ISO FORM 4

NEW WORK ITEM PROPOSAL (NP)

DATE OF CIRCULATION:
2023-06-18

CLOSING DATE FOR VOTING:
2023-09-12

REFERENCE NUMBER:
ISO 20384

PROPOSER:

☐ ISO member body:
Click or tap here to enter text.

☒ Committee, liaison or other:
ISO/TC 94/SC 13

☒ **WITHIN EXISTING COMMITTEE**
Document Number: N2119
Committee Secretariat: SNV

☐ **PROPOSAL FOR A NEW PC**

A proposal for a new work item within the scope of an existing committee shall be submitted to the secretariat of that committee.

A proposal for a new project committee shall be submitted to the Central Secretariat, which will process the proposal in accordance with ISO/IEC Directives, Part 1,Clause 2.3.

Guidelines for proposing and justifying new work items or new fields of technical activity (Project Committee) are given in ISO/IEC Directives, Part 1, Annex C.

IMPORTANT NOTE: Proposals without adequate justification and supporting information risk rejection or referral to the originator.

PROPOSAL
(to be completed by the proposer, following discussion with committee leadership if appropriate)

English title

Surgical clothing and drapes - Requirements and test methods

French title

Vêtements et champs chirurgicaux - Exigences et méthods d'essai

(Please see ISO/IEC Directives, Part 1, Annex C, Clause C.4.2).
In case of amendment, revision or a new part of an existing document, please include the reference number and current title

SCOPE
(Please see ISO/IEC Directives, Part 1, Annex C, Clause C.4.3)

This document gives information on the characteristics and performance requirements for surgical drapes, surgical gowns, and equipment covers used as medical devices for the purpose to create a sterile field, that are labelled with barrier performance claims and intended to minimize the transmission of infective agents between patients and clinical staff in health care facilities (e.g.,

single-use and reusable surgical gowns and surgical drapes used as medical devices for patients, clinical staff and equipment).

This standard specifies the following concerning the manufacturing and processing of the products specified above:

- test methods for evaluating the characteristics as identified in this document,

- performance requirements for these products,

- information to be supplied to users and third parties, for instance proper verifier authorities.

PURPOSE AND JUSTIFICATION

(Please see ISO/IEC Directives, Part 1, Annex C and additional guidance on justification statements in the brochure Guidance on New Work)

There is an undeniable, increasing, need for an international performance standard for surgical gowns, isolation gowns other protective apparel, surgical drapes, and drape accessories, especially regarding barrier performance.
Increasing globalization requires an international standard in order to facilitate global trade.
It is intended to promote global harmonization of the essential requirements of surgical gowns, isolation gowns and other protective apparel, and hence facilitating global patient safety goals.
(Please use this field or attach an annex)

PROPOSED PROJECT LEADER (name and email address)

Sven Schöppe (sven@leo-system.net)

PROPOSER (including contact information of the proposer's representative)

ISO/TC 94/SC 13 resolution 724/2022

☒ **The proposer confirms that this proposal has been drafted in compliance with ISO/IEC Directives, Part 1, Annex C**

PROJECT MANAGEMENT

Preferred document
☒ International Standard
☐ Technical Specification
☐ Publicly Available Specification*

* While a formal NP ballot is not required (no eForm04), the NP form may provide useful information for the committee P-members to consider when deciding to initiate a Publicly Available Specification.

Proposed Standard Development Track (SDT – to be discussed by the proposer with the committee manager or ISO/CS)

☐ 18 months ☐ 24 months ☒ 36 months

Proposed date for first meeting: 2023-09-14

Proposed TARGET dates for key milestones

- Circulation of 1st Working Draft (if any) to experts: 2023-09-14
- Committee Draft consultation (if any): 2024-06-30
- DIS submission*: 2025-06-30
- Publication*: 2026-06-30

* Target Dates for DIS submission and Publication should be set a few weeks ahead of the limit dates automatically determined when selecting the SDT.

It is proposed that this DOCUMENT will be developed by:

☒ An existing Working Group, add title ISO/TC 94/SC 13/WG 6

☐ A new Working Group Click or tap here to enter text.
(Note that the establishment of a new Working Group requires approval by the parent committee by a resolution)

☐ The TC/SC directly

☐ To be determined

☐ This proposal relates to a new ISO document

☐ This proposal relates to the adoption, as an active project, of an item currently registered as a Preliminary Work Item

☒ This proposal relates to the re-establishment of a cancelled project as an active project

☐ Other: Click or tap here to enter text.

