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

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

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

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 205.

If this draft becomes a European Standard, 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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (prEN 13795-1:2023) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 13795-1:2019.

prEN 13795-1:2023 includes the following significant technical changes with respect to EN 13795-1:2019:

a) Clarification of testing specifications and reporting of results;

b) Preparation of samples for testing of bursting strength in the wet state according to the test method standard EN ISO 13938-1:2019 (i.e. not any longer according to EN 29073-3:1992 as in the previous version);

c) Expansion of former Annex D “Environmental aspects” to include considerations regarding environmental impact and circular economy (now Annex D “Environmental impact”);

d) Alignment to Regulation (EU) 2017/745 (including updated Annex ZA);

e) 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*

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 General Safety and Performance Requirements (GSPR) arising from the Medical Device Regulation (EU) 2017/745, 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 General Safety and Performance Requirements (GSPR) of Regulation (EU) 2017/745 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 Essential Health and Safety Requirements of 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.

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 surgical gowns and surgical drapes used as medical devices for patients, clinical staff and equipment, 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 surgical drapes and gowns and sets performance requirements for these products.

This document does not include information on resistance to penetration by laser radiation of products.

NOTE If resistance to penetration by laser radiation is claimed for surgical drapes, suitable test methods together with an appropriate classification system are given in EN ISO 11810.

This document does not cover requirements for incision drapes or films.

This document does not cover requirements for antimicrobial treatments for surgical gowns and drapes. Antimicrobial treatment can cause environmental risks such as resistance and pollution. However, antimicrobial treated surgical gowns and drapes fall under the scope of this document with respect to their use as surgical gowns and drapes.

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 + Amd. 1:2011)*

EN ISO 811:2018, *Textiles - Determination of resistance to water penetration - Hydrostatic pressure test (ISO 811:2018)*

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)*

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

[2] Impacted by EN ISO 11737-1:2018/A1:2021

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 22610:2006, *Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Test method to determine the resistance to wet bacterial penetration (ISO 22610:2006)*

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/

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
cleanliness
freedom from unwanted foreign matter

Note 1 to entry: Such matter can be microorganisms, organic residues or particulate matter.

3.2.1
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'.

3.3
critical product area
product area with a greater probability to be involved in the transfer of infective agents to or from the wound, e.g. front and sleeves of surgical gowns

3.4
infective agent
micro-organism 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
less critical product area
product area less likely to be involved in the transfer of infective agents to or from the wound

3.6
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 their own name, regardless of whether these operations are carried out by that person themselves or on their behalf by a third party

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

3.7
particle release
release of fibre fragments and other particles during mechanical stress simulating handling and use

3.8
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 duration, mechanical stress and liquid challenge throughout the surgical procedure.

3.8.1
standard performance
classification addressing minimum performance requirements for various characteristics of products used as medical devices in invasive surgical procedures

3.8.2
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 elevated performance level should be considered are those where extensive exposure to liquid, mechanical stresses or longer surgical procedures can be expected.

3.9
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 13795-2 and this document to 'processors' include 'reprocessors' and to 'processing' include 'reprocessing'.

3.10
product
surgical gown, surgical drape including equipment covering

Note 1 to entry: In cases of surgical packs, each gown or drape is regarded as a product.

3.11
resistance to liquid penetration
ability of material to withstand the penetration of liquid(s) from one side of the material through to the other

3.12
resistance to microbial penetration
ability of material(s) to withstand penetration of micro-organisms from one side of the material through to the other

3.12.1
dry penetration
effect of a combination of air movement and mechanical action by vibration on microbial penetration in dry condition

3.12.2
wet penetration
effect of combination of wetness, pressure and rubbing on microbial penetration

3.13
reusable product
product intended by the manufacturer to be reprocessed and reused

3.14
single-use product
product intended to be used once only for a single patient

3.15
sterile field
area created by sterile surgical drape material where aseptic technique is practised

Note 1 to entry: A sterile field can be practised e.g. on a back table.

3.16
surgical drape
drape covering the patient or equipment to prevent transfer of infective agents

3.17
surgical gown
gown worn by a member of a surgical team to prevent transfer of infective agents

3.18
surgical procedure
surgical intervention performed by a surgical team

3.18.1
invasive surgical procedure
surgical procedure penetrating skin or mucosa

4 Performance requirements

To comply with this document, products shall meet all the requirements specified in this document including Tables 1 or 2 (as appropriate to the product), when tested according to Annex A throughout their useful life.

The biocompatibility of the product shall be evaluated and approved for acceptable risk.

If the manufacturer does not differentiate product areas, all areas shall meet the requirements for critical product areas.

If the intended purpose of a medical device specifies the use as a sterile field, the requirements for surgical drapes and equipment covers apply as per Table 2.

For general information on testing and details on the test methods given in this clause including Tables 1 and 2 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 Performance requirements are specified depending on product area and performance level. However, for some characteristics the performance requirement will apply for all performance levels and product areas of the medical device.

NOTE 3 Information on characteristics, which cannot be properly evaluated (as 'adhesion for fixation for the purpose of wound isolation' or 'liquid control') or which are not regarded normative (as 'comfort') is given in Annex C.

Table 1 — Characteristics to be evaluated and performance requirements for surgical gowns

Characteristic	Testing		Unit	Requirement			
				Standard performance		High performance	
	according to	as specified in this document in clause		Critical product area	Less critical product area	Critical product area	Less critical product area
Microbial penetration — Dry	EN ISO 22612:2005	A.2.6	CFU	Not required	≤ 300 [a]	Not required	≤ 300 [a]
Microbial penetration — Wet	EN ISO 22610:2006	A.2.7	I_B	≥ 2,8 [b]	Not required	6,0 [b c]	Not required
Cleanliness microbial/ Bioburden	EN ISO 11737-1:2018	A.2.1	CFU/ 100 cm^2	≤ 300	≤ 300	≤ 300	≤ 300
Particle release	EN ISO 9073-10:2004	A.2.2	$\log_{10}$ (lint count)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0
Liquid penetration	EN ISO 811:2018	A.2.3	cm H_2O	≥ 20	≥ 10	≥ 100	≥ 10
Bursting strength — Dry	EN ISO 13938-1:2019	A.2.4	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength — Wet	EN ISO 13938-1:2019	A.2.4	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength — Dry	EN ISO 9073-3:2023	A.2.5	N	≥ 20	≥ 20	≥ 20	≥ 20
Tensile strength — Wet	EN ISO 9073-3:2023	A.2.5	N	≥ 20	Not required	≥ 20	Not required

[a] Test conditions: challenge concentration 10^8 CFU/g talcum and 30 min vibration time.

