National Standards Authority of Ireland

IRISH STANDARD

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BLOOD GAS EXCHANGERS

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Descriptors: medical equipment, oxygenators, disposable equipment, definitions, specifications, physical properties, performance evaluation, flow rate, gases, blood, tests, testing conditions, information, packing, marking

English version

Blood gas exchangers

Echangeurs gaz/sang extra corporels

Blutgasaustauscher

This European Standard was approved by CEN on 10 June 1998.

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 Central Secretariat or to any CEN member.

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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Contents

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205 "Non-active 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of an identical text or by endorsement, at the latest by July 1999, and conflicting national standards shall be withdrawn at the latest by July 1999.

This European Standard is based on ISO 7199 'Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)', prepared by Technical Committee TC 150 of the International Organization for standardization.

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

Introduction

This European Standard is intended to ensure that devices designed to effect the exchange of gases in support of, or as a substitution for the normal respiratory function of the lungs have been adequately tested for both their safety and function, and that extracorporeal device characteristics are appropriately disclosed when labelling the device.

This European Standard therefore contains recommended procedures to be used for evaluation of extracorporeal blood gas exchangers. Type test procedures for determination of the gas transfer, blood cell damage and heat exchanger performance are described, although limits for these characteristics are not specified. Ready identification of the performance characteristics should, however, assist the user in the selection of a blood gas exchanger which will suit the needs of the patient.

This European Standard also includes minimum reporting requirements, which will allow the user to compare performance characteristics of blood gas exchangers of different designs in a standard way.

This European Standard makes reference to other standards where methods for determination of characteristics common to medical devices can be found.

No provisions have been made for quantification of microbubble generation or for non-formed elements of bovine blood, due to the fact that there is currently no consensus regarding satisfactorily reproducible test methods.

Requirements for animal and clinical studies have not been included in this European Standard. Such studies can be part of a manufacturer's quality system.

This European Standard contains only those requirements that are specific to blood gas exchangers. Non-specific requirements are covered by references to other standards listed in the normative references section. Since non-toxicity is anticipated to be the subject of a future standard, this European Standard does not cover non-toxicity.