SLOVENSKI STANDARD
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Nadomešča:
SIST EN 13795-1:2003+A1:2009
SIST EN 13795-2:2005+A1:2009
SIST EN 13795-3:2006+A1:2009

Operacijska pokrivala, pregrinjala in plašči ter čista oblačila, ki se uporabljajo kot medicinski pripomočki za paciente, zdravstveno osebje in opremo - Splošne zahteve za proizvajalce, predelovalce in izdelke, preskusne metode, zahtevane lastnosti in zahtevane stopnje

Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung zur Verwendung als Medizinprodukte für Patienten, Klinikpersonal und Geräte - Allgemeine Anforderungen für Hersteller, Wiederaufbereiter und Produkte, Prüfverfahren und Gebrauchsanforderungen

Champs chirurgicaux, casaques et tenues de bloc, utilisés en tant que dispositifs médicaux pour les patients, le personnel et les equipments - Exigences générales pour les fabricants, les prestataires et les produits, methods de test, prescriptions

Ta slovenski standard je istoveten z: **EN 13795:2011**

ICS:

11.140	Oprema bolnišnic	Hospital equipment

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EUROPEAN STANDARD
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English Version

Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - General requirements for manufacturers, processors and products, test methods, 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 - Exigences générales pour les fabricants, les prestataires et les produits, méthodes d'essai, exigences et niveaux de performance

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung zur Verwendung als Medizinprodukte für Patienten, Klinikpersonal und Geräte - Allgemeine Anforderungen für Hersteller, Wiederaufbereiter und Produkte, Prüfverfahren und Gebrauchsanforderungen

This European Standard was approved by CEN on 5 February 2011.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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Foreword

This document (EN 13795:2011) 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 September 2011, and conflicting national standards shall be withdrawn at the latest by September 2011.

This document will supersede EN 13795-1:2002+A1:2009, EN 13795-2:2004+A1:2009 and EN 13795-3:2006+A1:2009.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

Annex A provides details of significant changes between this European Standard and the previous edition represented by the three parts mentioned above.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, 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 the United Kingdom.

Introduction

The transmission of infective agents during invasive surgical procedures can occur in several ways (see informative Annex C).

Surgical drapes, including the intended use as a sterile field, surgical gowns and clean air suits are used to minimize the spread of infective agents to and from patients' operating wounds, thereby helping to prevent post-operative wound infections (see Annex C).

The performance required of coverings for patients, clinical staff and equipment varies with, for example, the type and duration of the procedure, the degree of wetness of the operation field, the degree of mechanical stress on the materials and the susceptibility of the patient to infection.

The use of surgical gowns with resistance to the penetration of liquids can also diminish the risk to the operating staff from infective agents carried in blood or body fluids.

EN 13795 is intended to assist the communication between users, manufacturers and third parties with regard to material or product characteristics and performance requirements. It focuses on Essential Requirements arising from the Medical Device Directive 93/42/EEC which are applicable to surgical drapes, gowns and clean air suits. The requirements and guidance in EN 13795 are expected to be of help to manufacturers and users when designing, processing, assessing and selecting products. It is the intention of EN 13795 to ensure the same level of safety from single-use and reusable surgical clothing and drapes throughout their useful life.

1 Scope

This European Standard specifies information to be supplied to users and third party verifiers in addition to the usual labelling of medical devices (see EN 980 and EN 1041), concerning manufacturing and processing requirements. This European Standard gives information on the characteristics of single-use and reusable surgical gowns, surgical drapes and clean air suits used as medical devices for patients, clinical staff and equipment, intended to prevent the transmission of infective agents between patients and clinical staff during surgical and other invasive procedures. This European Standard specifies test methods for evaluating the identified characteristics of surgical drapes, gowns and clean air suits and sets performance requirements for these products.

EN 13795 does not cover requirements for flammability of products. Suitable test methods for flammability and resistance to penetration by laser radiation, together with an appropriate classification system, are given in EN ISO 11810-1 and EN ISO 11810-2. Additional essential requirements that apply to surgical clothing and drapes are covered by other European Standards.

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 20811, *Textiles — Determination of resistance to water penetration — Hydrostatic pressure test*

EN 29073-3, *Textiles — Test methods for nonwovens — Part 3: Determination of tensile strength and elongation*

EN ISO 139, *Textiles — Standard atmospheres for conditioning and testing (ISO 139:2005)*

EN ISO 9073-10, *Textiles — Test methods for nonwovens — Part 10: Lint and other particles generation in the dry state (ISO 9073-10:2003)*

EN ISO 11737-1:2006, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)*

EN ISO 13938-1, *Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension (ISO 13938-1:1999)*

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)*

3 Terms and definitions

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

3.1
cfu (colony forming unit)
unit by which the culturable number of microorganisms is expressed

NOTE The culturable number is the number of microorganisms, single cells or aggregates, able to form colonies on a solid nutrient medium.

