SLOVENSKI STANDARD
oSIST prEN 13795-2:2017

01-september-2017

Operacijska oblačila in pokrivala - Zahteve in preskusne metode - 2. del: Čista oblačila

Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits

Operationsbekleidung und -abdecktücher - Anforderungen und Prüfverfahren - Teil 2: Rein-Luft-Kleidung

Vêtements et champs chirurgicaux - Exigences et méthodes d'essai - Partie 2 : Tenues de bloc

Ta slovenski standard je istoveten z: **prEN 13795-2**

ICS:

11.140	Oprema bolnišnic	Hospital equipment

oSIST prEN 13795-2:2017 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 13795-2

June 2017

ICS 11.140

Will supersede EN 13795:2011+A1:2013

English Version

Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits

Vêtements et champs chirurgicaux - Exigences et méthodes d'essai - Partie 2 : Tenues de bloc

Operationsbekleidung und -abdecktücher - Anforderungen und Prüfverfahren - Teil 2: Rein-Luft-Kleidung

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.

This draft European Standard was established by CEN 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.

CEN members are the national standards bodies of 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 United Kingdom.

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.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

European foreword

This document (prEN 13795-2:2017) 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.

Together with prEN 13795-1:2017 this document will supersede 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.

prEN 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*

Introduction

Clean air suits are used to minimize the spread of infective agents to patients' surgical sites and equipment, through prevention of dispersal of bacteria-carrying skin scales from the operating room staff, thereby helping to prevent post-operative surgical site infections.

The performance required of working clothes for clinical staff varies with, for example, the type and duration of the procedure, and the susceptibility of the patient to infection. In infection-prone invasive operations, a clean air suit can contribute to reduction of infection risks, in conjunction with ventilation and correct working methods.

prEN 13795-2 is intended to assist the communication between 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 clean air suits. The requirements and guidance in prEN 13795-2 are expected to be of help to manufacturers and users when designing, processing, assessing and selecting products. It is the intention of prEN 13795-2 to ensure the same level of safety from single-use and reusable clean air suits 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 1041 and EN ISO 15223-1), concerning manufacturing and processing requirements. This European Standard gives information on the characteristics of single-use and reusable clean air suits used as medical devices for clinical staff, intended to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures. This European Standard specifies test methods for evaluating the identified characteristics of clean air suits and sets performance requirements for these products.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 29073-3:1992, *Textiles - Test methods for nonwovens - Part 3: Determination of tensile strength and elongation*

EN ISO 139:2005+A1:2011, *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 11737-1:2006+AC:2009, *Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006/Cor. 1:2007)*

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 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 document, the following terms and definitions apply.

3.1
cfu (colony forming unit)
unit by which the culturable number of microorganisms is expressed

Note 1 to entry: 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, used as working garment, intended and shown to minimize contamination of the operating room air from skin scales originating on the skin of persons wearing it

Note 1 to entry: A scrub suit is a working garment for operating room staff, that does not need to meet the requirements for a clean air suit. The scrub suit is not primarily intended to prevent airborne dispersal from staff, and may be designed and processed as the manufacturer thinks fit.

Note 2 to entry: A clean air suit consists of coverall or blouse and trousers.

3.3
cleanliness
freedom from unwanted foreign matter

Note 1 to entry: 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 1 to entry: In practical use, microbial cleanliness is often referred to as 'bioburden'.

3.4
infective agent
microorganism that has been shown to cause wound infections or that might cause infection in a member of the surgical team or the patient

3.5
particle release
release of fibre fragments and other particles during mechanical stress simulating handling and use

3.6
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 1 to entry: For more details refer to the Medical Device Directive 93/42/EEC.

3.7
performance level
discrete standard defined to classify products according to the performance requirements of this standard

Note 1 to entry: With the introduction of two performance levels prEN 13795-2 acknowledges the fact that products are challenged to differing extents during surgical procedures, dependent upon the microbial cleanliness of the operating room required for the procedure.

3.7.1
standard performance
classification addressing minimum performance requirements for various characteristics of products used as medical devices in invasive surgical procedures

3.7.2
high performance
classification addressing elevated performance requirements for various characteristics of products used as medical devices in invasive surgical procedures

Note 1 to entry: Examples of surgical procedures where high performance level might be considered are infection prone clean surgical procedures where air counts in the operating room of ≤ 10 cfu/m^3 are required.

3.8
processor
natural or legal person who processes products so that their performance complies with the requirements of this European Standard

Note 1 to entry: A processor who places a product on the market is a manufacturer in the sense of this European Standard.

