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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.

This draft European Standard was established by CEN 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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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 13795-1:2023) 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.

This document will supersede EN 13795-1:2019.

prEN 13795-1:2023 includes the following significant technical changes with respect to EN 13795-1:2019:

a) Clarification of testing specifications and reporting of results;

b) Preparation of samples for testing of bursting strength in the wet state according to the test method standard EN ISO 13938-1:2019 (i.e. not any longer according to EN 29073-3:1992 as in the previous version);

c) Expansion of former Annex D “Environmental aspects” to include considerations regarding environmental impact and circular economy (now Annex D “Environmental impact”);

d) Alignment to Regulation (EU) 2017/745 (including updated Annex ZA);

e) Update of normative references and bibliography.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

EN 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.

This document is intended to assist the communication between manufacturers and third parties with regard to material or product characteristics and performance requirements.

Therefore, Annex B provides comprehensive information on characteristics, measurement of performance and performance requirements. Annex C clarifies that this document does not include environmental provisions. Annex D provides information on characteristics regarded relevant in context with surgical gowns and drapes, however but not covered normatively (i.e. without applicable performance requirements). Annex E explains the concept of performance levels and provides guidance to users for selecting products.

This document focuses on General Safety and Performance Requirements (GSPR) arising from the Medical Device Regulation (EU) 2017/745, which are applicable to surgical drapes and gowns. The requirements and guidance in this document are expected to be of help to manufacturers and users when designing, processing, assessing and selecting products. It is the intention of this document 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 General Safety and Performance Requirements (GSPR) of Regulation (EU) 2017/745 on Medical Devices. This document 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, this document does not formally address any Essential Health and Safety Requirements of 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 document specifies information to be supplied to users and third-party verifiers in addition to the usual labelling of medical devices (see EN ISO 20417 and EN ISO 15223-1) concerning manufacturing and processing requirements.

This document 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 document specifies test methods for evaluating the identified characteristics of surgical drapes and gowns and sets performance requirements for these products.

This document does not include information on resistance to penetration by laser radiation of products.

NOTE If resistance to penetration by laser radiation is claimed for surgical drapes, suitable test methods together with an appropriate classification system are given in EN ISO 11810.

This document does not cover requirements for incision drapes or films.

This document does not cover requirements for antimicrobial treatments for surgical gowns and drapes. Antimicrobial treatment can cause environmental risks such as resistance and pollution. However, antimicrobial treated surgical gowns and drapes fall under the scope of this document with respect to their use as surgical gowns and drapes.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 ISO 139:2005,[1] *Textiles — Standard atmospheres for conditioning and testing (ISO 139:2005 + Amd. 1:2011)*

EN ISO 811:2018, *Textiles - Determination of resistance to water penetration - Hydrostatic pressure test (ISO 811:2018)*

EN ISO 9073-3:2023, *Nonwovens - Test methods - Part 3: Determination of tensile strength and elongation at break using the strip method (ISO 9073-3:2023)*

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 10993-1:2020, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)*

EN ISO 11737-1:2018,[2] *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)*

[1] Impacted by EN ISO 139:2005/A1:2011

[2] Impacted by EN ISO 11737-1:2018/A1:2021

EN ISO 13938-1:2019, *Textiles - Bursting properties of fabrics - Part 1: Hydraulic method for determination of bursting strength and bursting distension (ISO 13938-1:2019)*

EN ISO 22610:2006, *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 22612:2005, *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.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp/

— IEC Electropedia: available at https://www.electropedia.org/

3.1
colony forming unit
CFU
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 microorganisms, 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
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 their own name, regardless of whether these operations are carried out by that person themselves or on their behalf by a third party

Note 1 to entry: For more details, refer to the Medical Device Regulation (EU) 2017/745.

3.7
particle release
release of fibre fragments and other particles during mechanical stress simulating handling and use

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

Note 1 to entry: With the introduction of two performance levels, this document 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 document

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

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 Regulation (EU) 2017/745). References in EN 13795-2 and this document 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 this document, products shall meet all the requirements specified in this document including Tables 1 or 2 (as appropriate to the product), when tested according to Annex A throughout their useful life.

The biocompatibility of the product shall 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 document, see Annex A.

NOTE 1 In order to reflect the broad variety of technologies currently used to manufacture and (if applicable) process surgical textiles and not to hinder technical development and innovation, the requirements set by this document are expressed in terms of quantifiable performance rather than specific technical design or descriptive characteristics.

NOTE 2 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 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 C.