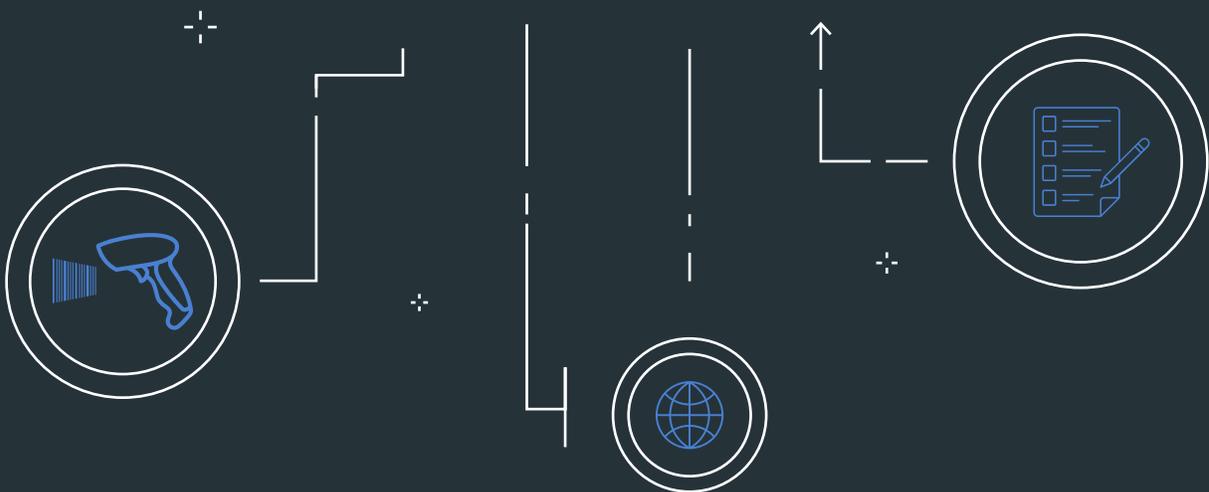


# EU MDR

## 10 Things Packaging Engineers Should Know



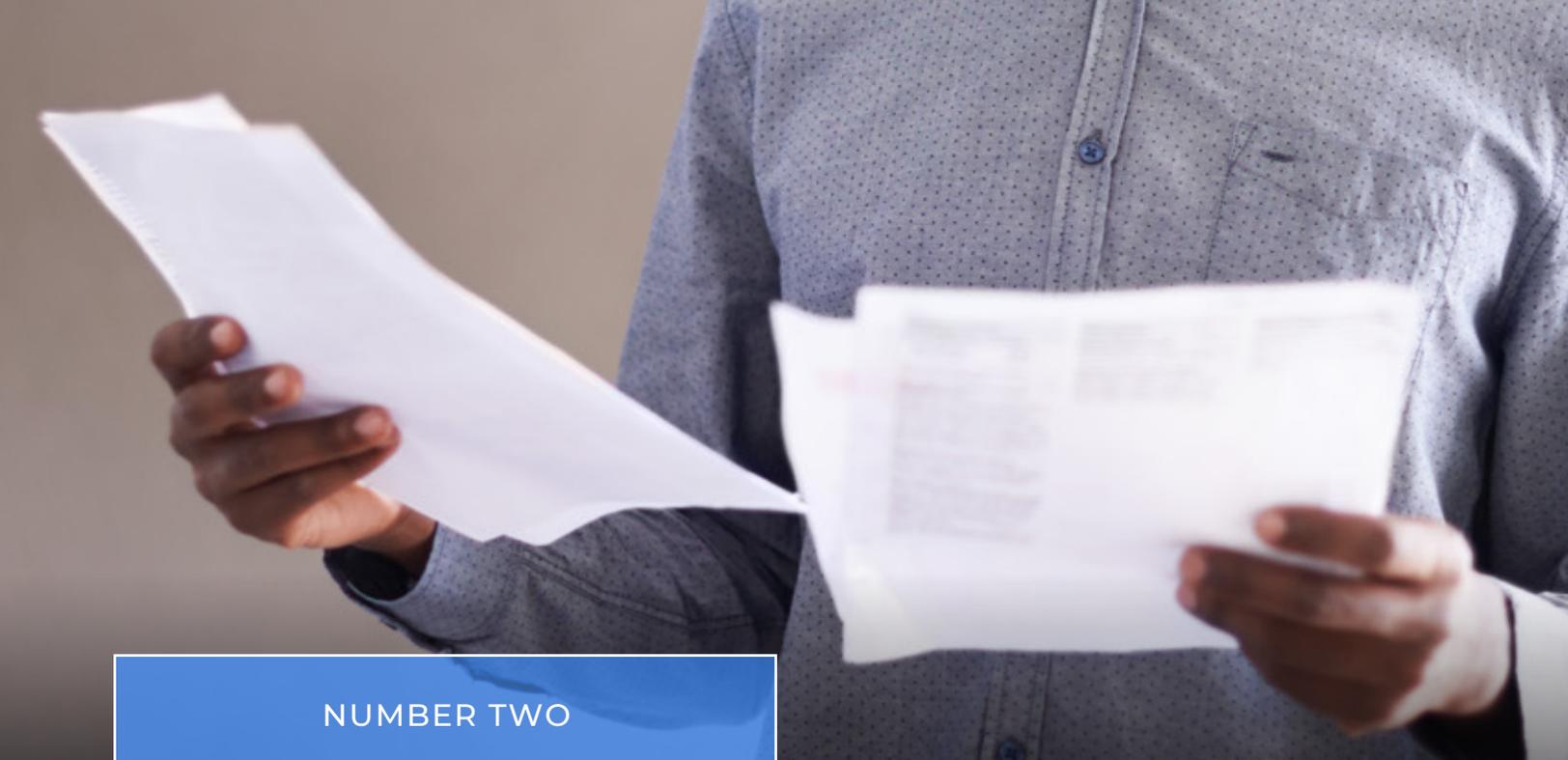
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# THE TIME FOR ACTION IS NOW