Additional guidance on project management is available here.

PREPARATORY WORK

☒ A draft is attached

☐ An existing document serving as the initial basis is attached

☐ An outline is attached
Note: at minimum an outline of the proposed document is required

The proposer is prepared to undertake the preparatory work required:

☒ Yes ☐ No

If a draft is attached to this proposal:

Please select from one of the following options:

☒ The draft document can be registered at Preparatory stage (WD – stage 20.00)

☐ The draft document can be registered at Committee stage (CD – stage 30.00)

☐ The draft document can be registered at enquiry stage (DIS – stage 40.00)

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RELATION OF THE PROPOSAL TO EXISTING INTERNATIONAL STANDARDS AND ON-GOING STANDARDIZATION WORK

To the best of your knowledge, has this or a similar proposal been submitted to another standards development organization or to another ISO committee?

☐ Yes ☒ No

If Yes, please specify which one(s) Click or tap here to enter text.

☒ The proposer has checked whether the proposed scope of this new project overlaps with the scope of any existing ISO project

☐ If an overlap or the potential for overlap is identified, the proposer and the leaders of the existing project have discussed on:
i. modification/restriction of the scope of the proposal to avoid overlapping,
ii. potential modification/restriction of the scope of the existing project to avoid overlapping.

☐ If agreement with parties responsible for existing project(s) has not been reached, please explain why the proposal should be approved
Click or tap here to enter text.

☐ Has a proposal on this subject already been submitted within an existing committee and rejected? If so, what were the reasons for rejection?
Click or tap here to enter text.

This project may require possible joint/parallel work with
☐ IEC (please specify the committee) Click or tap here to enter text.
☐ CEN (please specify the committee) Click or tap here to enter text.
☐ Other (please specify) Click or tap here to enter text.

Please select any UN Sustainable Development Goals (SDGs) that this proposed project would support (information about SDGs, is available at www.iso.org/SDGs)

☐ GOAL 1: No Poverty
☐ GOAL 2: Zero Hunger
☒ GOAL 3: Good Health and Well-being
☐ GOAL 4: Quality Education
☒ GOAL 5: Gender Equality
☐ GOAL 6: Clean Water and Sanitation
☐ GOAL 7: Affordable and Clean Energy
☒ GOAL 8: Decent Work and Economic Growth
☒ GOAL 9: Industry, Innovation and Infrastructure
☐ GOAL 10: Reduced Inequality
☐ GOAL 11: Sustainable Cities and Communities
☐ GOAL 12: Responsible Consumption and Production
☐ GOAL 13: Climate Action
☐ GOAL 14: Life Below Water
☐ GOAL 15: Life on Land
☐ GOAL 16: Peace, Justice and strong institutions
N/A GOAL 17: Partnerships for the goals

Identification and description of relevant affected stakeholder categories
(Please see ISO CONNECT)

Benefits/Impacts/Examples

Industry and commerce – large industry	Better protection of patients and NSBs, CEN TC 205/WG14, AAMI healthcare worker and outside US and EU. Promote global harmonization of the essential requirements. Facilitating global patient safety goals.
Industry and commerce – SMEs	Better protection of patients and NSBs, CEN TC 205/WG14, AAMI healthcare worker and outside US and EU. Promote global harmonization of the essential requirements. Facilitating global patient safety goals.
Government	Better protection of patients and NSBs, CEN TC 205/WG14, AAMI healthcare worker and outside US and EU. Promote global harmonization of the essential requirements. Facilitating global patient safety goals.
Consumers	Better protection of patients and NSBs, CEN TC 205/WG14, AAMI healthcare worker and outside US and EU. Promote global harmonization of the essential requirements. Facilitating global patient safety goals.
Labour	Better protection of patients and healthcare worker and outside US and EU.
Academic and research bodies	Click or tap here to enter text.
Standards application businesses	Promote global harmonization of the essential requirements. Facilitating global patient safety goals.
Non-governmental organizations	Click or tap here to enter text.
Other (please specify)	Click or tap here to enter text.

