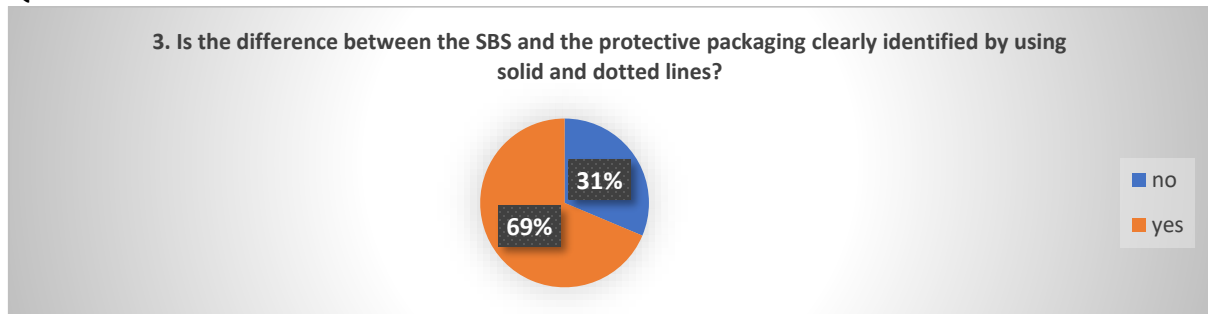
MDM votes are very close to the overall result, not surprisingly, as they represent 55% of all respondents.

Healthcare Professionals are voting with an absolute majority of 72% in favor of symbols 2) and 3) which represent the shape of commonly used SBS. Symbol 3) finds a simple but significant majority.

Question 2:



Question 3:



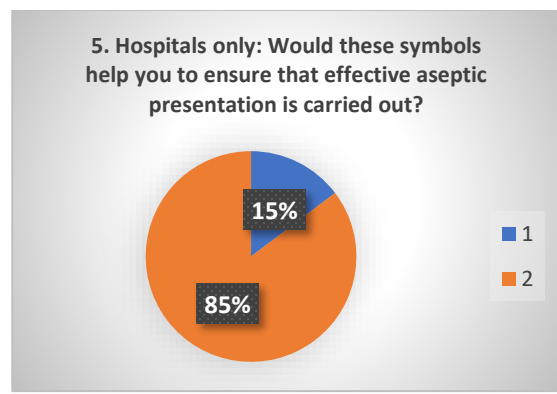
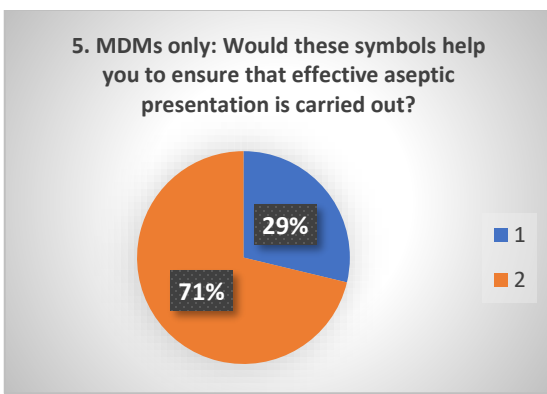
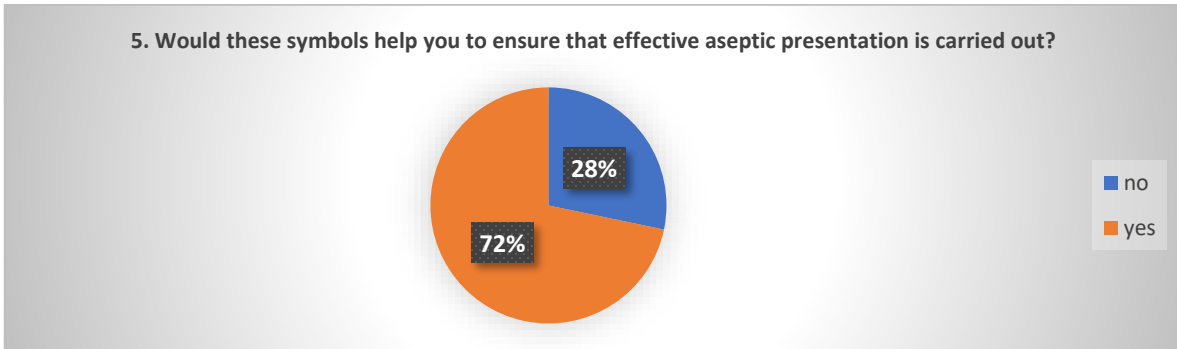
An absolute majority of 69% considers the distinction between sterile barrier layer indicated by solid lines, and protective packaging layer, indicated by dotted lines, as clearly understandable. If responses are filtered by sector, 77% of healthcare professionals agreed with this concept.

Question 4:



Indeed there are more packaging configurations possible, such as double SBS with inner and / or outer protective packaging, in theory there would be 8 packaging combinations in total. Taking into consideration printing challenges and visual identifiability focus on the 4 most often used packaging configurations is recommended and accepted by 73% of all respondents.

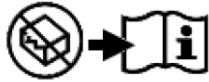

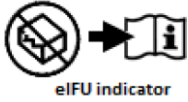

Question 5:



A big majority of 76% confirms that the symbols help to ensure that effective aseptic presentation is carried out.

The group of healthcare professionals confirms with an even larger majority of 85%.

Symbols for Instructions For Use (IFU): two alternative proposals 4 – 5

	Proposal 4	Proposal 5
Do not use if package (sterile barrier system) is damaged and check IFU		
Do not use if package (sterile barrier system) is damaged and check electronic IFU		

Question 7:

7. Are these symbols intuitively understandable?



Question 8:

8. Which of the proposals is easier to read if print size is reduced?



Question 9:

9. For MDMs: would any of these symbols present a challenge when printing?

