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Operationskläder och draperingsmaterial – Krav och testmetoder –

Del 1: Draperingsmaterial och operationsrockar

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

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Denna standard ersätter SS-EN 13795:2011+A1:2013, utgåva 1.

The European Standard EN 13795-1:2019 has the status of a Swedish Standard. This document contains the official version of EN 13795-1:2019.

This standard supersedes the SS-EN 13795:2011+A1:2013, edition 1.

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EUROPEAN STANDARD

EN 13795-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 2019

ICS 11.140

Supersedes EN 13795:2011+A1:2013

English Version

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.

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

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SS-EN 13795-1:2019 (E)

Contents		Page
European foreword		4
Introduction		6
1	Scope	7
2	Normative references	7
3	Terms and definitions	8
4	Performance requirements	11
5	Manufacturing and processing requirements and documentation	13
6	Information to be supplied with the product	13
6.1	Information to be supplied to the user	13
6.2	Information to be supplied to the processor	14
Annex A (normative) Testing		15
A.1	General	15
A.2	Test methods and conformance	15
A.2.1	Test method for evaluation of cleanliness microbial/bioburden	15
A.2.2	Test method for evaluation of particle release	16
A.2.3	Test method for evaluation of liquid penetration	16
A.2.4	Test method for evaluation of bursting strength in dry and wet state	16
A.2.5	Test method for evaluation of tensile strength in dry and wet state	17
A.2.6	Test method for evaluation of dry microbial penetration	17
A.2.7	Test method for evaluation of wet microbial penetration	17
A.2.8	Test method for evaluation of biocompatibility	17
A.3	Treatment of results	18
Annex B (informative) Rationales		19
B.1	General	19
B.2	Cleanliness - microbial	19
B.3	Particle release	19
B.4	Resistance to liquid penetration	20
B.5	Bursting strength - dry and wet	21
B.6	Tensile strength - dry and wet	21
B.7	Resistance to microbial penetration - dry	21
B.8	Resistance to microbial penetration - wet	23
B.9	Labelling	23
B.10	Treatment of results	24

Annex C (informative) Information on further characteristics	25
C.1 Comfort.....	25
C.2 Adhesion for fixation for the purpose of wound isolation.....	25
C.3 Liquid control.....	25
C.4 Flammability	26
C.5 Electrostatic discharge	26
Annex D (informative) Environmental aspects.....	27
Annex E (informative) Guidance to users for selecting products.....	28
E.1 Performance levels	28
E.2 Functional design.....	28
E.2.1 General	28
E.2.2 Critical and less critical areas	28
E.2.3 Size	29
E.2.4 Accessories.....	29
E.2.5 Comfort.....	29
E.2.5.1 General	29
E.2.5.2 Surgical gowns	29
E.2.5.3 Surgical drapes	30
E.3 Practical trials.....	30
Annex ZA (informative) Relationship between this European standard and the essential requirements of Directive 93/42/EEC [1993 OJ L 169] aimed to be covered	31
Bibliography	32

SS-EN 13795-1:2019 (E)

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.

SS-EN 13795-1:2019 (E)

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