[b] The Least Significant Difference (LSD) for I_B when estimated using EN ISO 22610:2006, was found to be 0,98 at the 95 % confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. Thus, materials varying by up to 0,98 I_B are probably not different; materials varying by more than 0,98 I_B probably are different. (The 95 % confidence levels means that an observer would be correct 19 times out of 20 to accept these alternatives.)

[c] I_B = 6,0 for the purpose of this document means: no penetration. I_B = 6,0 is the maximum achievable value.

Table 2 — Characteristics to be evaluated and performance requirements for surgical drapes

Characteristic	Testing		Unit	Requirement			
				Standard performance		High performance	
	according to	as specified in this document in clause		Critical product area	Less critical product area	Critical product area	Less critical product area
Microbial penetration — Dry	EN ISO 22612:2005	A.2.6	CFU	Not required	≤ 300 [a]	Not required	≤ 300 [a]
Microbial penetration — Wet	EN ISO 22610:2006	A.2.7	I_B	≥ 2,8 [b]	Not required	6,0 [b c]	Not required
Cleanliness microbial/ Bioburden	EN ISO 11737-1:2018	A.2.1	CFU/ 100 cm^2	≤ 300	≤ 300	≤ 300	≤ 300
Particle release	EN ISO 9073-10:2004	A.2.2	$\log_{10}$ (lint count)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0
Liquid penetration	EN ISO 811:2018	A.2.3	cm H_2O	≥ 30	≥ 10	≥ 100	≥ 10
Bursting strength — Dry	EN ISO 13938-1:2019	A.2.4	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength — Wet	EN ISO 13938-1:2019	A.2.4	kPa	≥ 40	Not required	≥ 40	Not required
Tensile strength — Dry	EN ISO 9073-3:2023	A.2.5	N	≥ 15	≥ 15	≥ 20	≥ 20
Tensile strength — Wet	EN ISO 9073-3:2023	A.2.5	N	≥ 15	Not required	≥ 20	Not required

[a] Test conditions: challenge concentration 10^8 CFU/g talcum and 30 min vibration time.

[b] The Least Significant Difference (LSD) for I_B when estimated using EN ISO 22610:2006, was found to be 0,98 at the 95 % confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. Thus, materials varying by up to 0,98 I_B are probably not different; materials varying by more than 0,98 I_B probably are different. (The 95 % confidence levels means that an observer would be correct 19 times out of 20 to accept these alternatives.)

[c] I_B = 6,0 for the purpose of this document means: no penetration. I_B = 6,0 is the maximum achievable value.

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.

5.2 The manufacturer/processor shall establish, document, implement and maintain a formal quality management system, which includes risk management and maintain its effectiveness. This quality management system shall include requirements throughout product realization, including development, design, manufacture, testing, packaging, labelling, distribution and, for reusable products, processing and life-cycle control.

Inputs for product realization shall include the outputs from risk management.

A quality system such as EN ISO 13485 is recommended, in case of processing of reusable products applied in accordance with EN 14065.

Packaging for terminally sterilized medical devices is recommended according to EN ISO 11607 series of standards.

For testing processes, quantitative physical, chemical and/or biological tests are preferred.

5.3 A clinical evaluation for surgical drapes and gowns shall be carried out and shall consider the performance of the full draping and gowning system to establish fitness for purpose. The evaluation shall include the critical review of the applicable clinical literature and the results of post market surveillance and vigilance.

6 Information to be supplied with the product

6.1 Information to be supplied to the user

6.1.1 In addition to the information to be supplied according to Medical Device Regulation (EU) 2017/745, if the manufacturer or processor differentiates between critical and less critical areas of the product, they shall supply information to identify them.

6.1.2 The following additional information shall be supplied on request:

a) the identity or information on the test methods used;

b) the results of testing and test conditions for the characteristics given in Clause 4.

6.1.3 The manufacturer shall inform the user of residual risks due to any shortcomings of the protection measures adopted.

6.1.4 The manufacturer shall provide sufficient information about intended use of the product or product system when conducting a surgical procedure. This shall include information on the performance level of the product.

6.1.5 The manufacturer shall provide information on the flammability of the product and fire risks in relation with it on request.

6.2 Information to be supplied to the processor

6.2.1 For reusable products the manufacturer shall obtain information to be supplied to the processor on the number of reuses based on standardized processes, together with information on measures for maintaining the technical and functional safety of the medical device and packaging.

6.2.2 For products to be terminally sterilized, the manufacturer shall supply instructions for the sterilization processes to be applied.

Annex A
(normative)

Testing

A.1 General

A.1.1 Testing for evaluation of the performance of products shall be done according to the test methods specified in A.2. All test results and test conditions including details of weak spots covered by the tests shall be recorded and retained.

A.1.2 Testing shall be performed on the finished product. If the product is to be used after sterilization, testing shall be performed on products after sterilization with the exception of microbial cleanliness. Testing shall include potential weak spots.

NOTE 1 Performance requirements can vary in relation to the areas of the product and the risk of involvement in the transfer of infective agents to or from the wound.

NOTE 2 To ensure product performance, combinations of materials or products in systems can be used.

NOTE 3 In particular, all types of joints in critical areas such as, e.g. seams in sleeves of surgical gowns, are regarded as potential weak spots.

A.1.3 During manufacture and processing, testing shall be conducted according to the requirements of the manufacturer's and processor's quality system.

A.1.4 Alternative test methods for monitoring may be used provided that they are validated and address the same characteristic and that the results have been shown to correlate with the test methods given in this document.

