SLOVENSKI STANDARD
SIST EN 13795-2:2019

01-julij-2019

Nadomešča:
SIST EN 13795:2011+A1:2013

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

Operationskleidung 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: **EN 13795-2:2019**

ICS:

11.140	Oprema bolnišnic	Hospital equipment

SIST EN 13795-2:2019 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13795-2

April 2019

ICS 11.140

Supersedes 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 European Standard was approved by CEN on 24 October 2018.

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.

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.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Contents

Page

European foreword

This document (EN 13795-2:2019) 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 October 2019, and conflicting national standards shall be withdrawn at the latest by October 2019.

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

Together with EN 13795-1:2019, this document supersedes 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.

EN 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*

The following changes have been introduced:

a) Restriction to the product 'clean-air suit' in this Part of the EN 13795 standard series (for surgical drapes and gowns see EN 13795-1);

b) Alignment of the Standard title and the Scope;

c) Revision of the Normative references and the Bibliography;

d) Alignment of the Clause 'Terms and definitions';

e) Revision of the performance requirements in Table 1;

f) Movement of former Clause 5 'Testing' to A.1 and editorial alignment;

g) Revision of Clause 'Manufacturing and processing requirements' by adding of documentary requirements and a section for the introduction of a QM system;

h) Enhancement and improved structuring of Clause 'Information to be supplied by the manufacturer or processor';

i) Deletion of the former Annex A 'Details of significant changes between this document and the previous edition';

j) Complete revision and extension of Annex A 'Testing' (formerly Annex B 'Test methods');

k) Inclusion of a new Annex B 'Rationales' which provides precise reasons for the essential requirements of this document and which is intended for users aware of the subject of this document, but who did not join whose development;

l) Deletion of the former Annex C 'Prevention of infection in the operating room';

m) Inclusion of a new Annex C 'Environmental aspects';

n) Inclusion of a new Annex D 'Guidance to users for selecting products';

o) Inclusion of a new Annex E 'Functional design';

p) Revision of Annex ZA on the relationship to the Medical Device Directive (93/42/EEC);

q) Complete editorial revision.

According to the CEN-CENELEC Internal Regulations, the national standards organisations 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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.

This document is intended to assist the communication between manufacturers and third parties with regard to material or product characteristics and performance requirements.

Therefore, Annex B provides comprehensive information on characteristics, measurement of performance and performance requirements. Annex C clarifies that this document does not include environmental provisions. Annex D explains the concept of performance levels and provides guidance to users for selecting products. Annex E gives information on the impact of the design of clean air suits and the source strength concept as an evaluation means for the impact of the entire clothing (including clean air suits) on particle release.

This document 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 this document are expected to be of help to manufacturers and users when designing, processing, assessing and selecting products. It is the intention of this document to ensure the same level of safety from single-use and reusable clean air suits throughout their useful life.

1 Scope

This document 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 document 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 document 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 are referred to in the text in such a way that some or all of their content constitutes requirements 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 29073-3:1992, *Textiles - Test methods for nonwovens - Part 3: Determination of tensile strength and elongation*

EN ISO 139:2005,[1] *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 11737-1:2018, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)*

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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

[1] Impacted by EN ISO 139:2005+A1:2011

3.1
colony forming unit
CFU
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 can be designed and processed as the manufacturer thinks fit.

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

3.3
cleanliness
freedom from unwanted foreign matter

Note 1 to entry: Such matter can be microorganisms, 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
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.

3.6
particle release
release of fibre fragments and other particles during mechanical stress simulating handling and use

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

Note 1 to entry: With the introduction of two performance levels this document 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 document

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

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 EN 13795-1 and this document 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
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 this document, products shall meet all the requirements specified in this document including Table 1, when tested according to Annex A of this document 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 document, see Annex A.

NOTE Information on characteristics which cannot be properly evaluated or which are not regarded normative (as e.g. 'comfort') is given in Annexes B, D and E.

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

Characteristic	Test method (for normative 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 talcum 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. A barrier hood should be worn, tucked into the gap at the neckline (see Annex E, E.1). If the clean air suit consists of blouse and trousers, the blouse should be tucked into the trousers or designed with a tightly fitting waist.