Note 2 to entry: 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 prEN 13795-1 and prEN 13795-2 to 'processors' include 'reprocessors' and to 'processing' include 'reprocessing'.

3.9
product
clean air suit

3.10
resistance to microbial penetration
ability of material(s) to withstand penetration of micro-organisms from one side of the material through to the other

3.10.1
dry penetration
effect of a combination of air movement and mechanical action by vibration on microbial penetration in dry condition

3.11
reusable product
product intended by the manufacturer to be reprocessed and reused

3.12
single-use product
product intended to be used once only for a single patient

3.13
source strength
the average number of bacteria-carrying particles (cfu) emitted per second from a person wearing a specified garment during a certain activity in a specified environment

3.14
surgical procedure
surgical intervention performed by a surgical team

3.14.1
invasive surgical procedure
surgical procedure penetrating skin or mucosa

4 Performance requirements

To comply with prEN 13795-2, products shall meet all the requirements specified in this standard including Table 1, when tested according to this European Standard throughout their useful life.

The biocompatibility of the product has to be evaluated and approved for acceptable risk in accordance with EN ISO 10993-1.

For general information on testing and details on the test methods given in this clause including Table 1 and their application for the purpose of this European Standard, see Annex A.

NOTE Information on characteristics, which cannot be properly evaluated or which are not regarded normative (as 'comfort') is given in Annex E.

Table 1 — Characteristics to be evaluated and performance requirements for clean air suits

Characteristic	Test method (for references, see Clause 2)	Unit	Requirement	
			Standard performance	High performance
Microbial penetration — Dry	EN ISO 22612	CFU	≤ 100[a]	≤ 50[a]
Cleanliness microbial / Bioburden	EN ISO 11737-1	CFU/ 100 cm^2	≤ 100	≤ 100
Particle release	EN ISO 9073-10	log_{10} (lint count)	≤ 4,0	≤ 4.0
Bursting strength — Dry	EN ISO 13938-1	kPa	≥ 40	≥ 40
Tensile strength — Dry	EN 29073-3	N	≥ 20	≥ 20
a Test conditions: challenge concentration 10^8 CFU/g talc and 30 min vibration time.				

The test methods given in Table 1 are materials tests. In order to manufacture a functioning clean air suit, design shall also be considered. When the material of the clean air suit is tight, bacteria are dispersed through the openings for head, arms and feet. Arm and feet openings shall therefore be closed by cuffs. A barrier hood should be worn, tucked into the gap at the neckline (see Annex B). If the clean air suit consists of blouse and trousers, the blouse should be tucked into the trousers or designed with a tightly fitting cuff at the waist.

5 Manufacturing and processing requirements and documentation

5.1 The manufacturer and processor shall document that the requirements of this European Standard are met and that the fitness for the intended purpose has been established for each use, both for single-use and reusable medical devices.

5.2 The manufacturer/processor shall establish, document, implement and maintain a formal quality management system, which includes risk management and maintain its effectiveness. This quality management system shall include requirements throughout product realization, including development, design, manufacture, testing, packaging, labelling, distribution and, for reusable products, processing and life-cycle control.

Inputs for product realization shall include the outputs from risk management.

A quality system such as EN ISO 13485 is recommended, in case of processing of reusable products applied in accordance with EN 14065.

For testing processes, quantitative biological, chemical and/or physical tests are preferred.

5.3 A clinical evaluation for clean air suits shall be carried out and shall consider the performance of the clothing system to establish fitness for purpose. The evaluation shall include the critical review of the applicable clinical literature and the results of post market surveillance and vigilance.

6 Information to be supplied with the product

6.1 Information to be supplied to the user

6.1.1 The following information shall be supplied on request:

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

b) the results of testing and test conditions for the characteristics given in Clause 4.

6.1.2 The manufacturer shall inform the user of residual risks due to any shortcomings of the protection measures adopted.

6.1.3 The manufacturer shall provide sufficient information about intended use of the product or product system when conducting a surgical procedure. This shall include information on the performance level of the product.

6.2 Information to be supplied to the processor

For reusable products the manufacturer shall obtain information to be supplied to the processor on the number of reuses based on standardized processes, together with information on measures for maintaining the technical and functional safety of the medical device, refurbishing and packaging.

NOTE EN ISO 15797, though dealing with workwear and PPE, may be useful in developing standardized methods for OR textiles since it contains information on the principles and equipment for simulated industrial laundering.