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INHALATIONAL NITRIC OXIDE SYSTEMS –

PART 1: DELIVERY SYSTEMS

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English version

Inhalational nitric oxide systems – Part 1: Delivery systems

Inhalationssysteme für Stickstoffmonoxid - Teil 1: Abgabesysteme

This Technical Specification (CEN/TS) was approved by CEN on 02 November 2002 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

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Foreword

This document (CEN/TS 14507-1:2003) has been prepared by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI.

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).

CEN/TS 14507 consists of the following Parts under the general title "Inhalational nitric oxide systems"

Part 1 - Delivery systems

Part 2 - Supply systems

Attention is drawn to the rationales and guidance on equipment for use with nitric oxide given in CR 13903

Annex AA of this Part of CEN/TS 14507 is given for information and contains rationale statements for this Part of CEN/TS 14507. The clauses which have corresponding rationale statements are marked with R) after their number.

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

Section one — General

1 Scope

This Part of CEN/TS 14507 refers to EN 60601-1:1990 "Medical electrical equipment — Part 1: General requirements for safety", as amended by its amendments 1 (1991) and 2 (1995). For brevity Part 1 is referred to in this Part of CEN/TS 14507 either as the General Standard or as the General requirements.

The scope given in clause 1 of the General Standard applies except that 1.1 is replaced by the following:

1.1 This Part of CEN/TS 14507 specifies particular requirements for inhalational nitric oxide delivery systems and their modules. It covers devices which can be supplied in combined units, integrated into another medical device, for example a lung ventilator, or as individual devices.

This Part of CEN/TS 14507 addresses the monitoring of nitric oxide and oxygen delivery to the patient and minimization of the production of nitrogen dioxide.

This Part of CEN/TS 14507 covers the requirements for inhalational nitric oxide delivery systems intended for medical use, for example, in critical care, anaesthesia, and emergency/transport environments.

NOTE It is recognized that from time to time innovations and designs will appear that offer advantages and yet are not covered by specific safety-related design or performance aspects of this Part of CEN/TS 14507; such innovations are not to be discouraged. As the techniques and technologies in these innovations advance, it is essential that the safety objectives of this Part of CEN/TS 14507 are considered as minimum requirements.

The requirements of clause 1.3 of the General Standard apply with the following additions:

The numbering of clauses and subclauses of this Part of CEN/TS 14507 corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words: