ILNAS

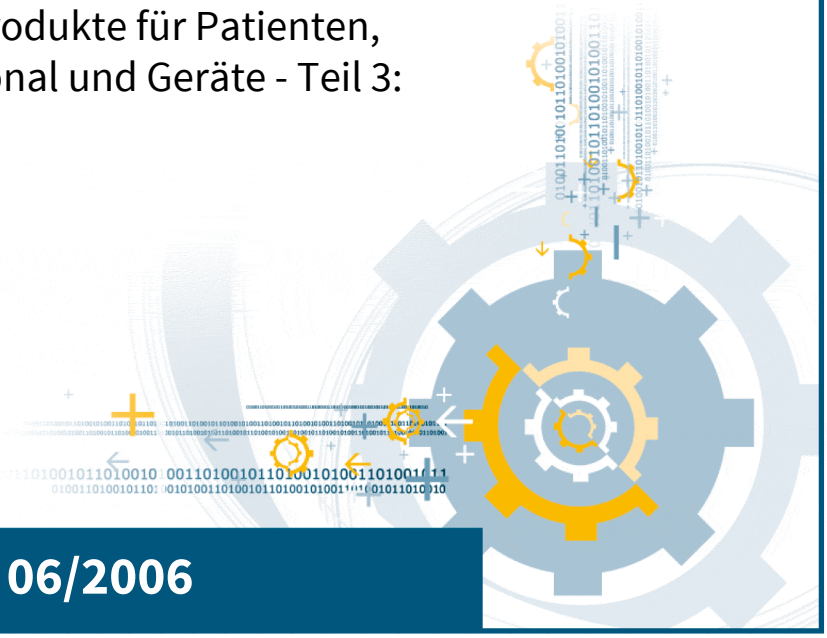
Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

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

This European Standard EN 13795-3:2006 was adopted as Luxembourgish Standard ILNAS-EN 13795-3:2006.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

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EUROPEAN STANDARD EN 13795-3

NORME EUROPÉENNE

EUROPÄISCHE NORM

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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.

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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Contents

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)

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.