SLOVENSKI STANDARD
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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

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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

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This European Standard was approved by CEN on 29 December 2024.

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COMITÉ EUROPÉEN DE NORMALISATION
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Contents

Page

European foreword

This document (EN 13795-2:2025) 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of an identical text or by endorsement, at the latest by July 2025, and conflicting national standards shall be withdrawn at the latest by July 2025.

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.

This document supersedes EN 13795-2:2019.

EN 13795-2:2025 includes the following significant technical changes with respect to EN 13795-2:2019:

a) clarification of testing specifications and reporting of results;

b) expansion of Annex C (formerly read “Environmental aspects”) to include considerations regarding environmental impact and circular economy (now Annex C “Environmental impact”);

c) alignment with Regulation (EU) 2017/745 (including updated Annex ZA);

d) update of normative references and bibliography.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, 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*.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye 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 includes considerations regarding environmental impact and circular economy. 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 General Safety and Performance Requirements (GSPR) arising from the Medical Device Regulation (EU) 2017/745, 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 ISO 20417 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 ISO 139:2005,[1] *Textiles — Standard atmospheres for conditioning and testing (ISO 139:2005)*

EN ISO 9073-3:2023, *Nonwovens — Test methods — Part 3: Determination of tensile strength and elongation at break using the strip method (ISO 9073-3:2023)*

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 10993-1:2020, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)*

EN ISO 11737-1:2018,[2] *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)*

EN ISO 13938-1:2019, *Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension (ISO 13938-1:2019)*

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 terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp/

— IEC Electropedia: available at https://www.electropedia.org/

[1] As impacted by EN ISO 139:2005/A1:2011.

[2] As impacted by EN ISO 11737-1:2018/A1:2021.

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 a pair of trousers and can also include a barrier hood.

3.3
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

3.4
manufacturer
natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark

Note 1 to entry: For more details, refer to the Medical Device Regulation (EU) 2017/745.

3.5
microbial cleanliness
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’.

3.6
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 Regulation (EU) 2017/745). 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
device that is intended to be used on one individual during a single procedure

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

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 shall be evaluated and approved for acceptable risk in accordance with EN ISO 10993-1:2020.

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 1 In order to reflect the broad variety of technologies currently used to manufacture and (if applicable) process surgical textiles and not to hinder technical development and innovation, the requirements set by this document are expressed in terms of quantifiable performance rather than specific technical design or descriptive characteristics.

NOTE 2 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	Testing		Unit	Requirement	
	according to	as specified in this document in clause		Standard performance	High Performance
Microbial penetration — Dry	EN ISO 22612:2005	A.2.5	CFU	≤ 100 [a]	≤ 50 [a]
Microbial cleanliness/ Bioburden	EN ISO 11737-1:2018	A.2.1	CFU/ 100 cm^2	≤ 100	≤ 100
Particle release	EN ISO 9073-10:2004	A.2.2	log_{10} (lint count)	≤ 4,0	≤ 4,0
Bursting strength — Dry	EN ISO 13938-1:2019	A.2.3	kPa	≥ 40	≥ 40
Tensile strength — Dry	EN ISO 9073-3:2023	A.2.4	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 a blouse and trousers, the blouse should be tucked into the trousers or designed with a tightly fitting waist.

5 Manufacturing and processing requirements and documentation

5.1 The manufacturer and processor shall document that the requirements of this document are met and that the fitness for the intended purpose has been established for each use, both for single-use and reusable medical devices. For reusable products the effects of clinical use (in addition to the effects of processing) shall be considered.