A.1.5 Where the test methods of this document do not specify the atmosphere for pre-conditioning, conditioning and testing, the specifications of EN ISO 139:2005 shall be applied, except for the microbial cleanliness (EN ISO 11737-1:2018), particle release (EN ISO 9073-10:2004) and the microbial barrier tests (EN ISO 22610:2006 an EN ISO 22612:2005) where external contaminations shall be avoided.

A.2 Test methods and conformance

A.2.1 Test method for evaluation of cleanliness microbial/bioburden

For evaluation of cleanliness — microbial, the product shall be tested according to EN ISO 11737-1:2018. Where products are intended to be sterilized, testing shall be performed before sterilization.

NOTE EN ISO 11737-1:2018 does not provide a fixed test method but specifies requirements for test methods and test mechanisms. The requirements of EN ISO 11737-1:2018 are such that different test methods developed in accordance with it provide comparable results.

Five specimens shall be tested. The results shall be expressed as CFU/100 cm^2. Report the individual results and determine M_d and U_q (see A.3). U_q shall be equal to or less than the performance requirements in Tables 1 and 2.

A.2.2 Test method for evaluation of particle release

For evaluation of particle release, the product shall be tested according to EN ISO 9073-10:2004 and calculations undertaken as below.

NOTE 1 EN ISO 9073-10:2004 allows for the test method to be conducted in a laminar flow hood. It is important to validate that laminar flow is occurring if equipment required for the test is located in the hood.

As specified in EN ISO 9073-10:2004, ten specimens, five for each side of the material, shall be tested. The result of the test, i.e. the coefficient of linting, shall be calculated for particles in the size range 3 µm to 25 µm and reported as $\log_{10}$ of the count value. Pool the 5 results from each side together and calculate the U_q value for each side. Report the individual results and determine M_d and U_q (see A.3). The U_q for each side shall be equal to or less than the performance requirements in Tables 1 and 2.

NOTE 2 Particles of this size range are considered to be capable of carrying microorganisms.

A.2.3 Test method for evaluation of liquid penetration

For evaluation of liquid penetration, the product shall be tested according to EN ISO 811:2018.

The following specific amendments to the procedure in EN ISO 811:2018 apply for the purpose of this document:

a) the test area shall be 100 cm^2;

b) the rate of increase of water pressure shall be (10 ± 0,5) cm/min;

c) the temperature of the water shall be (20 ± 2) °C;

d) the side of the product in contact with the test liquid shall be the outer side.

Five specimens shall be tested. Report the individual results and determine M_d and L_q (see A.3). L_q shall be equal to or greater than the performance requirements in Tables 1 and 2.

As the test may be stopped once the test limit hydrostatic pressure is exceeded or the measurement capability of the instrument is exceeded, the value to be used in the median and lower quartile calculations for hydrostatic pressure testing shall be the lower of the breakthrough number or the upper measurement capability if this has been exceeded.

A.2.4 Test method for evaluation of bursting strength in dry and wet state

For evaluation of bursting strength, the product shall be tested according to EN ISO 13938-1:2019. The size of the test area shall be 10 cm^2 (35,7 mm diameter).

The test conditions should be specified in the test report.

If there are differences in the test results of both sides of material, both sides should be tested, and the results should be recorded.

Five specimens shall be tested. The pressure needed to break or compromise the barrier of the sample shall be reported. Report the individual results and determine M_d and L_q (see A.3). L_q shall be equal to or greater than the performance requirements in Tables 1 and 2.

A.2.5 Test method for evaluation of tensile strength in dry and wet state

For evaluation of tensile strength, the product shall be tested according to EN ISO 9073-3:2023.

Five specimens shall be tested for each direction. The pressure needed to break or compromise the barrier of the sample shall be reported. Report the individual results and determine M_d and L_q (see A.3)

separately for each direction. L_q for each direction shall be equal to or greater than the performance requirements in Tables 1 and 2.

As some materials cannot fully fracture during this test (for example laminated products incorporating a plastic film), the tensile testing apparatus can reach its limit of elongation before the sample fractures. In these circumstances, the test limit for tensile strength shall be reported as the peak value recorded during the test.

NOTE This is in line with the principles of EN ISO 9073-3:2023 when several peaks occur for breaking strength,

A.2.6 Test method for evaluation of dry microbial penetration

For evaluation of dry microbial penetration, the product shall be tested according to EN ISO 22612:2005.

If both sides of the material to be tested are different, the side intended to cover the contamination source during medical use as stated by the manufacturer shall be exposed to the inoculated donor in the test.

NOTE The side intended to cover the contamination source during medical use is, e.g. the inner side of a surgical gown or the patient or equipment side of a surgical drape.

If the product has an antimicrobial treatment, it shall be mentioned in the test report since it can influence the results.

Ten specimens shall be tested. Report the individual results and determine M_d and U_q (see A.3). U_q shall be equal to or less than the performance requirements in Tables 1 and 2.

A.2.7 Test method for evaluation of wet microbial penetration

For evaluation of wet microbial penetration, the product shall be tested according to EN ISO 22610:2006.

If both sides of the material to be tested are different, the side intended to cover the contamination source during medical use as stated by the manufacturer shall be exposed to the inoculated donor in the test.

NOTE The side intended to cover the contamination source during medical use is, e.g. the inner side of a surgical gown or the patient or equipment side of a surgical drape.

If the product has a known antimicrobial treatment, it shall be mentioned in the test report since it can influence the results.

Five specimens shall be tested. Report the results as per EN ISO 22610:2006 including barrier index I_B as per EN ISO 22610:2006, C.4. The barrier index I_B shall be equal to or higher than the performance requirements in Tables 1 and 2 for all five samples.

A.2.8 Test method for evaluation of biocompatibility

The surgical drape/gown shall be evaluated according to EN ISO 10993-1:2020. The manufacturer shall report the results of the evaluation.