Listing of countries where the subject of the proposal is important for their national commercial interests (Please see ISO/IEC Directives, Part 1, Annex C, Clause C.4.8)

Click or tap here to enter text.

Listing of external international organizations or internal parties (other ISO and/or IEC committees) to be engaged in this work (Please see ISO/IEC Directives, part 1, Annex C, Clause C.4.9)

CEN TC 205/WG 14, AAMI

Listing of relevant documents (such as standards and regulations) at international, regional and national level (Please see ISO/IEC Directives, Part 1, Annex C, Clause C.4.6)

Click or tap here to enter text.

ADDITIONAL INFORMATION

Maintenance Agencies (MAs) and Registration Authorities (RAs)

☐ This proposal requires the designation of a maintenance agency.
If so, please identify the potential candidate:
Click or tap here to enter text.

☐ This proposal requires the designation of a registration authority.
If so, please identify the potential candidate
Click or tap here to enter text.

NOTE: Selection and appointment of the MA or RA are subject to the procedure outlined in ISO/IEC Directives, Part 1, Annex G and Annex H.

Known patented Items (Please see ISO/IEC Directives, Part 1, Clause 2.14)

☐ Yes ☒ No

If Yes, provide full information as an annex

Is this proposal for an ISO management System Standard (MSS)?

☐ Yes ☒ No

Note: If yes, this proposal must have an accompanying justification study. Please see the Consolidated Supplement to the ISO/IEC Directives, Part 1, Annex SL or Annex JG

ISO 20384:2023(E)

ISO TC 94/SC 13/WG 6

Secretariat: SNV

Surgical clothing and drapes — Requirements and test methods
(Introductory element — Main element — Part #: Part title)

WD/CD/DIS/FDIS stage

Warning for WDs and CDs

This document is not an ISO International Standard. It is distributed for review and comment. It is subject to change without notice and may not be referred to as an International Standard.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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Contents

To update the Table of Contents please select it and press "F9".

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO *[had/had not]* received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee *[or Project Committee]* ISO/TC *[or ISO/PC]* ###, *[name of committee]*, Subcommittee SC ##, *[name of subcommittee]*.

This second/third/… edition cancels and replaces the first/second/… edition (ISO #####:####), which has been technically revised.

The main changes are as follows:

— xxx xxxxxxx xxx xxxx

A list of all parts in the ISO ##### series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

ISO 20384 has been developed for both single-use and reusable surgical clothing and drapes.

Surgical gowns are intended to be used to minimize the transmission of infective agents between patients and clinical staff during surgical and other invasive procedures, helping to prevent post-operative wound infections and protect the clinical staff.

The transmission of infective agents during invasive surgical procedures may occur in several ways and consequently the performance required of coverings for patients, equipment and clinical staff depends on a variety of influences of which the most important are listed below:

- Type of the procedure
- Duration of the procedure
- Wetness of the operation field
- Mechanical stress on the materials
- Susceptibility of the patient to infection
- Resistance to the penetration of liquids

[TO-DO] Replace the list with formula from CDC - **info from G. Driessen**

ISO 20384 is intended to assist both manufacturers and users in various aspects as mentioned below:

1. Manufacturers
    a. Design
    b. Processing
    c. Selection of materials
2. Users
    a. Communication between manufacturers, healthcare worker users and third parties
    b. Product characteristics
    c. Selection of products
    d. Performance
    e. Requirements
    f. Assessment

The Classification system of protective apparel and medical drapes is elucidated and schematically shown in Annex B

Identification of patent holders: the following text shall be included if patent rights have been identified.

The International Organization for Standardization (ISO) *[and/or] International Electrotechnical Commission (IEC)* draw[s] attention to the fact that it is claimed that compliance with this document may involve the use of a patent.

ISO *[and/or] IEC* take[s] no position concerning the evidence, validity and scope of this patent right.

The holder of this patent right has assured ISO *[and/or] IEC* that he/she is willing to negotiate licences under reasonable and non-discriminatory terms and conditions with applicants throughout the world. In this respect, the statement of the holder of this patent right is registered with ISO *[and/or] IEC*. Information may be obtained from the patent database available at www.iso.org/patents.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights other than those in the patent database. ISO *[and/or] IEC* shall not be held responsible for identifying any or all such patent rights.