First, some background:

The EU Medical Device Regulation (MDR) was approved by the European Parliament on April 5, 2017 and, following its formal adoption, was published in the Official Journal of the EU on May 26, 2017. This means that the MDR will be fully enforceable on May 26, 2020. The first step in this process is for Notified Bodies (NBs) to apply for designation under the MDR, meaning NBs must receive approval from the European Commission before they can assess the conformity of products and before those products can be placed on the market. NBs can apply for designation on Nov 26, 2017, and the process could take nine to 12 months. It may be advisable to check with your NBs to understand their timelines and capacity. Not all NBs will apply for designation or be able to comply with the increased requirements. After an NB has been designated they can start conducting conformity assessments and certifying products to the MDR. To sell or continue to sell medical devices in the European Union, a CE mark indicating certification is required. There is no provision for grandfathering CE marks under the previous directives – all products sold in the EU must be CE marked under the Regulation 2017/745. The timeline for MDR implementation is 3 years, starting January 2018 and ending May 2020. There is a grace period for certificates granted under the prior directive which extends to June 2024.

Although packaging continues to be considered an accessory to a medical device, packaging and labeling are specifically addressed in the EU MDR and need to be included in your company's overall compliance timeline. The requirements in these areas have been enhanced and require a thorough review and assessment.



## NUMBER TWO

# ALIGNMENT BETWEEN EU MDR, ISO 13485:2016 & ISO 11607

ISO 13485:2016 [Medical Devices – Quality management systems — Requirements for regulatory purposes] is recognized as a harmonized standard in the EU MDR. While ISO 11607 is a harmonized standard and is aligned with relevant essential requirements of the MDD as applicable to sterile packaging systems, there are requirements in the EU MDR and ISO 13485:2016 not currently in EN ISO 11607:2017, such as specific expectations involving usability and package integrity. Additionally, the new standard has requirements for preventing contamination of sterile devices with particulate matter during assembly and packaging.

ISO TC 198/WG7 currently has a revision effort underway to more closely align ISO 11607 to the EU MDR [with an expected publication date of mid-2019]. Assuming the timing stays on schedule, the EN ISO 11607 revision would be published prior to the enforcement date of the EU MDR, which is May 26, 2020.

# FOCUS ON INFECTION REDUCTION & MICROBIAL CONTAMINATION

MDR Annex I, Chapter 2, 11 addresses infection and microbial contamination and has some new and enhanced requirements for packaging engineers to consider. For example, the devices and manufacturing processes “should be designed to eliminate or reduce as far as possible, the risk of infection to the patient,” and the design should “allow easy handling” and “minimize contamination.” These elements can be addressed using materials with high microbial barrier properties and designs that allow for effective aseptic presentation. Quantitative data for aseptic presentation can be demonstrated by conducting usability studies. Usability evaluation of aseptic presentation is also proposed in EN ISO DIS 11607:2107. In 2015 the Sterile Barrier Association (SBA) published a guidance document titled “Usability of sterile barrier systems for medical devices” (Ref 201509 rev.01), which provides sound advice for conducting usability studies.

