BRITISH STANDARD

BS EN
13795-2:2004
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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

ICS 11.140

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National foreword

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The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to CEN text carry the number of the CEN amendment. For example, text altered by CEN amendment A1 is indicated by [A1] ⟨A1⟩.

The UK participation in its preparation was entrusted by Technical Committee CH/205, Non-active medical devices, to Subcommittee CH/205/1, Medical textiles.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 6 December 2004

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13795-2:2004+A1

July 2009

ICS 11.140

Supersedes EN 13795-2:2004

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 bloc, utilisés en tant que dispositifs médicaux pour les patients, le personnel 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 and includes Amendment 1 approved by CEN on 13 June 2009.

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Foreword

This document (EN 13795-2:2004+A1:2009) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, 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of an identical text or by endorsement, at the latest by January 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.

This document includes Amendment 1, approved by CEN on 2009-06-13.

This document supersedes EN 13795-2:2004.

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.

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, 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.

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