A.3 Treatment of results

In order to determine whether a sample conforms to the performance requirements of this document, it is necessary to convert the replicate results from a test into an acceptance value (or test statistic). The median (M_d) was the chosen value (see Annex B), together with one of two test statistics a) the lower quartile value (L_q) for minimum performance (PR_{min}) and b) the upper quartile (U_q) for maximum performance (PR_{max}).

The conformance of the product shall be determined using the following calculated values:

— $L_q \geq PR_{min}$ (see Tables 1 and 2);

— $U_q \leq PR_{max}$ (see Tables 1 and 2); and

— M_d, L_q and U_q (or any percentile value).

It is recognized that most laboratories will wish to use software to calculate the test statistics. Therefore, to calculate the kth percentile (where k is 25 for identifying the lower quartile number and 75 for identifying the upper quartile value), use software which uses the Hyndman and Fan Method 7 [37]. The standard Excel functions QUARTILE and QUARTIL.INC calculate the quartiles based on Method 7. Other software packages may use this method by default or offer it as an option.

Annex B
(informative)

Rationales

B.1 General

This annex provides a concise rationale for the important requirements of this document and is intended for use by those who are familiar with the subject of this document but who have not participated in its development. An understanding of the reasons for the main requirements is considered essential for its proper application. Furthermore, as clinical practices and technologies change, it is believed that rationales for the present requirements will facilitate any revisions of this document necessitated by those developments.

The first task undertaken by CEN/TC 205/WG 14 in its early days was deciding on the key product characteristics which needed to be assessed. After much consideration four categories emerged, namely barrier properties, strength properties relevant to maintaining barrier properties, particle release and bioburden level to ensure successful sterilization. Most of the performance limits in this document are based on expert consensus.

B.2 Cleanliness – microbial

The test for microbial cleanliness is intended to estimate the numbers of viable organisms on the products, **before** they are sterilized. This is frequently referred to as the 'bioburden', which manufacturers routinely measure, and use to determine the appropriate sterilization criteria for their products.

Note that this test is **not** a sterility test. In a bioburden (cleanliness) test, the presence of microorganisms is expected, and the test is designed to quantify the amount of microorganisms present (for example, through rinsing, filtering and counting). In a sterility test, the **absence** of microorganisms is expected, and a different methodology is used.

The cleanliness limit of 300 CFU (Tables 1 and 2) is based on the experience of manufacturers and what is routinely achievable at present. It is also a figure which industry state is acceptable to Notified Bodies as representing a bioburden capable of being dealt with by the sterilization methods available. Finally, it was also chosen as being a reasonable level for products which will not undergo a cleaning/disinfecting process prior to sterilization, such as single-use products.

The Working Group acknowledges that the device will usually have undergone a 'terminal sterilization' [18] process before clinical users receive it. Consequently, the requirements for cleanliness – microbial are set in anticipation of the sterilization process to be applied terminally.

B.3 Particle release

This method is designed to measure the release of particles from the device.

Particle release is a concern during surgery as foreign body contamination can cause an increased frequency of postoperative complications such as keloids, wound dehiscence, incisional hernias, chronic abscesses, intestinal obstruction and, in some circumstances, even death [19], [20]. Fibres from gowns and drapes which have been deposited in wounds have been shown to cause post-operative granulomas [21], [22]. Blood clots around fibres can cause emboli, obstructing vital blood vessels [23]. Fibres can also reduce the ability of tissue to resist infection, due to impaired function of the blood and tissue macrophage systems [24], [25].

As well as having a direct effect clinically, an indirect effect is observed, whereby fibres and particles released from operating room materials can deposit on surfaces in the operating room, providing a potential vector for microorganisms to be carried into wounds and cavities [26]. See section on "Resistance to microbial penetration" for a discussion on contamination versus infection.

In 1997, CEN/TC 205/WG 14 passed resolutions requiring both linting and cleanliness to be covered as normative parts of this document. Linting was defined as material created by mechanical handling of the material (such as flexing and rubbing during normal use), originating from the material itself. The 'ad hoc' Linting group in 1999 discussed a proposal that 'foreign matter' is expected to be released at the beginning of a flexion test, but linting (release of particles from the material itself) will occur throughout the testing. A method was proposed which gave an estimate of foreign particles and lint, and this proposal was accepted by CEN/TC 205/WG 14 in 1999. Documents from that period state that the first three time-steps have significant peaks which are due to the foreign and loose matter, and subsequent counts are due to linting.

Thus the original version of this document included requirements for linting and particulate cleanliness, intended to differentiate loose particles from lint, and since there was no simple method, a cut-off point of 90 s was chosen based on examination of the graphs. Recently, CEN/TC 205/WG 14 has removed the requirement for particulate cleanliness from this document as it believes that the distinction between particulate cleanliness and linting was purely theoretical, with no evidence being presented to demonstrate that the original supposition of loose matter being released in the first 90 s was correct. Although there is no evidence that the theoretical concerns were unsubstantiated, it has been agreed that the performance characteristic which is of practical importance is total particles released from the material. Thus the new requirement is for a **total** particle release figure, which will also include loose particulate matter.

We do not believe that this will have any effect on the clinical acceptability or performance of the devices, as the amended test for 'Particle release' measures **all** the particles released during the test period which are thought to be clinically relevant.

The particulate size range of 3 µm to 25 µm has been chosen based on the opinion that particles smaller than 3 µm are too small to carry microorganisms, and particles larger than 25 µm are too large to remain airborne because of gravity. This is supported in work published by Noble in 1963 who found that "*Organisms associated with human disease or carriage were usually found on particles in the range 4 µm to 20 µm equivalent diameter*".

B.4 Resistance to liquid penetration

Also known as the 'hydrostatic head test', this test is a standard test used for textiles, which measures how high a column of water has to be before it penetrates through the material under test. It is generally accepted to be a measure of the water-resistant properties of a material.

It is relevant to surgical fabrics as it is related to the ability of the fabric to prevent splashes of fluid and droplets penetrating the fabric under mechanical pressure.

The limits of 10 cm, 20 cm, 30 cm and 100 cm H_2O (Tables 1 and 2) are based on manufacturer experience with similar ranges of devices in the market place.

