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I.S. EN 13544-1:2007+A1:2009

Respiratory therapy equipment - Part 1: Nebulizing systems and their components

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English Version

Respiratory therapy equipment - Part 1: Nebulizing systems and their components

Matériel respiratoire thérapeutique - Partie 1: Systèmes de nébulisation et leurs composants

Atemtherapiegeräte - Teil 1: Verneblersysteme und deren Bauteile

This European Standard was approved by CEN on 22 March 2007 and includes Amendment 1 approved by CEN on 23 July 2009.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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Foreword

This document (EN 13544-1:2007+A1:2009) has been prepared by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, 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of an identical text or by endorsement, at the latest by February 2010 and conflicting national standards shall be withdrawn at the latest by March 2010.Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document includes Amendment 1, approved by CEN on 2009-07-23.

This document supersedes ⟦A1⟩ EN 13544-1:2001 ⟨A1⟧.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ⟦A1⟩ ⟨A1⟧.

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 Annex ZA, which is an integral part of this document.

This European Standard applies to respiratory therapy equipment and has been prepared in three parts. This Part addresses nebulizing systems; Parts 2 and 3 address respectively tubing and connectors, and air entrainment devices.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

This European Standard is based on EN 60601-1:1990.

In EN 60601-1:1990, this type of European Standard is referred to as a “Particular Standard”. As stated in 1.3 of EN 60601-1:1990 the requirements of this European Standard take precedence over those of EN 60601-1:1990.

Clauses, subclauses, tables and figures additional to those in EN 60601-1:1990 are numbered beginning at '101'. Additional annexes are lettered beginning at 'AA' except for Annex 'ZA'.

Additional items in lettered lists are lettered beginning 'aa)'.

Rationales for some of the requirements of this European Standard are given in Annex AA. Such requirements are indicated by the letter '**R**' after the clause number.

Section one – General

1 R) Scope

The scope given in Clause 1 of EN 60601-1:1990 applies except that 1.1 is replaced by the following:

1.1 This European Standard specifies requirements for nebulizing systems used for the delivery of drugs in an aerosol form to humans through the respiratory system.

This European Standard includes gas-powered nebulizers which may be derived from e.g. compressors, pipeline systems, cylinders etc., or electrically-powered nebulizers (e.g. ultrasonic and membrane devices) or manually-powered nebulizers.

NOTE Requirements for nebulizers having also a humidification function are specified in EN ISO 8185:1997 + AC: 2002 “Humidifiers” (see 56.102).

This European Standard does not apply to nebulizers precharged with a specific medicinal product (e.g. MDI, DPI).

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 556 (all parts), *Sterilization of medical devices — Requirements for medical devices to be designated “STERILE”*

EN 737-1, *Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum*

ENV 737-6, *Medical gas pipeline systems — Part 6: Dimensions and allocation of probes for terminal units for compressed medical gases and vacuum*

EN 739, *Low pressure hose assemblies for use with medical gases*

EN 980, [A1] *Symbols* [A1] *for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer* [A1] *of* [A1] *medical devices*

EN 1281-2[1)], *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2:1987 modified)*

EN 1707, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Lock fittings*

EN 20594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements (ISO 594-1:1986)*

EN 60601-1:1990, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:1988)*

[1)] Will be superseded by EN ISO 5356-2, which is currently under preparation.