

## The Standard for sterilisation packaging EN ISO 11607 – Definitions and concepts

Since April 2007, the familiar European standard EN 868-1 has been replaced by EN ISO 11607. Manufacturers of sterilisation packaging (wrap, pouches, containers,.. ) now can rely on one globally accepted standard to demonstrate compliance with the relevant regulations in their markets. The new standard is the result of the harmonisation project between ISO (International Standardisation Organisation) and CEN (European Standardization organisation) and consists of two parts.

Part 1 of the EN ISO 11607 specifies the general requirements for all sterile barrier systems. Part 2 of EN ISO 11607 describes the validation requirements for forming, sealing and assembly processes of sterile barrier systems.

Whilst the content of the standard is not greatly different from the previous version, the introduction of a new set of definitions does seem to cause confusion among the users and even the suppliers of the products that are within the scope of the standard. The confusion has to a great extent been caused by the fact that requirements and customs of use have been interpreted differently by hospital and industrial sterilisation users.

This article therefore aims to help the reader better understand those newly introduced definitions in the context of the hospital application of sterile barrier systems , along with describing the responsibilities of the manufacturer in terms of data collection and communication to the customer.

### Definitions

The previous versions of the standard contained confusing and contradicting terms such as ‘final pack’, ‘package’ or ‘primary pack’. The ISO standard used even other definitions, so it was clearly beneficial to better state the subject. Today, three levels of sterilization products are being defined:

1. **Sterile Barrier System:** minimum package that prevents ingress of micro-organisms and allows aseptic presentation of the product at the point of use
2. **Protective Packaging:** configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of assembly until the point of use
3. **Packaging system:** combination of the sterile barrier system and protective packaging

The **sterile barrier system (SBS)** can be made out of sheets, pouches (or other) or combination / configuration of materials. Independent of the material or the configuration, the SBS has to be able in itself, as specified and claimed by the manufacturer, to achieve sterilisation, keep the contents sterile up to the point of use and allow for aseptic presentation. It is important to note that manufacturers may have different interpretations of what this minimum configuration might be. Some claim that one layer of the product is adequate to assure ‘the prevention of ingress of micro-organisms’ and the aseptic presentation. Others only make claims on combined materials or multiple layers. Although both may be valid, the documentation needs to clearly show that the minimum requirements are met (preventing ingress of micro-organisms and allowing aseptic presentation). Users are therefore advised to ask their supplier for his test data.

### **What does 'preventing the ingress of micro-organisms' mean?**

The manufacturer/supplier needs to ensure that the sterile barrier system represents an efficient barrier and that the risk for microbial penetration is minimised under the conditions of use. This important ability of the sterile barrier system must be documented by laboratory data. Manufacturers can select the most appropriate test method to document this particular property of the sterile barrier system.

Annex A and the bibliography of the EN ISO 11607 standard lists the most commonly used test methods. Examples are the Bacterial Filtration Efficiency test and the Final Pack test. Typically, similar fabrics rely on the same test method to document the barrier properties, but historically companies and industries hold on to their experience, so comparing data of different suppliers is not always possible or easy. A hospital user will therefore not be in a position to determine what sterile barrier system is the best performing, unless a test method is developed that allows all materials to be bench-marked.

### **Aseptic presentation**

The second condition to meet the definition of and requirements for a sterile barrier system is that the system allows for **aseptic presentation**. This characteristic of a sterile barrier system is more difficult to document by means of a laboratory test. Here, evidence and tests in use, combined with clear instructions for packing, handling and opening, will allow customers to evaluate the acceptability of the configuration proposed by the manufacturer. Again, it is the supplier or manufacturer who is responsible for proving the product works, i.e. that it meets the set requirements of the standard. In the technical file and the instructions for use, manufacturers are expected to clearly explain the technique involved with presenting the contents in an aseptic manner. As with test methods, many techniques exist, but not all may be applicable for the same sterile barrier systems. Good communication between manufacturer and hospital user is definitely a must to ensure the best outcomes.

### **What is meant by Protective Packaging?**

Protective packaging is the 'configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of assembly until the point of use'. Recognizing the above, i.e. that sterile barrier systems (SBS) are the minimum configuration for working in the CSSD, a protective packaging is any additional system or material which is put in place to protect the SBS from being damaged, for instance in case of challenging logistics. If a component of a SBS is considered crucial to the SBS (e.g. it is a barrier material), then it is not considered part of the protective packaging. Examples of protective packaging are dust covers, basins or trays. But if the manufacturer claims that two layers of sterilisation wrap or two individual pouches are mandatory for meeting all SBS requirements, then the outer layer of the system is not a protective packaging.

Whether protective packaging is needed or not, depends on the specific user's situation. Durability of the materials of the SBS is one contributing element in the process to decide whether or not additional measures are required.

## Conclusion

Hospital sterilisation experts are best placed to evaluate the appropriateness of the sterile barrier systems they want to procure for their specific needs. As manufacturers need their product to comply with the essential requirements of the Medical Device Directive, they have to document the efficacy and safety of their sterile barrier system showing how it prevents the ingress of micro-organisms and allows aseptic presentation. The protective packaging can be used if the user feels the need for it but it is not obligatory as per the standard. This protective packaging is only intended to mechanically protect the sterile barrier system depending on the user situation and needs.

The standard does not exclude or promote any existing or future sterile barrier systems from legitimate presence in the market. However, every manufacturer will need to justify his product's compliance to the regulatory bodies using the standard as a guideline.

The hospital expert is best served by a clear communication on the factors that demonstrate performance directly with his supplier.

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