This particular test is based on water and that whilst CEN/TC 205/WG 14 is aware that these devices are exposed to other substances such as fats in the operating room, the water test is an established and well accepted test to characterize barrier fabrics by the textile industry.

The liquid penetration test is also acknowledged as a useful and simple test to monitor both single-use and reusable fabrics during processing and between uses, as performing wet bacterial barrier penetration tests routinely on batches is impractical.

EN ISO 811:2018 allows for two different temperatures and two different rates of rise for testing. Both test conditions influence the test result and hence the evaluation of conformity with the requirements of this document. As a consequence, the temperature and rate of rise was specified in this document.

Based on the condition usually used for testing by laboratories and manufacturers the temperature has been specified as (20 ± 2) °C.

As for the rate of rise members of CEN/TC 205/WG 14 have undertaken tests of multiple materials. The analyses of this data show that a wider spread of results is seen in the results with the faster rate rise (60 cm/min), which implies less precision in the test results. In addition, when tested at 60 cm/min rise, the results are elevated compared to the results at 10 cm/min, and some materials considered unsatisfactory, which fail at 10 cm/min would pass at 60 cm/min. Therefore, to ensure consistency, a decision has been made by CEN/TC 205/WG 14 to only allow a 10 cm/min rate of rise when testing to compliance for this document.

B.5 Bursting strength – dry and wet

This test is designed to assess the device's ability to withstand pressure over, for example, a clinician's elbow and to ensure its barrier properties are not prejudiced by mechanical failure.

Materials with more than one layer can show several break points when tested for bursting strength, e.g. one corresponding to each layer. In order to address the scope of the requirement it was agreed to evaluate the performance of the material based on the pressure needed to break or compromise the barrier of the sample.

The limits (Tables 1 and 2) are based on manufacturer's experience of products deemed to be clinically suitable in the market place.

Previous versions of this document allowed laboratories to undertake the burst test using all test piece sizes allowed in EN ISO 13938-1:2019. Expert advice from the Working Group members that the test results would differ between different sized test pieces (larger surfaces give lower values) has resulted in a decision to standardize the sample dimensions to 10 cm^2, ensuring that results from different laboratories are comparable.

B.6 Tensile strength – dry and wet

The 'tensile strength' of a material is the maximum stress, generated by pulling or stretching the material that a material can withstand before failing.

The test is designed to assess whether the basic strength of the device material is sufficient to ensure its barrier properties are not prejudiced. It is a standard textile material test.

Materials with more than one layer can show several break points when tested for tensile strength, e.g. one corresponding to each layer. In order to address the scope of the requirement it was agreed to evaluate the performance of the material based on the force needed to break or compromise the barrier of the sample.

The limits (Tables 1 and 2) are based on manufacturer's experience of products deemed to be clinically suitable in the market place.

Tables 1 and 2 have limits for the material in both the wet and dry states, as gowns and drapes are expected to be subjected to wet and dry conditions during use.

B.7 Resistance to microbial penetration – dry

Dry bacterial penetration EN ISO 22612:2005 is a test method that was designed to simulate the penetration of bacteria-carrying skin scales through fabrics.

This test provides a means for assessing the resistance to penetration through barrier materials of bacteria-carrying particles.

Whilst the relationship between contamination and infection is complex - contamination of the surgical field does not necessarily lead to infection - it is generally agreed that healthcare facilities should consider methods to reduce levels of airborne particles carrying bacteria in operating rooms [27].

The skin is the most important source of airborne contamination in the operating room. A person releases approximately 10^4 skin particles per minute when walking and approximately 10 % of these carry bacteria. Activity and friction against the skin, e.g. from clothing, increase the dispersal. When skin scales pass through relatively impermeable clothing, they can also become fragmented, with the result that more than 50 % of the bacteria-carrying particles can be less than 5 µm. Bacteria-carrying skin scales are dispersed from the human body surface mainly from the lower part of the torso.

Normal shedding of human skin cells (keratinocytes) produces individual cells which are approximately 25 µm to 30 µm in diameter (when hydrated) [28]. Whyte and Bailey [29] noted that bacterial-carrying skin scales are on average about 20 µm in size, whilst Mackintosh and colleagues [30] showed that dispersed skin fragments had a wide size range extending below 5 µm for the minimum projected diameter (MPD), with a median MPD about 20 µm, and with 7 % to 10 % less than 10 µm.

The skin scales behave aerodynamically as particles of unit density and size approximately 10 µm. These particles are distributed in the operating room with air currents and settle on exposed surfaces, thereby contaminating the sterile field and causing infection of the surgical site.

For microorganisms to penetrate the material in the dry state, they shall be carried on a physical particle, for example, skin scales. In this test, the physical particles are composed of talcum, where 95 % of the particles shall be ≤ 15 µm. The referenced talcum (Finntalc M15) has a median particle size of 4,5 µm, a maximum size of approximately 17 µm, and approximately 18 % of the particles are ≤ 2 µm.

During the dry penetration test, the talcum particles are sifted through the material to be tested, and spore-forming bacteria are used as marker organisms. The test is intended to measure penetration of dust, e.g. skin scales through clothes, and has been shown to correlate well to airborne dispersal of bacteria.

The size range in the test talcum covers the range of skin fragments found in practice down to particle sizes smaller than we would expect from skin fragmentation.

Penetration in this test method is influenced more by the physical properties of the materials e.g. pore size and tortuosity factor than by their hydrophobic/hydrophilic characteristics.

The limit of ≤ 300 CFU (Tables 1 and 2) appears to be partially based on the results of the BIOBAR project[3)] which showed that a standard cotton fabric would allow 1 000 CFU to 10 000 CFU through during the test period that various woven and non-woven laminates allowed no penetration, and that non-woven single-use materials allowed between 150 CFU and 1 000 CFU through. The test is designed to discriminate between materials based on their anticipated particulate penetration properties. Recent tests show that newer materials, both reusable and single-use, are available on the market with lower or no measurable dry penetration.

