Kirurgilised linad, kitlid ja kaitseülikonnad, mida kasutatakse meditsiiniliste seadmetena patsientide ja seadmete puhul ning kliinilise personali poolt. Üldnõuded tootjatele, töötlejatele ja toodetele, katsemeetodid, toimimisnõuded ja -tasemed

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 13795:2011+A1:2013 sisaldab Euroopa standardi EN 13795:2011+A1:2013 ingliskeelset teksti.	This Estonian standard EVS-EN 13795:2011+A1:2013 consists of the English text of the European standard EN 13795:2011+A1:2013.
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 06.02.2013.	Date of Availability of the European standard is 06.02.2013.
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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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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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 and includes Amendment 1 approved by CEN on 8 January 2013.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 13795:2011+A1:2013: E

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Foreword

This document (EN 13795:2011+A1:2013) 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 August 2013, and conflicting national standards shall be withdrawn at the latest by August 2013.

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

This document ▌A1⟩ supersedes EN 13795:2011 ⟨A1▌.

This document includes Amendment 1 approved by CEN on 2013-01-08.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ▌A1⟩ ⟨A1▌.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, 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 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.