KIRURGILISED RÕIVAD JA DRAPEERINGUD. NÕUDED JA KATSEMEETODID. OSA 1: KIRURGILISED DRAPEERINGUD JA KITLID

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 13795-1:2019 sisaldab Euroopa standardi EN 13795-1:2019 ingliskeelset teksti.	This Estonian standard EVS-EN 13795-1:2019 consists of the English text of the European standard EN 13795-1:2019.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 03.04.2019.	Date of Availability of the European standard is 03.04.2019.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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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 European Standard was approved by CEN on 24 October 2018.

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European foreword

This document (EN 13795-1:2019) 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of an identical text or by endorsement, at the latest by October 2019, and conflicting national standards shall be withdrawn at the latest by October 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Together with EN 13795-2:2019, this document supersedes 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.

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*

The following changes have been introduced:

a) The product 'clean-air suit' has been moved to Part 2 of the EN 13795 standard series because of distinctive requirements and test methods;

b) Alignment of the document title and the Scope;

c) Revision of the Normative references and the Bibliography;

d) Alignment of the Clause 'Terms and definitions';

e) Review of the performance requirements in Table 1 and Table 2 especially with regard to 'Cleanliness - Particulate matter' and 'Linting', which have been combined as 'Particle release;

f) Movement of former Clause 5 'Testing' to A.1 and editorial alignment;

g) Revision of Clause 'Manufacturing and processing requirements' by adding of documentary requirements and a section for the introduction of a QM system;

h) Enhancement and improved structuring of Clause 'Information to be supplied by the manufacturer or processor';

i) Deletion of the former Annex A 'Details of significant changes between this document and the previous edition' which consisted of 3 parts;

j) Complete revision and extension of Annex A 'Testing' (formerly Annex B 'Test methods');

k) Inclusion of a new Annex B ‚Rationales' which provides precise reasons for the essential requirements of this document and which is intended for users aware of the subject of this document, but who have not participated in its development;

l) Deletion of the former Annex C 'Prevention of infection in the operating room';

m) Revision and extension of Annex C (formerly Annex D) 'Information on further characteristics'; e.g. inclusion of a Clause on , Flammability' and 'Electrostatic discharge';

n) Inclusion of a new Annex D 'Environmental aspects';

o) Inclusion of a new Annex E 'Guidance to users for selecting products';

p) Revision of Annex ZA on the relationship to the Medical Device Directive (93/42/EEC);

q) Complete editorial revision.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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 Essential Requirements arising from the Medical Device Directive 93/42/EEC, 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 essential requirement 1 of Directive 93/42/EEC 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 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 document 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 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 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.

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

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

EN ISO 139:2005,[1] *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 11737-1:2018, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)*

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)*

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

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 terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

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