



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.

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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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## 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.