SLOVENSKI STANDARD
SIST EN 13795-1:2003+A1:2009

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Operacijska pokrivala, pregrinjala in plaģļ i ter ļ ista oblaļ ila, ki se uporabljajo kot medicinski pripomoļ ki za paciente, zdravstveno osebje in opremo - 1. del: Sploģne zahteve za proizvajalce, predelovalce in izdelke

Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Part 1: General requirements for manufacturers, processors and products

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung zur Verwendung als Medizinprodukte für Patienten, Klinikpersonal und Geräte - Teil 1: Allgemeine Anforderungen für Hersteller, Aufbereiter und Produkte

Champs chirurgicaux, casaques et tenues de bloc, utilisés en tant que dispositifs médicaux pour les patients, le personnel et les équipements - Partie 1: Exigences générales pour les fabricants, les prestataires et les produits

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11.140	Oprema bolnišnic	Hospital equipment

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EUROPEAN STANDARD

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This European Standard was approved by CEN on 2 October 2002 and includes Amendment 1 approved by CEN on 13 June 2009.

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 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 Management Centre has the same status as the official versions.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

Foreword

This document (EN 13795-1:2002+A1:2009) 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 January 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.

This document includes Amendment 1, approved by CEN on 2009-06-13.

This document supersedes EN 13795-1:2002.

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, 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.

Annexes A, B and C are informative.

This document includes a Bibliography.

EN 13795 is expected to consist of the following parts under the general title *"Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment"*:

Part 1: *General requirements for manufacturers, processors and products*

Part 2: *Test methods*

Part 3: *Performance requirements and performance levels*

Originally EN 13795 was also to include Part 3: *Test method for resistance to dry microbial penetration* and Part 4: *Test method for resistance to wet microbial penetration.* However, it has been decided that these parts will now be developed by the Vienna Agreement/CEN lead route in conjunction with ISO/TC 94/SC 13. As a result, what was to have been EN 13795-3 will be published as EN ISO 22612 Clothing *for protection against infectious agents – Test method for resistance to penetration by biologically contaminant dust through protective clothing materials*, what was to have been EN 13795-4 will be published as EN ISO 22610 *Clothing for protection against infectious agents – Test method for determination of penetration by bacteria through protective clothing materials* and what was to have been EN 13795-5 will be published as EN 13795-3.

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, 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 United Kingdom.

Introduction

The transmission of infective agents during invasive surgical procedures can occur in several ways (see annex C).

〈A1〉 Surgical drapes, including the intended use as a sterile field, 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). 〈A1〉

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 blood-borne infective agents carried in blood or body fluids.

The EN 13795 series of European Standards, together with EN ISO 22610 and EN ISO 22612, is intended to assist the communication between users, manufacturers and third party verifiers with regard to material or product characteristics. It focuses on relevant Essential Requirements arising from the Medical Device Directive 93/42/EEC. The general requirements and guidance in EN 13795-1 are expected to be of help to manufacturers, test houses 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 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 standard gives general guidance 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. It is intended to prevent the transmission of infective agents between patients and clinical staff during surgical and other invasive procedures.

Surgical masks, surgical gloves, packaging materials, foot and head wear and incision drapes are not covered by EN 13795. Requirements for medical gloves are given in the EN 455 series of European Standards and packaging materials are covered by the EN 868 series. Requirements for surgical masks and head coverings will be specified in future CEN/TC 205 standards.

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. Additional essential requirements that apply to surgical clothing and drapes are covered by other European Standards.

2 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

2.1
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 operation room, the clean air suit is designed to reduce the operating room air contamination by personnel.

2.2
cleanliness
freedom from unwanted foreign matter

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

2.2.1
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“.

2.2.2
cleanliness — particulate matter
freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact

2.3
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

2.4
drapeability
ability of a material to conform to a given shape or object

2.5
fabric
cloth made from yarn or fibres by weaving, knitting and/or other types of binding or manufacture

2.6
fixation
adhesion of a surgical drape to the patient for the purpose of wound isolation

NOTE See annex B.

2.7
infective agent
micro-organism that has been shown to cause a wound infection or that might cause infection in a member of the surgical team or the patient

2.8
linting
release of fibre fragments and other particles during handling and use

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

2.9
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 From the Medical Device Directive 93/42/EEC.

2.10
processor
natural or legal person who processes reusable product items so that their performance complies with the requirements of this standard

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

2.11
resistance to liquid penetration
ability of material to resist the penetration of liquid(s) from one side of the material through to the other

2.12
resistance to microbial penetration
ability of material(s) to withstand penetration of micro-organisms from one side through to the other

2.12.1
dry penetration
effect of a combination of air movement and mechanical action by vibration on microbial penetration in dry condition

2.12.2
wet penetration
effect of combination of wetness, pressure and rubbing on microbial penetration

2.13
reusable product
product intended by the manufacturer to be reprocessed and reused

2.14
single-use product
product intended by the manufacturer to be used for only one surgical procedure before disposal

〈A1〉

2.15
sterile field
area created by sterile surgical drape material where aseptic technique is practised

NOTE A sterile field can be practised e.g. on a back table. 〈A1〉

2.16
surgical drape
drape covering the patient or equipment to prevent transfer of infective agents

2.17
surgical gown
gown worn by a member of a surgical team to prevent transfer of infective agents

2.18
surgical procedure
surgical intervention penetrating skin or mucosa, performed by a surgical team

2.18.1
clean operation
operation performed on uninfected, non-traumatised tissue and in which respiratory, alimentary or genito-urinary tracts are not entered

2.18.2
infection-prone operation
operation where the nature of the operation or the condition of the patient is such that infection can occur with minimal contamination

2.18.3
invasive surgical procedure
procedure that reaches the inside of the body through the body surface

2.19
water-vapour resistance
water-vapour pressure difference between the two faces of a material divided by the resultant evaporative heat flux per unit area in the direction of the gradient. The evaporative heat flux can consist of both diffusive and convective components

3 Information to be supplied by the manufacturer or processor

3.1 The following information shall be supplied:

a) if the device is intended by the manufacturer to be reused, information on the appropriate processes to allow reuse, including cleaning, disinfection, packing and, if appropriate, the methods of sterilization of the device to be resterilized, the number of reuses and any restriction to the reuse;

b) if the device is supplied with the intention that it be sterilized before use, instructions for sterilization methods;

c) if the manufacturer differentiates between critical and less critical areas of the product, the identification of these areas.

3.2 The following information shall be supplied on request:

a) the identity or information on the test methods used;

b) the results of testing for the characteristics given in Tables 1, 2 and 3;

c) if the manufacturer differentiates between critical and less critical areas of the product, the rationale for this distinction.

Table 1 – Characteristics to be evaluated for surgical gowns

Characteristic
Resistance to microbial penetration – Dry
Resistance to microbial penetration – Wet
Cleanliness – Microbial
Cleanliness – Particulate matter
Linting
Resistance to liquid penetration
Bursting strength – Dry
Bursting strength – Wet
Tensile strength – Dry
Tensile strength – Wet