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Sjukvårdstextil – Uppdukningsmaterial, operationsrockar och specialarbetsdräkter, avsedda som medicintekniska produkter för patienter, personal och utrustning – Allmänna krav för tillverkare, rekonditionerare och produkter, provningsmetoder, funktionskrav och funktionsnivåer

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

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Denna standard ersätter SS-EN 13795-1+A1:2009, utgåva 1; SS-EN 13795-2:2004+A1:2009, utgåva 1 och SS-EN 13795-3:2006+A1:2009, utgåva 1.

The European Standard EN 13795:2011 has the status of a Swedish Standard. This document contains the official version of EN 13795:2011.

This standard supersedes the Swedish Standard SS-EN 13795-1+A1:2009, edition 1; SS-EN 13795-2:2004+A1:2009, edition 1 and SS-EN 13795-3:2006+A1:2009, edition 1.

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EUROPEAN STANDARD

EN 13795

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2011

ICS 11.140

Supersedes EN 13795-1:2002+A1:2009,
EN 13795-2:2004+A1:2009, EN 13795-3:2006+A1:2009

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.

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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Foreword

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 September 2011, and conflicting national standards shall be withdrawn at the latest by September 2011.

This document will supersede EN 13795-1:2002+A1:2009, EN 13795-2:2004+A1:2009 and EN 13795-3:2006+A1:2009.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland 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.

3.2
clean air suit
suit intended and shown to minimize contamination of the operating wound by the wearer's skin scales carrying infective agents via the operating room air thereby reducing the risk of wound infection

NOTE Unlike the suit usually worn in the operating room, the clean air suit is designed to reduce the operating room air contamination by personnel.

3.3
cleanliness
freedom from unwanted foreign matter

NOTE Such matter can be micro-organisms, organic residues or particulate matter.

3.3.1
cleanliness — microbial
freedom from population of viable micro-organisms on a product and/or a package

NOTE In practical use, microbial cleanliness is often referred to as 'bioburden'.

3.3.2
cleanliness — particulate matter
freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact

3.4
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

3.5
fabric
cloth made from yarn or fibres by weaving, knitting and/or other types of binding or manufacture

3.6
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

3.7
less critical product area
product area less likely to be involved in the transfer of infective agents to or from the wound

3.8
linting
release of fibre fragments and other particles during handling and use

NOTE These fragments and particles are originally from the fabric itself.

3.9
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 For more details refer to the Medical Device Directive 93/42/EEC.

3.10

performance level

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

NOTE 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.

3.10.1

standard performance

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

3.10.2

high performance

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

NOTE 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.

3.11

processor

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

NOTE 1 A processor who places a product on the market is a manufacturer in the sense of this European Standard.

NOTE 2 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 EN 13795 to 'processors' include 'reprocessors' and to 'processing' include 'reprocessing'.

3.12

product

surgical gown, surgical drape including equipment covering and clean air suit

NOTE In cases of surgical packs, each gown or drape is regarded as a product.

3.13

resistance to liquid penetration

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

3.14

resistance to microbial penetration

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

3.14.1

dry penetration

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

3.14.2

wet penetration

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

3.15

reusable product

product intended by the manufacturer to be reprocessed and reused