The decision to only require dry penetration performance for ‘less critical product areas’ in Tables 1 and 2 is based on agreement in CEN/TC 205/WG 14 that if the critical product area meets the requirements for wet microbial penetration and hydrostatic head, then it will probably also provide

3) Project BIOBAR (Contract SMT4-CT96-2123) was funded through the Standards, Measurement and Testing programme, part of the Fourth Framework Programme funded by the European Commission, which investigated test methods for the evaluation of the barrier properties of textile materials against biological infective agents.

resistance against dry microbial penetration. However, the two penetration mechanisms are different, and the argument has never been demonstrated.

Dry penetration is intended to examine the ability of a material to prevent airborne transmission. The test is particularly relevant for the clean air suit, which is intended to prevent airborne transmission when made from a tight material and adequately designed.

There are, however, a variety of views on the relevance of airborne transmission for gowns. Whilst there is some evidence that airborne transmission is not prevented by a gown when used in operating rooms with turbulent ventilation [31], [32], many European countries do not use CAS, and therefore there is a body of opinion which believes that good dry penetration properties of gowns are necessary. There is also evidence for the role of gowns in controlling airborne bacterial counts when worn over standard surgical scrubs in operating rooms with laminar vertical downflow ultraclean air ventilation systems [33].

The current requirements in this document are a compromise between these two views.

B.8 Resistance to microbial penetration – wet

This test determines the resistance of a material to the penetration of bacteria from a dry surface through a material by the combined effect of friction, pressure and wetting [34]. The pressure is intended to mimic the type of pressure exerted by a surgeon's elbow during a procedure [35] and was developed specifically to measure the penetration by bacteria through operation materials of reusable or single-use material.

The method has been difficult to standardize, and multiple inter-laboratory comparisons have taken place where it has been difficult to demonstrate consistent results between laboratories. The method went into immediate revision after initial publication.

As the effects of the modifications of the test protocol on the test results have not yet been investigated and CEN/TC 205/WG 14 has not yet taken a decision on the presentation of results based on the modified test protocol the committee decided to prolong the existing requirements based on EN ISO 22610:2006. CEN/TC 205/WG 14 intends to adapt the performance requirements to the new test protocol as soon as sufficient data are available.

As in former versions of EN 13795-1, the barrier index I_B is specified to evaluate the conformity of materials with the wet microbial penetration requirements. For critical areas of high-performance products, a I_B of 6,0 is required. 6,0 is the maximum achievable value and means ‘no penetration’ for the purpose of this document. The requirements for critical areas of standard performance products have been agreed at lower level to anticipate the lower performance level.

The decision not to require wet microbial penetration performance for less critical product areas is based on experts’ opinion that a hydrostatic head of 10 cm offered sufficient resistance in these areas and reduced the requirement for extra wet microbial penetration testing. In addition, the pressure on less critical areas is lower, and the risks of strike-through of blood [36] and microbes are also reduced.

B.9 Labelling

The Medical Device Regulation allows manufacturers to use and explain symbols in their instructions for use. In principle experts regarded specifying a uniform set of instructions or symbols which would cover, for example, how to use drapes, as being a benefit for users when using different products. However, such a specification has not yet been developed und hence not included in this document. As labelling requirements are adequately covered in Section 23.2 of Annex I (General Safety and Performance Requirements) of the Medical Device Regulation (EU) 2017/745 the experts found no or only very little need to further specify the requirements in this document.

B.10 Treatment of results

The median, M_d, was chosen as the preferred summary statistic to the Mean because of the small sample size and its greater robustness to the influence of outliers. As a consequence, 25th and 75th percentiles (L_q and U_q respectively) were chosen as the test statistics for assessing compliance against the performance requirements in Tables 1 and 2. More simply, for PR_{min}, for five replicates the highest four shall pass and for 10 replicates the highest eight shall pass.

It was recognized that manufacturers and processors may wish to use means and standard deviations for quality assurance purposes, especially where more data would be generated leading to better estimates of population statistics and the more reliable setting of processing conditions.

Annex C
(informative)

Information on further characteristics

C.1 Comfort

The concept of comfort is based on several different factors, such as physiological comfort, ease of movement or factors that will influence and/or affect the individual's satisfaction with the product.

The thermophysiological comfort of a product depends on such properties as its thermal resistance, air permeability, water-vapour resistance, drapeability, tactile comfort and other properties like stretchability, weight, size, fit, fibres and manufacture.

NOTE 1 Drapeability addresses the ability of a material to conform to a given shape or object.

NOTE 2 Water-vapour resistance is defined as the water-vapour pressure difference between the two faces of a material divided by the resultant evaporative heat flux per unit area in the direction of the gradient. The evaporative heat flux can consist of both diffusive and convective components. EN ISO 11092 provides a test method for measuring the thermal and water-vapour resistance under steady-state conditions.

NOTE 3 Thermal resistance is a property of a material that can be measured by a thermal manikin in view to determine important parameters relevant to clothing thermal comfort.

NOTE 4 Tactile comfort also indicated as softness, is highly dependent on the fibre smoothness and the finish technologies.

NOTE 5 Properties such as stretchability, size fit, weight, can be measured.

Discomfort properties, such as rustling tendency, softness and skin irritation are difficult to measure. Evaluation should be based on trials of the products or practical experience.

C.2 Adhesion for fixation for the purpose of wound isolation

Adhesives are used to attach materials during the preparation for an operation and to attach drapes to a patient on the operating table. Different adhesives are chosen for different materials, e.g. material to material and material to the skin.

In choosing an adhesive, the following considerations should be taken into account:

a) Adhesives should not cause damage to the skin.

b) When used on reusable materials, the adhesives should be removable during processing without damaging the material.

c) The adhesive should create a seal-off from liquid and secure a sterile field.

C.3 Liquid control

The control of liquids, like body liquids or other liquids used or generated close to the wound during a surgical procedure, is regarded relevant to reduce the risk of transfer of infective agents.

Liquid control can be achieved by several means. Examples of test methods are given in the bibliography but it is regarded as technically impossible to specify a single test method, which addresses all aspects of liquid control and provides comparable results.

