SLOVENSKI STANDARD
oSIST prEN 13795-1:2017

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Operacijska oblačila in pokrivala - Zahteve in preskusne metode - 1. del: Operacijska pokrivala in plašči

Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns

Operationskleidung und -abdecktücher - Anforderungen und Prüfverfahren - Teil 1: Operationsabdecktücher und -mäntel

Vêtements et champs chirurgicaux - Exigences et méthodes d'essai - Partie 1 : Champs et casaques chirurgicaux

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Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns

Vêtements et champs chirurgicaux - Exigences et méthodes d'essai - Partie 1 : Champs et casaques chirurgicaux

Operationskleidung und -abdecktücher - Anforderungen und Prüfverfahren - Teil 1: Operationsabdecktücher und -mäntel

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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European foreword

This document (prEN 13795-1:2017) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

Together with prEN 13795-2:2017 this document will supersede EN 13795:2011+A1:2013.

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.

prEN 13795 consists of the following parts, under the general title *Surgical clothing and drapes — Requirements and test methods*:

— *Part 1: Surgical drapes and gowns*

— *Part 2: Clean air suits*

Introduction

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

Surgical drapes, including the intended use as a sterile field, and surgical gowns 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 B).

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.

prEN 13795-1 is intended to assist the communication between 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 and gowns. The requirements and guidance in prEN 13795-1 are expected to be of help to manufacturers and users when designing, processing, assessing and selecting products. It is the intention of prEN 13795-1 to ensure the same level of safety from single-use and reusable surgical clothing and drapes throughout their useful life.

Surgical gowns are used to minimize the transmission of infective agents between patients and clinical staff during surgical and other invasive procedures. Hereby, surgical gowns contribute to the clinical condition and the safety of patients as well as to the safety and health of users following up essential requirement 1 of Directive 93/42/EEC on Medical Devices. prEN 13795-1 addresses the same level of protection for patients and users (i.e. the surgical team) by not differentiating the performance requirements for surgical gowns respectively. However, prEN 13795-1 does not formally address any basic health and safety requirements of the Directive 89/686/EEC or Regulation (EU) 2016/425 on Personal Protective Equipment and does not provide specific guidance for surgical gowns intended by the manufacturer for dual use as medical device and personal protective equipment.

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 1041 and EN ISO 15223-1), concerning manufacturing and processing requirements. This European Standard gives information on the characteristics of single-use and reusable surgical gowns and surgical drapes used as medical devices for patients, clinical staff and equipment, intended to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures. This European Standard specifies test methods for evaluating the identified characteristics of surgical drapes and gowns and sets performance requirements for these products.

prEN 13795-1 does not cover requirements for resistance to penetration by laser radiation of products. Suitable test methods for resistance to penetration by laser radiation, together with an appropriate classification system, are given in EN ISO 11810.

prEN 13795-1 does not cover requirements for incise drapes or films.

prEN 13795-1 does not cover requirements for antimicrobial treatments for surgical gowns and drapes. Antimicrobial treatment may cause environmental risks such as resistance and pollution. However, antimicrobial treated surgical gowns and drapes fall under the scope of this standard with respect to their use as surgical gowns and drapes.

2 Normative references

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

EN 20811:1992, *Textiles - Determination of resistance to water penetration - Hydrostatic pressure test*

EN 29073-3:1992, *Textiles - Test methods for nonwovens - Part 3: Determination of tensile strength and elongation*

EN ISO 139:2005+A1:2011, *Textiles - Standard atmospheres for conditioning and testing (ISO 139:2005 + Amd. 1:2011)*

EN ISO 9073-10:2004, *Textiles - Test methods for nonwovens - Part 10: Lint and other particles generation in the dry state (ISO 9073-10:2003)*

EN ISO 10993-1:2009, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)*

EN ISO 11737-1:2006+AC:2009, *Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006/Cor. 1:2007)*

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

prEN ISO 22610:2015, *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/DIS 22610.2:2015)*

EN ISO 22612:2005, *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 1 to entry: The culturable number is the number of microorganisms, single cells or aggregates, able to form colonies on a solid nutrient medium.

3.2
cleanliness
freedom from unwanted foreign matter

Note 1 to entry: Such matter can be micro-organisms, organic residues or particulate matter.

3.2.1
cleanliness — microbial
freedom from population of viable micro-organisms on a product and/or a package

Note 1 to entry: In practical use, microbial cleanliness is often referred to as 'bioburden'.

3.3
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

3.4
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

3.5
less critical product area
product area less likely to be involved in the transfer of infective agents to or from the wound

3.6
particle release
release of fibre fragments and other particles during mechanical stress simulating handling and use

3.7
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 1 to entry: For more details refer to the Medical Device Directive 93/42/EEC.

3.8
performance level
discrete standard defined to classify products according to the performance requirements of this standard

Note 1 to entry: 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.

3.8.1
standard performance
classification addressing minimum performance requirements for various characteristics of products used as medical devices in invasive surgical procedures

3.8.2
high performance
classification addressing elevated performance requirements for various characteristics of products used as medical devices in invasive surgical procedures

Note 1 to entry: 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.

3.9
processor
natural or legal person who processes products so that their performance complies with the requirements of this European Standard

Note 1 to entry: A processor who places a product on the market is a manufacturer in the sense of this European Standard.

Note 2 to entry: 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 prEN 13795-1 and prEN 13795-2 to 'processors' include 'reprocessors' and to 'processing' include 'reprocessing'.

3.10
product
surgical gown, surgical drape including equipment covering

Note 1 to entry: In cases of surgical packs, each gown or drape is regarded as a product.

3.11
resistance to liquid penetration
ability of material to withstand the penetration of liquid(s) from one side of the material through to the other

3.12
resistance to microbial penetration
ability of material(s) to withstand penetration of micro-organisms from one side of the material through to the other

3.12.1
dry penetration
effect of a combination of air movement and mechanical action by vibration on microbial penetration in dry condition

3.12.2
wet penetration
effect of combination of wetness, pressure and rubbing on microbial penetration

3.13
reusable product
product intended by the manufacturer to be reprocessed and reused

3.14
single-use product
product intended to be used once only for a single patient

3.15
sterile field
area created by sterile surgical drape material where aseptic technique is practised

Note 1 to entry: A sterile field can be practised e.g. on a back table.

3.16
surgical drape
drape covering the patient or equipment to prevent transfer of infective agents

3.17
surgical gown
gown worn by a member of a surgical team to prevent transfer of infective agents

3.18
surgical procedure
surgical intervention performed by a surgical team

3.18.1
invasive surgical procedure
surgical procedure penetrating skin or mucosa

4 Performance requirements

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

The biocompatibility of the product has to be evaluated and approved for acceptable risk.

If the manufacturer does not differentiate product areas, all areas shall meet the requirements for critical product areas.

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.

For general information on testing and details on the test methods given in this clause including Tables 1 and 2 and their application for the purpose of this European Standard, see Annex A.

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 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 C.

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
Microbial penetration — Dry	EN ISO 22612	CFU	Not required	≤ 300 [a]	Not required	≤ 300 [a]
Microbial penetration — Wet	prEN ISO 22610	P(%)	Not required	Not required	0	Not required
Cleanliness microbial / Bioburden	EN ISO 11737-1	CFU/ 100 cm^2	≤ 300	≤ 300	≤ 300	≤ 300
Particle release	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.