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

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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

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

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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of an identical text or by endorsement, at the latest by October 2019, and conflicting national standards shall be withdrawn at the latest by October 2019.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)*

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