Additionally, MDR section 11.4 states:

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 at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.

This term “clearly evident” is somewhat ambiguous and subjective, leaving room for interpretation. This ambiguity has resulted in a lot of questions and discussions. It is not too late for clarifications in the verbiage. As engineers, we may be reading into the term too literally, where the intent of the regulation may mean clearly evident by a visual scan, i.e. the sterile barrier has to appear intact to an unaided eye. At this point, the intent or interpretation is not fully understood. The industry will likely continue to debate the meaning of “clearly evident.” In the meantime, the SBA’s “Moving from MDD to MDR” position paper, recommends seeking feedback from users to gauge the typical user’s ability to assess the integrity of specific sterile barrier system (SBS) designs.



## NUMBER FOUR

EU MDR vs. ISO 13485:2016

# INTERPRETING STORAGE & HANDLING REQUIREMENTS

How will the industry interpret the ISO 13485:2016 requirement to protect the product from “alteration, contamination or damage where exposed to expected conditions and hazards during processing, storage, handling, and distribution”?

The key term in this verbiage is “expected conditions.” By now, we’ve all seen how sterile barrier systems are handled within the walls of a hospital’s central supply operation, typically without the protection of the shelf carton. With these known handling conditions, with sterile barrier systems traveling, sometimes numerous times, between central supply and various OR settings, are device manufacturers now expected to test SBS for package integrity after handling without the shelf and shipping container?

EU MDR phrases the requirement slightly differently, stating the package must “remain sterile under the transport **and storage conditions specified by the manufacturer** until that packaging is opened at the point of use.” The real question is: Is the ‘point of use’ when the product arrives at the customer dock, or is it when the package is opened to use the product? Standards groups have discussed this topic, and their recommendations will either encourage a clarified definition or a new standard, though it is too early to tell which.



## NUMBER FIVE

# NEW REQUIREMENTS FOR TECHNICAL DOCUMENTATION

Packaging, Sterilization & Maintenance of Sterility

Technical documentation and the evidence of validation is nothing new for packaging engineers. MDR Annex II provides a prescriptive format for technical documentation, and Annex VIII details requirements for the QMS.

The EU MDR now specifically requires:

In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilization and maintenance of sterility. The validation report shall address bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues. (Annex II, 6.2 (e))

Previously, claiming compliance to ISO 11607 checked this box for the Notified Bodies. Now, NBs will need to review all of the validation methods and reports to confirm compliance with the EU MDR.

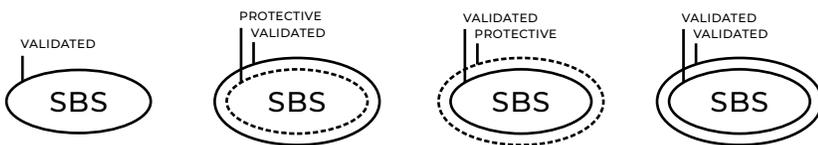


NUMBER SIX

# LABELING, LABELING & MORE LABELING

New EU MDR labeling requirements fall into three distinct categories: requirements applying to the sterile barrier system (SBS), requirements applying to general labeling of the product (i.e. carton label) and requirements included in the instructions for use (IFU). Let's begin with the new labeling requirements for sterile barrier systems. This information is contained in EU MDR Annex I, Chapter III, 23.3 and states that sterile packaging must include "an indication permitting the sterile packaging to be recognized as such." The Sterile Barrier Association (SBA) proposed symbols use solid line ovals and dotted line ovals to distinguish between "validated" and "protected" layers of packaging. The symbols will help healthcare professionals understand which parts of the package are sterile so they can aseptically present devices into the sterile field. While the industry is strongly in favor of these logical and easily understandable symbols, the European Commission has yet to accept them. The SBA is currently surveying the industry to better understand manufacturer acceptance.

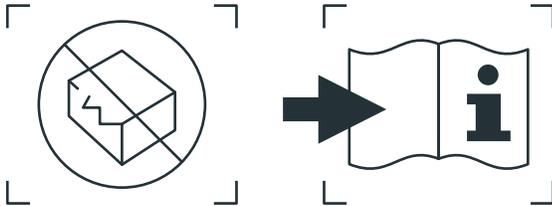
## Sterile Barrier Association Proposed Symbols to Designate "Validated" and "Protective"



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The SBS must also have “a declaration that the device is in sterile condition” (Annex I, Chapter III, 23.3 (b)). This is different than the current sterilization method symbols. Additionally, there must be “**an instruction to check the instructions for use** for what to do if the sterile packaging is damaged or unintentionally opened before use” (Annex I, Chapter III, 23.3 (j)).