C.4 Flammability

Though surgical gowns and drapes do not provide ignition sources or oxidizer both products might serve as fuel, when a fire breaks out. Manufactures are required to supply information regarding fire risks in relation to the use of their products. This document does not specify further General Safety and Performance Requirements (GSPR) of Regulation (EU) 2017/745 on Medical Devices or Essential Health and Safety Requirements of Regulation (EU) 2016/425 on Personal Protective Equipment regarding flammability of surgical gowns and drapes.

C.5 Electrostatic discharge

CEN/TC 205/WG 14 discussed whether specific tests for Electrostatic Discharge (ESD) were necessary in this document.

After taking advice from clinicians, hospital engineers, experts in electromedical equipment and electrostatic engineers, CEN/TC 205/WG 14 note the following:

a) There are three potential risks from ESD:

   ESD damage to equipment;

   ESD ignition of flammable anaesthetic agents;

   ESD ignition of flammable vapours (specifically alcohols).

b) The electrostatic immunity requirement in IEC 60601-1-2:2014 is 15 kV. EN 61000-4-2:2009 has a useful graph in informative Annex A showing that synthetic fabrics can generate a maximum electrostatic voltage of 13 kV in rooms without humidity control (down to 15 %RH). Therefore, medical electrical equipment comply to the latest version of EN 60601-1-2 should be adequately protected from ESD.

c) Traditional risks associated with flammable anaesthetic agents no longer exist in hospitals as these agents have all been replaced with safer alternatives.

d) Use of flammable liquids in theatres is controlled, as diathermy would not be viable if there were a risk from sparks. Diathermy is a much greater risk than ESD.

Nowadays, the theoretical risks from ESD therefore appear low.

In addition, CEN/TC 205/WG 14 is unaware of actual reports of patient safety related incidents from ESD, and in the absence of such evidence believes there is no requirement to include ESD testing for gowns and drapes in this document.

CEN/TC 205/WG 14 notes that there are user comfort issues associated with static charge and ESD, and manufacturers can wish to take this into account when selecting materials and designing devices.

Annex D
(informative)

Environmental impact

In 2015, the European Commission called on European standardization organizations such as CEN to develop standards to help enable the transformation to a circular economy. This included material efficiency - the conservation of materials by making products more durable, resource-efficient and which facilitates the reuse or recycling of parts and/or materials at the end of life.

The goal of this Annex is to encourage inventors, designers, procurement, manufacturers, reprocessors, recyclers and users to also include environmental considerations when designing, using, and disposing surgical drapes and gowns, with the objective to minimize the environmental impact.

As this standard relates to both single-use and reusable products, end-of-life impacts are particularly important.

The need to minimize the potential adverse impacts on the environment of any products/material and of their packaging which occur over the life cycle, is recognized, and increasingly regulated around the world.

Surgical drapes and gowns, as with any other products, have an impact on the environment during all stages of their life cycle, e.g. extraction of resources; consumption of raw materials, water, and energy during production processes; emissions to water, soil, and air; and distribution and storage methods. Furthermore, it includes the intended usage, re-usage, recycling, and the end-of-life treatment including final disposal. All these impacts can range from slight to significant and are important to investigate.

The use of “life cycle thinking”, meaning consideration for all the environmental impacts of a product at all stages of its life cycle, applied to a product when making surgical drapes and gowns design decisions can have a significant impact.

Environmental aspects can be documented using a standard template, such as Table 1 of CEN Guide 4:2008. Manufacturers can use such a table to track performance, while others can use it to compare products for procurement.

The potential to reduce the environmental impact can be achieved by considerations in your procurement and tender process, for example:

— Consider how you can minimize water, energy and detergent use, both during manufacture and when reprocessing the medical devices;

— Consider minimizing raw material use during manufacturing;

— Consider materials which reduce greenhouse gas emissions and minimize the product's carbon footprint;

— Consider the environmental impact of the transport of both the raw materials and the final products, and how to minimize the supply chain to reduce unwanted emissions.

Manufacturers may take into consideration the different requirements, facilities and ability for recycling and recovery for a given geographical area. Manufacturers are encouraged to provide practical advice to purchasers and consumers on how to recycle or recover these resources. Modern supply chain technologies for traceability can be used to evaluate performance across the life cycle of a product.

Documents which are useful to manufacturers when considering the environmental impact of their design and material selection decisions include:

1. The Waste Framework Directive 2008/98/EC, which provides the concept of waste hierarchy, and which ranks the waste management practices from highest to lowest priority as follows: prevention, preparing for reuse, recycling, recovery, and disposal.

2. CEN Guide 4:2008, Guide for addressing environmental issues in product standards adopted by the CEN Technical Board through resolution BT C065/2008.

3. The ISO 59000 series of standards, currently under development by ISO/TC 323 (Circular Economy).

4. ISO 14001, Environmental management systems — Requirements with guidance for use

5. An Environmental Product Declaration (EPD) is defined by International Organization for Standardization (ISO) 14025 as a Type III declaration that "quantifies environmental information on the life cycle of a product to enable comparisons between products fulfilling the same function."(1) The EPD methodology is based on the Life Cycle Assessment (LCA)(2) tool that follows ISO series 14040.

6. "A European Strategy for Plastics in a Circular Economy" from the European Commission (2018).

7. ISO 14006:2020, Environmental management systems — Guidelines for incorporating ecodesign

8. "A new Circular Economy Action Plan For a cleaner and more competitive Europe" from the European Commission (2020)

Annex E
(informative)

Guidance to users for selecting products

E.1 Performance levels

This document introduces two performance levels ('standard performance' and 'high performance') for surgical gowns and drapes, thereby acknowledging the fact that products are challenged to differing extents during surgical procedures, dependent upon the duration, mechanical stress and liquid challenge throughout the surgical procedure. The differentiation of 'standard performance' from 'high performance' products is based on the barrier performance of the products in critical product areas.

NOTE 1 For details of the differences in the required barrier performance, see Tables 1 and 2.

By establishing two performance classes this document facilitates the assessment of the barrier performance of products. However, this document does not include specific recommendations for selecting surgical gowns or drapes with regard to the type of surgical procedure the product is to be used with.

