SLOVENSKI STANDARD
SIST EN 13795-3:2006

01-julij-2006

Operacijska pokrivala, pregrinjala in plaġļ i ter ļ ista oblaļ ila, ki se uporabljajo kot medicinski pripomoļ ki za paciente, zdravstveno osebje in opremo - 3. del: Zahtevane lastnosti in zahtevane stopnje

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

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

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 niveaux de performance

Ta slovenski standard je istoveten z: EN 13795-3:2006

ICS:

11.140	Oprema bolnišnic	Hospital equipment

SIST EN 13795-3:2006 en,fr,de

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13795-3

June 2006

ICS 11.140

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

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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.

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

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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.

Introduction

The series of EN 13795 specifies requirements for single-use and reusable coverings (i. e. surgical gowns, surgical drapes and clean air suits) used as medical devices for patients, clinical staff and equipment and intended to prevent the transmission of infective agents between patients and clinical staff during invasive surgical procedures.

General requirements for surgical drapes, gowns and clean air suits, used as medical devices, for patients clinical staff and equipment are specified in EN 13795-1. In this respect EN 13795-1 specifies the relevant characteristics to be evaluated for products covered by this European Standard. EN 13795-2 specifies test methods for evaluating these characteristics.

NOTE For more information on products contained within the scope of this European Standard it is recommended to refer to EN 13795-1.

1 Scope

This part of the series of EN 13795 specifies performance requirements for surgical drapes, gowns and clean air suits.

NOTE General performance requirements are specified for various characteristics as per EN 13795-1:2002 Tables 1, 2 and 3 and should be evaluated according to EN 13795-2, EN ISO 22610 and EN ISO 22612.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 13795-1, *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*

EN 13795-2, *Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Part 2: Test methods*

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)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
less critical product area
product area less likely to be involved in the transfer of infective agents to or from the wound

NOTE 1 For the definition of critical product area please see EN 13795-1.

NOTE 2 If the manufacturer differentiates between critical and less critical areas of the product, EN 13795-1 requires the manufacturer to identify these areas, and, if requested, to supply information on the rationale for this distinction. For more information see EN 13795-1.

3.2
performance level
refers to products designated as “standard” or “high performance” according to Clause 4 of this standard

NOTE With the introduction of two performance levels the EN 13795 series of standards acknowledges the fact that products are challenged to differing extents during surgical procedures, dependent upon the duration, mechanical stress and liquid challenge throughout the surgical procedure.

3.2.1
standard performance
classification addressing minimum performance requirements for various characteristics of products (see Clause 4) used as medical devices in invasive surgical procedures

3.2.2
high performance
classification addressing elevated performance requirements for various characteristics of products used as medical devices in invasive surgical procedures

NOTE Examples of surgical procedures where elevated performance level should be considered are those where extensive exposure to liquid, mechanical stresses or longer surgical procedures can be expected

3.3
product
surgical gown, surgical drape including equipment coverings and clean air suit

4 Performance requirements

To comply with the EN 13795 series of standards, products shall meet all the requirements specified in either Tables 1, 2 or 3 (as appropriate to the product),when tested according to EN 13795-2 throughout their useful life.

NOTE 1 General requirements and guidance for manufactures, processors and products, on the information to be supplied, for manufacturing, processing and testing are given in EN 13795-1.

NOTE 2 Test methods for evaluation of all characteristics are specified in EN 13795-2, EN ISO 22610 and EN ISO 22612.

NOTE 3 Performance requirements are specified depending on product area and performance level. However for some characteristics the performance requirement will apply for all performance levels and product areas of the medical device.

Table 1 — Performance requirements for surgical gowns

Characteristic	Unit	Requirement			
		Standard performance		High performance	
		Critical product area	Less critical product area	Critical product area	Less critical product area
Resistance to microbial penetration – Dry	Log_{10} (CFU)	Not required	≤ 2 [a, c]	Not required	≤ 2 [a, c]
Resistance to microbial penetration – Wet	I_B	≥ 2,8 [b]	Not required	6,0 [b, d]	Not required
Cleanliness – Microbial	Log_{10} (CFU/dm^2)	≤ 2 [c]	≤ 2 [c]	≤ 2 [c]	≤ 2 [c]
Cleanliness – Particulate matter	IPM	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5
Linting	Log_{10} (lint count)	≤4,0	≤4,0	≤4,0	≤4,0
Resistance to liquid penetration	cm H_2O	≥ 20	≥ 10	≥ 100	≥ 10
Bursting strength – Dry	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength – Wet	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength – Dry	N	≥ 20	≥ 20	≥ 20	≥ 20
Tensile strength – Wet	N	≥ 20	Not required	≥ 20	Not required

[a] Test conditions: challenge concentration 10^8 CFU/g talc. and 30 min vibration time.

[b] The Least Significant Difference (LSD) for I_B when estimated using EN ISO 22610, was found to be 0,98 at the 95% confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. Thus materials varying by up to 0,98 I_B are probably not different; materials varying by more than 0,98 I_B probably are different. (The 95% confidence levels means that an observer would be correct 19 times out of 20 to accept these alternatives).

[c] For the purpose of this standard, log_{10} CFU ≤ 2 means maximum 300 CFU.

[d] I_B = 6,0 for the purpose of this standard means: no penetration. I_B = 6,0 is the maximum achievable value.