Sterile Barrier Association

Review of current relevant legislation and standards affecting Sterile Barrier Systems for the European Medical Device Market

During the past 30 years, the medical technology industry has developed an amazing number of life saving and life enhancing products. These products and therapies have helped millions of patients to live longer, better quality lives. With continuing innovation and the rapid advancement of technologies, medical devices are currently one of the fastest growing industries.

Government policies translated into national regulations that are enforced by legislation form a necessary part of a country's overall national health system in order to ensure access to high quality, affordable medical devices that are used and disposed of safely and appropriately. Health care-associated infection is a major issue in patient safety even in countries with well developed regulatory and healthcare systems. Regulatory controls for medical devices play an vital role in the fight against health care-associated infections.

Sterility and its maintenance, together with the prevention of cross-infection, are at the top of any list of critical factors in patient care. The packaging around medical devices that allow those devices to be **sterilised,** provides a microbial barrier and maintains **sterility** effectively up to the point of use is known as a **sterile barrier system**. A **sterile barrier system** is an essential part of a **sterile** medical device.

*(A **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". This is distinct from protective packaging which is defined as 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".)*

Manufacturing medical devices and their **sterile barrier systems** in a highly regulated environment can be extremely challenging and traceability throughout the whole life cycle is essential. This is amply illustrated by the lists of product recalls for medical devices which can be found on national regulatory agency websites in Europe, for example, on the Medicines and Healthcare Products Regulatory Agency (UK) website and on the FDA website, at List of Device Recalls in the USA.

MEDICAL DEVICE REGULATION IN EUROPE

LEGAL REQUIREMENT

The main Directives regulating the Medical Device industry in Europe are:

Directive 2007/47/EC of the European Parliament and the Council of 5 September 2007 amending:

Council Directive 93/42/EEC on Medical Devices (MDD) (1992)
Council Directive 90/385/EEC on Active Implantable Medical Devices Directive (AIMDD) (1990) and Council Directive 98/79/EC on In vitro Diagnostics Medical Devices (IVDMD) (1998)

The Directives concerning medical devices are based on the principles of the New Approach. Read more about the New Approach .Under this approach, the Directives define the essential requirements i.e. the legal requirements that devices have to meet when they are put on the market or put into service.

Sterile Barrier systems are considered to be 'accessories' to medical devices as defined under the MDD i.e. 'an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device'. For the purposes of the Directive, accessories are treated as medical devices in the requirement to comply with the essential requirements as set out in Annex 1 of the Directive.

The essential requirements are concerned with eliminating or reducing risks as far as possible. They refer to, for example, risks associated with the chemical, physical and biological properties of materials including toxicity, bio-compatibility and compatibility with sterilisation systems. They also refer to the risk of infection and microbial contamination and specify the use of non- reusable packaging and/or appropriate procedures to minimise the risks for devices which are to be delivered in a **sterile** state.

To demonstrate conformity with the essential requirements assessments must be carried out. Generally, **sterile barrier systems** are taken into account as an accessory or part of the device in the overall conformity assessment process carried out by a device manufacturer on the final product. However, **sterile barrier systems** sold directly to the hospitals are considered as Class 1 devices (generally regarded as low risk) under the Directive and the responsibility for the conformity assessment lies with the sterile barrier manufacturer.

Devices considered to meet the essential requirements must bear the CE marking of conformity when placed on the market. It is usual, to avoid confusion with the CE mark for the final product, for sterile barrier systems considered as Class 1 devices sold separately to the device prior to sterilisation to carry the CE mark on the sales packaging rather than on the individual bag, pouch or sheet. The CE mark is a symbol of quality, safety and efficiency. Please refer to the SBA document on CE marking of sterile barriers.

STANDARDS

Harmonised European standards, published in the Official Journal, facilitate compliance with the essential requirements. For the purposes of the MDD, this also includes the European Pharmacopoeia monographs. Whilst the essential requirements are obligatory, the standards remain voluntary. Follow the link for a summary list of titles and references of harmonised standards related to medical devices.

Members of the SBA use the published standards to demonstrate conformity of their products with the essential requirements of EU Directive 93/42/EEC.

CEN is the European Committee for Standardization. The CEN Technical committee CEN/TC102 drafts standards that address the Essential Requirements of EU Directive 93/42/EEC and EU Directive 90/385 as they apply to sterilisers, wash-disinfectors and their associated accessories in order to ensure **sterilisation** and **sterile** products. **Sterile Barrier Systems** fall into this category. A list of the standards published by this committee can be found by following the link CEN Published Standards . In particular, the **868 series** relate to packaging materials and systems for medical devices which are to be sterilised.

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Standards for 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 one of the standard deals with materials and design as well as design validation, while part two 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.

EXAMPLES OF OTHER RELEVANT STANDARDS

Members of the SBA are expected to be able to demonstrate good controls over all business risks particularly those associated with product quality, health & safety and the environment. Although it is not mandatory to have certification to the standards referred to below in order to supply s**terile barrier systems** into the Medical Device market in Europe, they are examples of what is generally recognised as representative of best practice.

ISO 9001- Quality Management Systems (QMS) – Requirements

ISO 9001 allows an organisation to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements. Quality management requirements are complimentary to the technical requirements for the products. For **sterile barrier systems** certification of manufacturers to ISO 9001 is normally sufficient to satisfy the requirements of the customer.

ISO 13485 – Medical Devices – Quality Management Systems – Requirements for Regulatory purposes

ISO 13485 was developed to fulfil the requirement of the EC declaration of conformity procedures for most medical devices described in the Annexes II to VI in the MDD. ISO 13485 contains **ISO 9001** plus additional requirements for medical device manufacturers. It excludes the elements of continuous improvement and customer satisfaction in ISO 9001 that are not suitable to fulfil regulatory requirements.
The standard is closer to **GMP** (Good Manufacturing Practice) and FDA expectations in the Quality System Regulation (QSR) in Title 21 Code of Federal Regulations Part 820 than ISO 9000 with increased emphasis on design & development, validation and process controls and it includes risk analysis. See www.fda.gov for more information on GMP. It is best practice within the industry for manufacturers of **sterile barrier systems** to incorporate elements of GMP in their processes where appropriate and it is an increasing customer expectation. Some manufacturers of **sterile barrier systems** have also chosen to be certified against ISO 13485.

ISO 14971 – Application of risk management to medical devices

Although not directly applicable to sterile barrier systems, ISO 14971 provides a model for risk management and accepted tools for conducting risk assessment.

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ISO 14001- Environmental Management

ISO 14001 is designed to help organisations to effectively minimise the risk to the environment from their products and processes.

OHSAS 18001

Standards similar to OHSAS 18001 can help organisations to effectively control their occupational health and safety (OH&S) risks and continually improve their OH&S management systems.

Hygiene Standards

Hygiene standards like The British Retail Consortium/Institute of Packaging technical standard focus on the risks to consumer safety and product integrity and the control of hygiene in the manufacture and supply of food packaging. CEN is also actively developing a European standard for hygiene management.