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Institut luxembourgeois de la normalisation
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des produits et services

ILNAS-EN 13795-1:2019

Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns

Operationskleidung und -abdecktücher - Anforderungen und Prüfverfahren - Teil 1: Operationsabdecktücher und -mäntel

Vêtements et champs chirurgicaux - Exigences et méthodes d'essai - Partie 1 : Champs et casaques chirurgicaux

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National Foreword

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Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns

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Operationskleidung und -abdecktücher - Anforderungen und Prüfverfahren - Teil 1: Operationsabdecktücher und -mäntel

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

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Contents

Page

European foreword ... 4
Introduction ... 6
1 Scope ... 7
2 Normative references ... 7
3 Terms and definitions ... 8
4 Performance requirements ... 11
5 Manufacturing and processing requirements and documentation ... 13
6 Information to be supplied with the product ... 13
6.1 Information to be supplied to the user ... 13
6.2 Information to be supplied to the processor ... 14
Annex A (normative) **Testing** ... 15
A.1 General ... 15
A.2 Test methods and conformance ... 15
A.2.1 Test method for evaluation of cleanliness microbial/bioburden ... 15
A.2.2 Test method for evaluation of particle release ... 16
A.2.3 Test method for evaluation of liquid penetration ... 16
A.2.4 Test method for evaluation of bursting strength in dry and wet state ... 16
A.2.5 Test method for evaluation of tensile strength in dry and wet state ... 17
A.2.6 Test method for evaluation of dry microbial penetration ... 17
A.2.7 Test method for evaluation of wet microbial penetration ... 17
A.2.8 Test method for evaluation of biocompatibility ... 17
A.3 Treatment of results ... 18
Annex B (informative) **Rationales** ... 19
B.1 General ... 19
B.2 Cleanliness – microbial ... 19
B.3 Particle release ... 19
B.4 Resistance to liquid penetration ... 20
B.5 Bursting strength – dry and wet ... 21
B.6 Tensile strength – dry and wet ... 21
B.7 Resistance to microbial penetration – dry ... 21
B.8 Resistance to microbial penetration – wet ... 23
B.9 Labelling ... 23
B.10 Treatment of results ... 24

Annex C (informative) **Information on further characteristics** **25**
C.1 Comfort **25**
C.2 Adhesion for fixation for the purpose of wound isolation **25**
C.3 Liquid control **25**
C.4 Flammability **26**
C.5 Electrostatic discharge **26**
Annex D (informative) **Environmental aspects** **27**
Annex E (informative) **Guidance to users for selecting products** **28**
E.1 Performance levels **28**
E.2 Functional design **28**
E.2.1 General **28**
E.2.2 Critical and less critical areas **28**
E.2.3 Size **29**
E.2.4 Accessories **29**
E.2.5 Comfort **29**
E.2.5.1 General **29**
E.2.5.2 Surgical gowns **29**
E.2.5.3 Surgical drapes **30**
E.3 Practical trials **30**
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** **31**
Bibliography **32**

European foreword

This document (EN 13795-1:2019) 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 13795-2:2019, 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) The product 'clean-air suit' has been moved to Part 2 of the EN 13795 standard series because of distinctive requirements and test methods;

b) Alignment of the document title and the Scope;

c) Revision of the Normative references and the Bibliography;

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

e) Review of the performance requirements in Table 1 and Table 2 especially with regard to 'Cleanliness - Particulate matter' and 'Linting', which have been combined as 'Particle release;

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' which consisted of 3 parts;

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 have not participated in its development;

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

m) Revision and extension of Annex C (formerly Annex D) 'Information on further characteristics'; e.g. inclusion of a Clause on , Flammability' and 'Electrostatic discharge';

n) Inclusion of a new Annex D 'Environmental aspects';

o) Inclusion of a new Annex E 'Guidance to users for selecting products';

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

The transmission of infective agents during invasive surgical procedures can occur in several ways (see informative Annex B).

Surgical drapes, including the intended use as a sterile field, and surgical gowns are used to minimize the spread of infective agents to and from patients' operating wounds, thereby helping to prevent post-operative wound infections (see Annex B).

The performance required of coverings for patients, clinical staff and equipment varies with, for example, the type and duration of the procedure, the degree of wetness of the operation field, the degree of mechanical stress on the materials and the susceptibility of the patient to infection.

The use of surgical gowns with resistance to the penetration of liquids can also diminish the risk to the operating staff from infective agents carried in blood or body fluids.

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 provides information on characteristics regarded relevant in context with surgical gowns and drapes, however but not covered normatively (i.e. without applicable performance requirements). Annex E explains the concept of performance levels and provides guidance to users for selecting products.

This document focuses on Essential Requirements arising from the Medical Device Directive 93/42/EEC, which are applicable to surgical drapes and gowns. 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 surgical clothing and drapes throughout their useful life.

Surgical gowns are used to minimize the transmission of infective agents between patients and clinical staff during surgical and other invasive procedures. Hereby, surgical gowns contribute to the clinical condition and the safety of patients as well as to the safety and health of users following up essential requirement 1 of Directive 93/42/EEC on Medical Devices. This document addresses the same level of protection for patients and users (i.e. the surgical team) by not differentiating the performance requirements for surgical gowns respectively. However, this document does not formally address any basic health and safety requirements of the Directive 89/686/EEC or Regulation (EU) 2016/425 on Personal Protective Equipment and does not provide specific guidance for surgical gowns intended by the manufacturer for dual use as medical device and personal protective equipment.