1 Scope

This European Standard specifies the requirements for an aseptically processed medical device to be designated 'STERILE'.

NOTE For the purpose of the EU Directive(s) for medical devices (see Bibliography), designating that a medical device is 'STERILE' is only permissible when a validated sterilization process has been applied. Requirements for validation and routine control of aseptic processes are specified in prEN 13824 (in preparation).

2 Normative references

This Europeans Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 550, *Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization*

EN 552, *Sterilization of medical devices - Validation and routine control of sterilization by irradiation*

EN 554, *Sterilization of medical devices - Validation and routine control of sterilization by moist heat*

EN ISO 13485, *Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)*

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply

3.1
aseptic processing
handling and filling of sterile containers and devices, or their components, in a controlled environment in which the air supply, materials, equipment and personnel are regulated to control microbial and particulate contamination to acceptable levels.

NOTE Aseptic processing can include formulation (compounding), filtration and filling into pre-sterilized containers.

3.2
bioburden
population of viable micro-organisms on a product and/or package

3.3
media fills
simulation of an aseptic process in which a microbial growth medium is used to assess the effectiveness of the controls applied