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

Táto norma obsahuje anglickú verziu európskej normy.

This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/25

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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

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

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

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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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EN 13795-2:2025 (E)

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of an identical text or by endorsement, at the latest by July 2025, and conflicting national standards shall be withdrawn at the latest by July 2025.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

EN 13795-2:2025 (E)**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)*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN

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

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