



NSAI
Standards

Irish Standard
I.S. EN 16442:2015

Controlled environment storage cabinet for processed thermolabile endoscopes

I.S. EN 16442:2015

Incorporating amendments/corrigenda/National Annexes issued since publication:

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I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

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This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

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This document is based on:

EN 16442:2015

Published:

2015-03-18

This document was published under the authority of the NSAI and comes into effect on:

2015-04-06

ICS number:

11.140

NOTE: If blank see CEN/CENELEC cover page

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EUROPEAN STANDARD

EN 16442

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2015

ICS 11.140

English Version

Controlled environment storage cabinet for processed thermolabile endoscopes

Enceinte de stockage à atmosphère contrôlée pour
endoscopes thermosensibles traités

Lagerungsschrank mit geregelten Umgebungsbedingungen
für aufbereitete, thermolabile Endoskope

This European Standard was approved by CEN on 19 December 2014.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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EN 16442:2015 (E)

Foreword

This document (EN 16442:2015) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by September 2015 and conflicting national standards shall be withdrawn at the latest by September 2015.

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Introduction

Endoscope storage cabinets are designed to provide a controlled environment for the storage of endoscope(s) (with or without channels) and, if necessary, drying of the endoscope(s) including the endoscope(s) channels.

The controlled environment provided by the storage cabinet ensures that during storage there is no deterioration of the microbiological quality of the endoscope. The drying function is intended to supplement, if necessary, any drying conducted during automated or manual processing of the endoscope.

The storage cabinet is designed to allow for the safe use of endoscopes at an extended period from the time of processing improving availability for use.

NOTE 1 Drying of an endoscope in a washer-disinfector can require a prolonged cycle time. The use of a storage cabinet including a drying function can increase the number of endoscopes that can be processed in the washer-disinfector for a defined time period.

NOTE 2 It is strongly recommended to verify the microbiological quality of the endoscopes intended to be stored in the cabinet before installation of the storage cabinet.

NOTE 3 The storage cabinet is not designed to clean and/or disinfect endoscopes and any contaminated endoscope stored in the cabinet can still be contaminated after the storage period.

NOTE 4 Storage cabinets for processed thermolabile endoscopes are not considered as medical devices.

EN 16442:2015 (E)

1 Scope

This European Standard specifies the performance requirements applying to cabinets designed to store, or store and dry, thermolabile endoscopes following automated or manual processing.

The storage cabinets are designed to provide a controlled environment for storage of endoscope(s), with or without channels, and when necessary drying of the endoscope(s), including the endoscope(s) channels.

The controlled environment provided by the storage cabinet ensures that during storage there is no deterioration of the microbiological quality of the endoscope. The drying function is intended to supplement, if necessary, any drying provided as part of the automated or manual processing cycle.

This European Standard specifies storage cabinets which flush the channels and the external surfaces of endoscopes with air.

NOTE 1 The storage cabinet is one of the means that can allow the safe use of the endoscope for an extended period from the time of processing and improve availability for emergency use.

NOTE 2 Thorough drying of an endoscope in a washer-disinfector can require a prolonged cycle time; the use of a storage cabinet including a drying function can enhance throughput of the endoscopes.

The cabinet is not intended to provide any cleaning or disinfection function.

This European Standard does not include the use of other chemicals for drying and maintaining the quality of endoscopes during storage

2 Normative references

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

EN 60584-1:2013, *Thermocouples — Part 1: EMF specifications and tolerances (IEC 60584-1:2013)*

EN 60751:2008, *Industrial platinum resistance thermometers and platinum temperature sensors (IEC 60751:2008)*

EN ISO 14644-3:2005, *Cleanrooms and associated controlled environments — Part 3: Test methods (ISO 14644-3:2005)*

3 Terms and definitions

For the purposes of this document the following terms and definitions apply.

3.1

drying function

additional feature of a storage cabinet carried out in the sequence as regulated by the automatic controller to remove moisture

3.2

drying phase

part of the storage cycle that is dedicated to the drying of the endoscope

3.3

drying temperature band

range of temperatures expressed as the minimum and the maximum controlled temperatures, which may prevail throughout the load during drying

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