REGULATORY

- Overview of relevant legislation
  - Medical Device Legislation in Europe
    - Standards
      - Packaging materials and systems for medical devices which are to be sterilised.
      - Other relevant standards
  - List of standards relevant for sterile barrier systems
- Position papers and guidance documents
- Members only

Packaging materials and systems for medical devices which are to be sterilised.

Home > Regulatory > Overview of relevant legislation > Medical Device Legislation in Europe > Standards > Packaging materials and systems for medical devices which are to be sterilised.

Since 2007 **EN ISO 11607** "Devices that are sterilised after being completely sealed or enclosed in at least the primary packaging" is harmonized with the medical device directives in Europe. It consists of 2 parts:

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

In this standard four key terms are defined. **Sterile barrier system** 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 could include the transit packaging.

As a harmonized standard, EN ISO 11607 provides presumption of conformity with the essential requirements of the MDD 93/42/EEC as they apply to sterile packaging. Part 1 of the standard deals with materials and design as well as design validation, while Part 2 covers packaging process validation. Process validation applies to assembly and sealing processes, the final seal as well as the seals of the preformed sterile barrier systems. Manufacturers of preformed sterile barrier systems including pouches, header bags and opened reusable sterilisation containers, have to validate their processes for making the seals and closure systems.

In Europe EN ISO 11607 Part 1 replaced EN 868-1:1997 while EN 868 parts 2 – 10 have been referenced as informative documents in EN ISO 11607. Where packaging is covered by one or more of EN 868 parts 2-10 they can be used to demonstrate compliance with the new EN ISO standard.

Historically, CEN in Europe had developed the horizontal standard EN 868-1, published in 1997 along with several vertical standards (published later) to address specific performance requirements for various types of products used in medical packaging (EN 868 parts 2-10). Although these specific requirements were not mandatory, compliance with them could be used to demonstrate compliance with EN 868 Part 1.

At the same time as the CEN standards were being developed, the International Organisation for Standardisation (ISO) developed ISO 11607 -1997 (Packaging for terminally sterilised medical devices) where a single standard addressed the attributes of medical packaging without establishing specific performance criteria. The Association for the Advancement of Medical Instrumentation (AAMI) Technical Information developed and adopted a report (TIR 22-1998) (Guidance for American National Standards Institute (ANSI)/AAMI/ISO 11607-1997) to address the issues surrounding the implementation of ISO 11607 and what test methods are typically used to show compliance with the various requirements of the standard.

From 1997 to 2006 there was a continuing effort to harmonize the global standards for medical packaging as well as development in the standardisation of test methods to assess the performance of medical packaging. A working group of ISO Technical Committee TC198 developed a single document adopted by both ISO and CEN as the global medical packaging document. Since 2007, ISO 11607 has been adopted by many countries in the world and has become the global standard for sterile medical packaging including the process.

Work continues on standardisation of test methods.

In the USA, medical device manufacturers do not have to comply with ISO 11607 but because the FDA recognises the standard many choose to declare conformity in their 510(k) premarket notification submissions. 510(k) refers to a section of the Food, Drug and Cosmetic Act which requires device manufacturers, who must register, to notify the

FDA, at least 90 days in advance, of their intent to market a medical device and to provide extensive information about the device.

Go to www.fda.gov for more information. **Read more**

THE STERILE BARRIER ASSOCIATION
4 King Square
Bridgwater
Somerset
TA6 3YF
United Kingdom
Tel: +44 7802 266 202