The user will select surgical gowns and drapes based on their performance in order to meet the anticipated challenges of the surgical procedure (e.g. in terms of duration, mechanical stress and liquids). If the classification scheme provided by this document is not considered suitable to address the anticipated challenges during use, discrete test results for the characteristics to be evaluated can be taken as a basis for selecting products.

NOTE 2 The selection and use of surgical gowns and drapes for specific surgical procedures can be covered by risk assessment and quality management carried out by the user and can be subject to local, regional or national infection prevention regime, guidelines, directives or regulation.

E.2 Functional design

E.2.1 General

This document does not include specific requirements for the functional design of surgical gowns and drapes. The impact of functional design on the performance of products is acknowledged by requiring testing on the finished product including potential weak spots.

However, the functional design – in particular critical and less critical areas, the over-all size of the product and the characteristics of accessories (if any) – and its impact on the working situation (thermophysiological comfort and ergonomics) should be considered when selecting products for use.

E.2.2 Critical and less critical areas

This document acknowledges the fact that not all areas of the product are involved in the transfer of infective agents to or from the wound to the same extent. In order to set different performance requirements and allow for different product areas this document introduces 'critical product areas' and 'less critical product areas'.

NOTE 1 In general 'critical product areas' include those areas most likely to be exposed to blood and other body liquids as, e.g. front and sleeves of surgical gowns or the parts of surgical drapes adjacent to the surgical wound. The back of a surgical gown and part of surgical drapes being far from the wound are usually considered as 'less critical product areas'.

NOTE 2 For details of the differences in the required performance of 'critical product areas' and 'less critical product areas', see Tables 1 and 2.

This document does not include provisions for the size and position of 'critical' or 'less critical' product areas. The user needs to decide whether or not size and position of 'critical' and 'less critical' product areas are suitable to meet the anticipated challenges of a certain surgical procedure.

E.2.3 Size

This document does not include provisions for specifying the size of products in a standardized way.

Selecting products of suitable size in order to appropriately cover persons, patients and equipment is up to the user in order to ensure the intended use of the respective product.

NOTE Using products of inappropriate size might lead to insufficient covering, i.e. jeopardize the aim of minimizing the transfer of infective agents, and might impact freedom or safety of movements (e.g. with gowns to small or too big for the wearer).

E.2.4 Accessories

This document does not include specific provisions for accessories such as, e.g. cuffs or buttons.

As accessories do therefore not need to meet any requirements of this document, the user should assess the functional design with consideration to the placement of accessories so that the intended uses of the products are not compromised. The user should also assess the quality of any accessories in order to ensure that the intended uses of the products are not compromised.

E.2.5 Comfort

E.2.5.1 General

The functional design of products has an impact on the thermophysiological comfort.

NOTE 1 For more information on comfort, see C.1.

The user when selecting products for use should assess the comfort of products in order to exclude any significant limitations of the intended use of the product. Combinations of materials and design of clothing systems (including technical underwear or garments) that will minimize the physiological stress during work are to be encouraged.

NOTE 2 The comfort of surgical gowns and drapes depends on various characteristics, most of which can be evaluated using standardized test methods. More easily the overall comfort of surgical gowns and drapes can be assessed with trials (i.e. personal experience).

E.2.5.2 Surgical gowns

The overall comfort of surgical gowns can be influenced by a number of factors: design, fit, breathability, weight, surface thickness, electrostatic properties, colour, light reflectance, odour and skin sensitivity.

Other important variables that can influence comfort include undergarments, health and physical conditions, workload, mental stress and environmental conditions, such as temperature, relative humidity, and air changes in operating room.

The perception of comfort is subjective and can be influenced by one or a combination of the aforementioned factors.

E.2.5.3 Surgical drapes

Surgical drapes should be flexible so that they will cover the patient closely and smoothly, allowing placement and manipulation of instruments and draping of other related equipment, such as ring stands, back tables, and Mayo stands.

Liquid control is important for surgical drapes in operations with much blood or other liquids such as saline.

E.3 Practical trials

Not all the necessary properties of a product can be tested according to this document. The products should be tested practically in clinical situations where the end-user is going to apply them, to ensure that they are suitable from all important aspects including functionality and comfort. The practical trials should be evaluated before choice of products.

Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex ZA. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / subclause(s) of this EN	Remarks / Notes
6	5.1	Fitness for use considering the effects of clinical use and processing (if applicable) required
10.2	4, second sentence, A.2.8	Biocompatibility required
10.3	4, A.2.6, A.2.7	Protection against infective agents required
10.6	4, A.2.2	Limitation of particle release required
11.1, first sentence	4, A.2.1, A.2.6, A.2.7	Low bioburden of products and protection against microbial penetration required
11.2	5.2, 6.3	Requirements for processing of products including sterilization
14.2 b)	4, A.2.4, A.2.5	Requirements for bursting and tensile strength address the impact of pressure
14.2 c)	4, A.2.3	Resistance to liquid penetration required
23.4 i)	6.2	Requirement for provision of information on processing including sterilization
23.4 n)	6.2	Requirement for provision of information on processing including sterilization

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

Bibliography

[1] EN 14065, *Textiles - Laundry processed textiles - Biocontamination control system*

[2] EN 62366, *Medical devices — Application of usability engineering to medical devices*

[3] EN ISO 9073-6, *Textiles - Test methods for nonwovens - Part 6: Absorption (ISO 9073-6)*

[4] EN ISO 9073-11, *Textiles - Test methods for nonwovens - Part 11: Run-off (ISO 9073-11)*

[5] EN ISO 9073-12, *Textiles - Test methods for nonwovens - Part 12: Demand absorbency (ISO 9073-12)*

[6] EN ISO 9237, *Textiles - Determination of permeability of fabrics to air (ISO 9237)*

[7] EN ISO 10993-5, *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5)*

[8] EN ISO 10993-10, *Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10)*

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[10] EN ISO 11607-1, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1)*

[11] EN ISO 11607-2, *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2)*

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[14] EN ISO 15223-1, *Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1)*

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