



# 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

Ta slovenski standard je istoveten z: **EN 13795-2:2019**

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#### **ICS:**

11.140

Oprema bolnišnic

Hospital equipment

**SIST EN 13795-2:2019**

**en,fr,de**

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EUROPEAN STANDARD

EN 13795-2

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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

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## EN 13795-2:2019 (E)

| <b>Contents</b>  | <b>Page</b> |
|--|-------------|
| <b>European foreword</b> .....   | <b>4</b>    |
| <b>Introduction</b> .....  | <b>6</b>    |
| <b>1 Scope</b> .....   | <b>7</b>    |
| <b>2 Normative references</b> .....  | <b>7</b>    |
| <b>3 Terms and definitions</b> .....   | <b>7</b>    |
| <b>4 Performance requirements</b> .....  | <b>10</b>   |
| <b>5 Manufacturing and processing requirements and documentation</b> .....       | <b>11</b>   |
| <b>6 Information to be supplied with the product</b> .....                       | <b>11</b>   |
| <b>6.1 Information to be supplied to the user</b> .....                          | <b>11</b>   |
| <b>6.2 Information to be supplied to the processor</b> .....                     | <b>11</b>   |
| <b>Annex A (normative) Testing</b> .....   | <b>12</b>   |
| <b>A.1 General</b> .....   | <b>12</b>   |
| <b>A.2 Test methods and conformance</b> .....                                    | <b>12</b>   |
| <b>A.2.1 Test method for evaluation of cleanliness microbial/bioburden</b> ..... | <b>12</b>   |
| <b>A.2.2 Test method for evaluation of particle release</b> .....                | <b>12</b>   |
| <b>A.2.3 Test method for evaluation of bursting strength in dry state</b> .....  | <b>13</b>   |
| <b>A.2.4 Test method for evaluation of tensile strength in dry state</b> .....   | <b>13</b>   |
| <b>A.2.5 Test method for evaluation of dry microbial penetration</b> .....       | <b>13</b>   |
| <b>A.2.6 Test method for evaluation of biocompatibility</b> .....                | <b>13</b>   |
| <b>A.3 Treatment of results</b> .....  | <b>13</b>   |
| <b>Annex B (informative) Rationales</b> .....                                    | <b>15</b>   |
| <b>B.1 General</b> .....   | <b>15</b>   |
| <b>B.2 Cleanliness – microbial</b> .....   | <b>15</b>   |
| <b>B.3 Particle release</b> .....  | <b>15</b>   |
| <b>B.4 Bursting strength – dry</b> .....   | <b>16</b>   |
| <b>B.5 Tensile strength – dry</b> .....  | <b>16</b>   |
| <b>B.6 Resistance to microbial penetration – dry</b> .....                       | <b>16</b>   |
| <b>B.7 Labelling</b> .....   | <b>17</b>   |
| <b>B.8 Treatment of results</b> .....  | <b>17</b>   |
| <b>B.9 Flammability</b> .....  | <b>18</b>   |
| <b>B.10 Electrostatic discharge</b> .....  | <b>18</b>   |
| <b>Annex C (informative) Environmental aspects</b> .....                         | <b>19</b>   |
| <b>Annex D (informative) Guidance to users for selecting products</b> .....      | <b>20</b>   |

|              |   |           |
|--------------|---|-----------|
| <b>D.1</b>   | <b>General</b> .....  | <b>20</b> |
| <b>D.2</b>   | <b>Performance levels</b> .....   | <b>20</b> |
| <b>D.3</b>   | <b>Functional design aspects</b> .....  | <b>20</b> |
| <b>D.3.1</b> | <b>Size</b> .....   | <b>20</b> |
| <b>D.3.2</b> | <b>Accessories</b> .....  | <b>20</b> |
| <b>D.4</b>   | <b>Comfort</b> .....  | <b>21</b> |
| <b>D.4.1</b> | <b>General</b> .....  | <b>21</b> |
| <b>D.4.2</b> | <b>Clean air suits</b> .....  | <b>21</b> |
| <b>D.4.3</b> | <b>Practical trials</b> .....   | <b>21</b> |
|              | <b>Annex E (informative) Functional design</b> .....  | <b>22</b> |
| <b>E.1</b>   | <b>General</b> .....  | <b>22</b> |
| <b>E.2</b>   | <b>Test method for measuring source strength</b> .....  | <b>22</b> |
| <b>E.2.1</b> | <b>Dispersal chamber</b> .....  | <b>22</b> |
| <b>E.2.2</b> | <b>Operating room</b> .....   | <b>23</b> |
| <b>E.2.3</b> | <b>Measuring bacteria carrying airborne particles</b> .....   | <b>23</b> |
| <b>E.2.4</b> | <b>Source strength</b> .....  | <b>23</b> |
| <b>E.3</b>   | <b>Use of source strength measurements</b> .....  | <b>24</b> |
|              | <b>Annex ZA (informative) Relationship between this European standard and the essential requirements of Directive 93/42/EEC [1993 OJ L 169] aimed to be covered</b> ..... | <b>26</b> |
|              | <b>Bibliography</b> .....   | <b>27</b> |

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## EN 13795-2:2019 (E)

### 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’);



## EN 13795-2:2019 (E)

### 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.

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## 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,<sup>1</sup> *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>

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<sup>1</sup> Impacted by EN ISO 139:2005+A1:2011

**EN 13795-2:2019 (E)****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  $\leq 10$  CFU/m<sup>3</sup> 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