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SURGICAL DRAPES, GOWNS AND CLEAN AIR SUITS, USED AS MEDICAL DEVICES FOR PATIENTS, CLINICAL STAFF AND EQUIPMENT - PART 2: TEST METHODS

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EUROPEAN STANDARD

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EN 13795-2

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English version

Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - Part 2: Test methods

Champs chirurgicaux, casaques et tenues de blocs, utilisés comme dispositifs médicaux, pour les patients, le personnel medical et les équipements - Partie 2: Méthodes d'essai

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung zur Verwendung als Medizinprodukte für Patienten, Klinikpersonal und Geräte - Teil 2: Prüfverfahren

This European Standard was approved by CEN on 15 October 2004.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

This document (EN 13795-2:2004) 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of an identical text or by endorsement, at the latest by May 2005, and conflicting national standards shall be withdrawn at the latest by May 2005.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 Annex ZA, which is an integral part of this document.

EN 13795 is expected to consist of the following parts under the general title *"Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment"*:

Part 1: *General requirements for manufacturers, processors and products*

Part 2: *Test methods*

Part 3: *Performance requirements*

Originally EN 13795 was also to include Part 3: *Test method for resistance to dry microbial penetration* and Part 4: *Test method for resistance to wet microbial penetration.* However, it has been decided that these parts will now be developed by the Vienna Agreement/CEN lead route in conjunction with ISO/TC 94/SC 13. As a result, what was to have been EN 13795-3 is published as EN ISO 22612 Clothing *for protection against infectious agents – Test method for resistance to dry microbial penetration,* what was to have been EN 13795-4 will be published as EN ISO 22610 *Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff, and equipment - Test method to determine the resistance to wet bacterial penetration (ISO/DIS 22610:2004)* and what was to have been EN 13795-5 will be published as EN 13795-3.

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

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Introduction

General requirements for surgical drapes, gowns and clean air suits, used as medical devices, for patients clinical staff and equipment are specified in EN 13795-1. In this respect, EN 13795-1 specifies the relevant characteristics to be evaluated for products covered by this document.

NOTE For more information on products which are either included or not included in this document, refer to EN 13795-1.

The EN 13795 series of European Standards, together with EN ISO 22610 and EN ISO 22612, is intended to assist the communication between users, manufacturers and third party verifiers with regard to material or product characteristics. It focuses on relevant Essential Requirements arising from the Medical Device Directive 93/42/EEC. The general requirements and guidance in EN 13795-1 are expected to be of help to manufacturers, test houses and users when designing, processing, assessing and selecting products. It is the intention of EN 13795 to ensure the same level of safety from single-use and reusable surgical clothing and drapes throughout their useful life.

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