3.2
clean air suit
suit intended and shown to minimize contamination of the operating wound by the wearer's skin scales carrying infective agents via the operating room air thereby reducing the risk of wound infection

NOTE Unlike the suit usually worn in the operating room, the clean air suit is designed to reduce the operating room air contamination by personnel.

3.3
cleanliness
freedom from unwanted foreign matter

NOTE Such matter can be micro-organisms, organic residues or particulate matter.

3.3.1
cleanliness — microbial
freedom from population of viable micro-organisms on a product and/or a package

NOTE In practical use, microbial cleanliness is often referred to as 'bioburden'.

3.3.2
cleanliness — particulate matter
freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact

3.4
critical product area
product area with a greater probability to be involved in the transfer of infective agents to or from the wound, e.g. front and sleeves of surgical gowns

3.5
fabric
cloth made from yarn or fibres by weaving, knitting and/or other types of binding or manufacture

3.6
infective agent
micro-organism that has been shown to cause wound infections or that might cause infection in a member of the surgical team or the patient

3.7
less critical product area
product area less likely to be involved in the transfer of infective agents to or from the wound

3.8
linting
release of fibre fragments and other particles during handling and use

NOTE These fragments and particles are originally from the fabric itself.

3.9
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

NOTE For more details refer to the Medical Device Directive 93/42/EEC.

3.10
performance level
discrete standard defined to classify products according to the performance requirements of this standard

NOTE With the introduction of two performance levels EN 13795 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.

3.10.1
standard performance
classification addressing minimum performance requirements for various characteristics of products used as medical devices in invasive surgical procedures

3.10.2
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.

3.11
processor
natural or legal person who processes products so that their performance complies with the requirements of this European Standard

NOTE 1 A processor who places a product on the market is a manufacturer in the sense of this European Standard.

NOTE 2 A processor of reusable products is often referred to as a 'reprocessor' and processing reusable products is often referred to as 'reprocessing' (as e.g. in Medical Device Directive 93/42/EEC). References in EN 13795 to 'processors' include 'reprocessors' and to 'processing' include 'reprocessing'.

3.12
product
surgical gown, surgical drape including equipment covering and clean air suit

NOTE In cases of surgical packs, each gown or drape is regarded as a product.

3.13
resistance to liquid penetration
ability of material to withstand the penetration of liquid(s) from one side of the material through to the other

3.14
resistance to microbial penetration
ability of material(s) to withstand penetration of micro-organisms from one side of the material through to the other

3.14.1
dry penetration
effect of a combination of air movement and mechanical action by vibration on microbial penetration in dry condition

3.14.2
wet penetration
effect of combination of wetness, pressure and rubbing on microbial penetration

3.15
reusable product
product intended by the manufacturer to be reprocessed and reused

3.16
single-use product
product intended to be used once only for a single patient

NOTE According to Medical Device Directive 93/42/EEC.

3.17
sterile field
area created by sterile surgical drape material where aseptic technique is practised

NOTE A sterile field can be practised e.g. on a back table.

3.18
surgical drape
drape covering the patient or equipment to prevent transfer of infective agents

3.19
surgical gown
gown worn by a member of a surgical team to prevent transfer of infective agents

3.20
surgical procedure
surgical intervention performed by a surgical team

3.20.1
invasive surgical procedure
surgical procedure penetrating skin or mucosa

4 Performance requirements

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

If the intended purpose of a medical device specifies the use as a sterile field the requirements for surgical drapes and equipment covers apply as per Table 2.

NOTE 1 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.

NOTE 2 General information on testing is given in Clause 5. For details on the test methods given in Tables 1, 2 and 3 and their application for the purpose of this European Standard, see Annex B.

NOTE 3 Information on characteristics, which cannot be properly evaluated (as ‘adhesion for fixation for the purpose of wound isolation’ or ‘liquid control’) or which are not regarded normative (as ‘comfort’) is given in Annex D.

Table 1 — Characteristics to be evaluated and performance requirements for surgical gowns

Characteristic	Test method (for references, see Clause 2)	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	EN ISO 22612	CFU	Not required	≤ 300 [a]	Not required	≤ 300 [a]
Resistance to microbial penetration — Wet	EN ISO 22610	I_B	≥ 2,8 [b]	Not required	6,0 [b c]	Not required
Cleanliness — Microbial	EN ISO 11737-1	CFU/ 100 cm^2	≤ 300	≤ 300	≤ 300	≤ 300
Cleanliness — Particulate matter	EN ISO 9073-10	IPM	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5
Linting	EN ISO 9073-10	$\log_{10}$ (lint count)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0
Resistance to liquid penetration	EN 20811	cm H_2O	≥ 20	≥ 10	≥ 100	≥ 10
Bursting strength — Dry	EN ISO 13938-1	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength — Wet	EN ISO 13938-1	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength — Dry	EN 29073-3	N	≥ 20	≥ 20	≥ 20	≥ 20
Tensile strength — Wet	EN 29073-3	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] I_B = 6,0 for the purpose of this European Standard means: no penetration. I_B = 6,0 is the maximum achievable value.