ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN 13824:2004

Sterilization of medical devices - Aseptic processing of liquid medical devices - Requirements

Stérilisation des dispositifs médicaux - Traitement aseptique des dispositifs médicaux liquides - Exigences

Sterilisation von Medizinprodukten - Aseptische Herstellung flüssiger Medizinprodukte - Anforderungen

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National Foreword

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This European Standard was approved by CEN on 14 October 2004.

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Contents

Foreword

This document (EN 13824:2004) has been prepared by Technical Committee CEN/TC 204 “Sterilization of medical devices”, the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2005, and conflicting national standards shall be withdrawn at the latest by May 2005.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annexes ZA and ZB, which are integral parts of this document.

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Introduction

Medical devices that are labelled ‘sterile’ have to be prepared using appropriate and validated methods. CEN TC 204 has prepared standards relating to terminal sterilization of medical devices by irradiation (EN 552), by moist heat (EN 554), by liquid chemical sterilants (EN ISO 14160) and by ethylene oxide (EN 550). When a medical device is intended to be sterile and cannot be terminally sterilized, aseptic processing provides an alternative method.

Aseptic processing requires the application of validated sterilization processes to all equipment components that come into contact with the aseptically processed material prior to the use of that equipment. This is also necessary for container components. The sterilized equipment and container components are then assembled in a manner that maintains their sterility. The product is processed in a controlled environment where microbial and particulate levels are maintained at defined levels and where human intervention is minimized.

Sterilization practice is an exacting and demanding discipline. Manufacturers require validated systems, adequately trained personnel, controlled environments and well-documented systematic processes to ensure a sterile product. The application of this to aseptic processing is discussed below.

While terminal sterilization involves the use of a process of known lethality, the assurance of sterility associated with aseptic processing can only be inferred, as facilities, equipment and people are all factors associated with the process and its control. Issues that need particular attention for aseptic processing include:

a) personnel;

b) layout and specifications for buildings, equipment and facilities;

c) particulate and microbial environmental monitoring programmes;

d) the satisfactory function of validated systems for production of water, steam and other process gases of appropriate quality;

e) descriptions of and procedures for manufacturing operations including people, materials, material flow, solution preparation and associated acceptance criteria;

f) validation and routine control of cleaning, disinfection and sterilization processes;

g) validation methods and data requirements for media fills and container/closure systems and

h) operating practices for acceptance criteria, investigation reviews and release/reject decisions.

1 Scope

This document specifies requirements for the design and operation of aseptic processing facilities and the validation and routine control of aseptic processes for the preparation of sterile liquid medical devices. It is not applicable to those pharmaceutical products where the requirements of the relevant good manufacturing practices are applicable.

NOTE Many of the principles included in this document can be applied to certain aseptically processed sterile solid medical devices.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 980, *Graphical symbols for use in the labelling of medical devices.*

EN 1174-1, *Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 1: Requirements.*

EN 1174-2, *Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 2: Guidance.*

EN 1174-3, *Sterilization of medical devices — Estimation of the population of micro-organisms on product - Part 3: Guide to the methods for validation of microbiological techniques.*

EN 1822-1:1998, *High efficiency air filters (HEPA and ULPA) — Part 1: Classification, performance testing, marking*.

EN 1822-2:1998, *High efficiency air filters (HEPA and ULPA) — Part 2: Aerosol production, measuring equipment, particle-counting statistics.*

EN ISO 14644-1:1999, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness (ISO 14644-1:1999).*

EN ISO 14644-2:2000, *Cleanrooms and associated controlled environments — Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 (ISO 14644-2:2000).*

prEN ISO 14644-3:2002, *Cleanrooms and associated controlled environments — Part 3: Metrology and test methods (ISO/DIS 14644-3:2002).*

EN ISO 14644-4:2001, *Cleanrooms and associated controlled environments — Part 4: Design, construction and start up (ISO 14644-1:2001).*

prEN ISO 14644-7:2001, *Cleanrooms and associated controlled environments — Part 7: Separative enclosures (clean air hoods, gloveboxes, isolators, minienvironments) (ISO 14644-7:2004).*

European Pharmacopoeia: monographs for Purified Water and Water for Injections. European Department for the Quality of Medicines

European Pharmacopoeia: Test for sterility. European Department for the Quality of Medicines

Rules governing medicinal products in the European Union, Volume 4, Guide to Good Pharmaceutical Manufacturing Practices, Commission of European Communities, Brussels/Luxembourg (current edition available from http://pharmacos.eudra.org/F2/eudralex/vol-4/home.htm.