

ILNAS

Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN 13795-3:2006

Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - Part 3: Performance requirements and

Champs chirurgicaux, casaques et tenues de bloc utilisés en tant que dispositifs médicaux pour les patients, le personnel et les équipements - Partie 3 : Exigences

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung zur Verwendung als Medizinprodukte für Patienten, Klinikpersonal und Geräte - Teil 3:

06/2006



National Foreword

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English Version

Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - Part 3: Performance requirements and performance levels

Champs chirurgicaux, casaques et tenues de bloc utilisés en tant que dispositifs médicaux pour les patients, le personnel et les équipements - Partie 3 : Exigences et seuil de performance

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung zur Verwendung als Medizinprodukte für Patienten, Klinikpersonal und Geräte - Teil 3: Gebrauchsanforderungen und Leistungsstufen

This European Standard was approved by CEN on 27 April 2006.

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.

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Foreword

This document (EN 13795-3:2006) 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of an identical text or by endorsement, at the latest by December 2006, and conflicting national standards shall be withdrawn at the latest by December 2006.

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

EN 13795 consists 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 and performance levels*

Attention is also drawn to the following:

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 22610:2006)

EN ISO 22612 Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration (ISO 22612:2005)

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