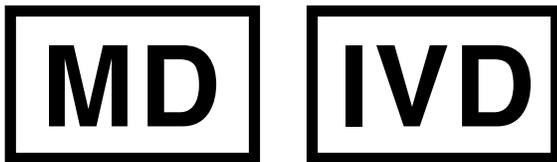
The SBA has proposed the following symbol to check the IFU for further information.



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The most significant change to the general labeling or carton labeling is “an indication that the device is a medical device” (Annex I, Chapter III, 23.3 (q))

The proposed symbol to indicate that a device is a medical device is “MD” contained in a solid line rectangle, like the current identification of an in vitro diagnostic device (IVD).



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Concerning the instructions for use, the MDR states that, if the device is supplied sterile, packaging must include “instructions in the event of the sterile packaging being damaged or unintentionally opened before use” (Annex I, Chapter III, 23.4 (l)). Thus, packaging engineers may be asked to provide guidance for the IFU.

Although there are only a handful of new labeling requirements in the EU MDR, they affect every label and every IFU.

It is a significant amount of work to make all the updates necessary for conformance. Implementing labeling changes can be significantly streamlined using a validated Global Labeling System (GLS). The absence of a GLS makes the process extensive and tedious with a high probability for errors.

## EU MDR & ITS EFFECT ON PACKAGING MATERIAL SUPPLIERS

The EU MDR holds Notified Bodies to a higher standard and level of accountability. Although NBs were required to conduct unannounced audits of manufacturers and manufacturers' critical suppliers and contractors under the previous directive, now NBs must conduct unannounced audits a minimum of once every five years. Critical suppliers should be integrated into manufacturers' quality systems. This also means that any risks related to the production of a device must be identified and mitigated. Mitigating risk related to SBS components could mean qualifying secondary sources of supply or identifying alternative materials. For example, you might qualify a second, back-up supplier for critical packaging components.

## UDI IS BACK FOR ANOTHER ROUND OF COMPLIANCE

Each device needs to be fully traceable utilizing a unique device identification (UDI) system. A manufacturer must obtain a UDI code from a UDI supplier, upload device-specific data into Eudamed, link the UDI code to the Eudamed data set, and place the UDI code on the device label prior to distribution of the product. The EU MDR requirements for UDI have not been finalized, however it's likely they will closely resemble the United State's current UDI requirements.



## NUMBER NINE

EU MDR Compliance Sounds Like a Ton of Work.

# WHERE DO I START?

There's no question compliance with the EU MDR is a lot of work. The packaging requirements represent a very small portion of the overall work necessary to achieve compliance. Most medical device manufacturers will assemble a cross functional team to address the various articles and annexes of the EU MDR. Packaging engineers have a critical role in the overall process. Staying current with the latest published information, providing subject matter expertise, and being a solid partner to your colleagues charged with getting the company positioned for compliance is a good start. Starting early with a robust road map is key to a successful implementation. The bulk of the assessment and remediation will likely focus on legacy packaging.

Here are some key steps to take:

- 1 Become familiar with the EU MDR items related to packaging and labeling.
- 2 Conduct an analysis of all packaging technical files to determine the gaps between actual testing conducted and testing required to comply with the latest standards. Become an expert in what testing exists and what's missing.
- 3 Quantify the impact. Once the gap analysis is complete the real work of remediation begins.
- 4 Plan your labeling strategy. Every label needs revision. Understand the impact. For most companies the assessment phase and subsequent remediation phase will take most of the 3-year transition period to complete. **Start today!**



NUMBER TEN

## NEED ASSISTANCE WITH EU MDR COMPLIANCE FOR PACKAGING AND LABELING?

Network Partners provides comprehensive EU MDR packaging and labeling compliance for medical device manufacturers.

Take the burden of EU MDR packaging & labeling compliance off your to-do list and put it onto ours. Our team of subject matter experts execute our proprietary playbook to efficiently bring packaging and labeling into compliance with the EU MDR. Visit us at HealthPack to receive a complimentary EU MDR booklet containing the applicable packaging and labeling sections, and learn more about our EU MDR compliance services.

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Visit us at [NetworkPartners.com](https://www.networkpartners.com) to learn more.

# SOURCES

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