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norm

NEN-EN 13795

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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Normcommissie 301087 "OK-jassen en afdekmateriaal"

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 13795

October 2009

ICS 11.140

Will supersede EN 13795-1:2002, EN 13795-2:2004, EN 13795-3:2006

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 equipments - Exigences générales pour les fabricants, les prestataires et les produits, methods de test, prescriptions

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 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.

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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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Contents

Foreword

This document (prEN 13795:2009) 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 13795-1:2002, EN 13795-2:2004, EN 13795-3:2006.

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.

Annex A provides details of significant changes between this European Standard and the previous edition represented by above mentioned three parts.

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 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 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 used in laser surgery. 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 20811:1992, *Textiles — Determination of resistance to water penetration — Hydrostatic pressure test (ISO 811:1981)*

EN 29073-3:1992, *Textiles — Test methods for nonwovens — Part 3: Determination of tensile strength and elongation (ISO 9073-1:1989)*

EN ISO 139:2005, *Textiles — Standard atmospheres for conditioning and testing (ISO 139:2005)*

EN ISO 9073-10:2004, *Textiles — Test methods for nonwovens — Part 10: Lint and other particles generation in the dry state (ISO 9073:2003)*

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 13938-1:1999, *Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension (ISO 13938-1:1999)*

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 European Standard, 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
refers to products designated as ‘standard’ or ‘high performance’ according to Clause 4 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 (see Clause 4) 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 reusable product items so that their performance complies with the requirements of this standard

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

NOTE 2 A processor is often referred to as a ‘reprocessor’ and processing is often referred to as ‘reprocessing’ (as e.g. in Medical Device Directive 93/42/EEC with the amendments of Council Directive 2007/47/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

3.13
resistance to liquid penetration
ability of material to resist 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

NEN
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