National Standards Authority of Ireland

IRISH STANDARD

I.S. EN ISO 22610:2006

ICS 13.340.10

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)

National Standards
Authority of Ireland
Glasnevin, Dublin 9
Ireland

Tel: +353 1 807 3800
Fax: +353 1 807 3838
http://www.nsai.ie

Sales
http://www.standards.ie

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on:

15 September 2006

Price Code H

Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 22610

July 2006

ICS 13.340.10

English Version

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)

Champs chirurgicaux, casaques et tenues de bloc, utilisés en tant que dispositifs médicaux, pour les patients, le personnel et les équipements - Méthode d'essai de résistance à la pénétration de la barrière bactérienne à l'état humide (ISO 22610:2006)

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung, zur Verwendung als Medizinprodukte, für Patienten, Klinikpersonal und Geräte - Prüfverfahren für die Widerstandsfähigkeit gegen Keimdurchtritt im feuchten Zustand (ISO 22610:2006)

This European Standard was approved by CEN on 24 May 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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 22610:2006: E

Foreword

This document (EN ISO 22610:2006) has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 94 "Personal safety - Protective clothing and equipment".

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 2007, and conflicting national standards shall be withdrawn at the latest by January 2007.

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.

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.

ANNEX ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clauses/subclause(s) of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4, 5, 6, 7, 8, 9	3, 4, 7	ISO 22610 is intended to be used in conjunction with EN 13795-1, EN 13795-2 and prEN 13795-3
5, 6, 7, 8	8	
5, 6, 7	9	

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.