Oliver
HEALTHCARE PACKAGING

EU MDR: Top Things Packaging Engineers Need to Know

Webinar Q&A

Q&A with Tommy Smith, PhD
Technical Leader – EMEA

Q: Is the SBS symbol already compulsory?

A: Yes, the symbol for Sterile Medical Devices processed using aseptic technique is required.

Q: Is there a minimum size for the label?

A: The label must be visible to the end user; we recommend you check with your notified body to ensure alignment.

Q: If you have a device sealed within a sterile barrier (i.e., a Tyvek pouch), which is then placed within a cardboard box, do you need "this is not a sterile barrier" symbol on the box or just a "this is a/the sterile barrier" on the pouch? Or do you need to label both, and in this instance, what symbol would you apply to the box?

A: The symbology is required only if the package is opened at the point of use and has more than one packaging layer. Although a box or carton is a part of the packaging system it is not to be confused as being a sterile barrier and therefore not typically required. We would recommend you speak to your customer on their specific requirements for identification.

Q: Could you briefly explain the terminology: "Last mile, 1000 ft. 100 yds."?

A: It is the last place where the primary packaging is used, so that is very often the hospital. And although packaging is tested a lot, this is usually performed on the transportation and handling of the packaging up until the final point of use. So that is why the industry started to encourage investigating that last stretch of the process too; that is what is meant by that last mile or 1000 ft.

Q: In your historical example with a sterile barrier inside an oxygen/moisture barrier with different labeling: what defines a barrier being a sterile barrier? Apparently, a foil that prevents gas molecules to ingress should also be a sterile barrier.

A: The definition of sterile barrier is the packages that are validated as a sterile barriers. In the historically example the inner pouch is the sterile barrier since it is sterilized and validated as such. Whereas, the foil is not sterilized or validated as a sterile barrier.

Q: To limit the upper peel strength is often a problem if you use a "pre-manufactured" SBS. What would you propose to assure that the Usability Study does not fail because of a tearing lid?

A: Validating your primary packaging to ensure your sealing is repeatable and within acceptable limits. In other words, obtain Lower/Nominal and Higher limits of sealing and ensure your CQA are listed and adhered to.

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Q: We have major focus here on sterile barriers. How about oxygen/moisture barriers, where integrity failure can (in the worst case) lead to death of the patient (if undiscovered). Should such packaging be handled like a sterile barrier? Or, are demands different from a regulatory perspective?

A: It is important in your design stage that you think about your primary packaging and what barrier you need – we have a wide selection of materials available to cover all requirements. We can set up a call to introduce you to our capability.

Q: Could serialization one day be mandatory for an implantable DM?

A: Sure, that is possible. We are living in a constantly changing environment, so this could change too.

Q: Is it possible to conclude that a packaging (polypropylene blister sealed with Tyvek) is sterile after steam sterilization if I bring evidence that the polypropylene and Tyvek are microbial barriers that are suitable for steam sterilization?

A: No, unfortunately you need to complete integrity testing either at stability or performance testing (or both) to ensure the sterile barrier is intact post testing. There are many variables in steam sterilization that can affect the integrity of the sterile barrier, so testing pre and post sterilization is important.

Q: What about the green EtO Sterilization Indicator Label? Does it have to be on packaging?

A: This can vary between companies and notified bodies, so we would recommend you discuss this with your customer to see if they need this kind of label on their packaging.

Q: MDR requires labelling temperature and humidity ranges for transportation and storage. How do I ensure I give secure ranges and in what type of packaging this applies?

A: You need to complete performance testing of your product and package of choice; all testing should be driven by your approved protocol, which will involve worst case scenario testing and products. The standards we mentioned in the presentation can give guidance on setting up the protocol.

Q: Can we start using the symbols presented in annex ISO 11607-1:2019? Or is this in draft form?

A: The best thing to do is speak to your customer and regulatory body on their requirements for identification. They can give guidance on what is best for you to use.

To watch the full MDR webinar or to speak with a technical expert, please visit: www.oliverhcp.com/galway