Surgical clothing and drapes — Requirements and test methods
(Introductory element — Main element — Part #: Part title)

1 Scope

This document gives information on the characteristics and performance requirements for surgical drapes, surgical gowns and equipment covers used as medical devices for the purpose of creating a sterile field, that are labelled with barrier performance claims and intended to minimize the transmission of infective agents between patients and clinical staff in health care facilities (e.g., single-use and reusable surgical gowns and surgical drapes used as medical devices for patients, clinical staff and equipment).

This document specifies the following concerning the manufacturing and processing of the products specified above:

1. test methods for evaluating the characteristics as identified in this document,
2. performance requirements for these products,
3. information to be supplied to users and third parties, for instance proper verifier authorities.

The above-mentioned products shall meet the requirements of this document. However, this document does not cover requirements for antimicrobial treatment of those products. Antimicrobial treated medical gowns and drapes shall meet the requirements of this document.

This document does not cover the following products, requirements and provisions.

1. Protective apparel for the hands, such as surgical gloves, patient examination gloves, and other medical gloves;
2. Protective apparel for the head, face, and eyes, such as goggles, face shields, surgical caps, surgical masks, and respirators;
3. Protective apparel for the feet, such as operating room shoes, shoe covers, and surgical boots;
4. Other types of protective clothing worn by health care personnel, such as apparel that is not intended or labelled as a barrier to liquid or microorganisms (e.g., surgical scrubs, cover coats) and apparel or equipment that is used when handling hazardous chemicals, chemotherapeutic agents, or hazardous wastes;
5. Absorbent operating room towels;
6. Interfaces between products, such as the gown/glove interface;
7. Requirements for incise drapes and drape accessories like fluid collection pouches,
8. All of the requirements necessary to ensure the safety and effectiveness of the products within the scope of this document;
9. All of the labelling or other information that a health care facility might deem necessary or desirable in product selection;
10. Protection from dry particulate and dry microbial penetration;

11. Manufacturing, quality assurance, or purchasing specifications;

2 Normative references

Two options of text (remove the inappropriate option).

1) The normative references shall be introduced by the following wording.

[2021 ISO SIMPLE Template text requirement] 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.

[2020-12 WD 20384 Text proposal] The following referenced documents are indispensable for the application 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.

ISO 811: *Textiles — Determination of resistance to water penetration — Hydrostatic pressure test*

ISO 9073-3: *Textiles — Test methods for nonwovens — Part 3: Determination of tensile strength and elongation*

ISO 139: *Textiles — Standard atmospheres for conditioning and testing (ISO 139:2005)*

ISO 9073-10: *Textiles — Test methods for nonwovens — Part 10: Lint and other particles generation in the dry state*

ISO 9073-*16: Textiles — Test methods for nonwovens — Part 16: Determination of resistance to penetration by water (hydrostatic pressure)*

ISO 10993-1: *Biological evaluation of Medical devices — Part 1: Evaluation and testing within a risk management system*

ISO 11737-1: *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)*

ISO 13938-1: *Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension (ISO 13938-1:1999)*

ISO 16603: *Clothing for protection against contact with blood and body fluids -- Determination of the resistance of protective clothing materials to penetration by blood and body fluids -- Test method using synthetic blood*

ISO 16604: *Clothing for protection against contact with blood and body fluids -- Determination of resistance of protective clothing materials to penetration by blood-borne pathogens -- Test method using Phi-X 174 bacteriophage*

ISO 18659: *Textiles -- Determination of resistance to water penetration -- Impact penetration test*

ISO 22610: *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)*

ISO 22612: *Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration (ISO 22612:2005)*

ASTM F1671: *Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System*

ANSI/AAMI PB70:2012: *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities*

AATCC 127: Water Resistance: Hydrostatic Pressure Test

3 Terms and definitions

Four options of text (remove the inappropriate options).

1) If all the specific terms and definitions are provided in Clause 3, use the following introductory text:

For the purposes of this document, the following terms and definitions apply.

3.1 barrier properties

Ability of a protective product to resist the penetration of liquids, airborne and liquid borne microorganisms, or dry microorganisms.

[Source AAMI PB70:2012 - modified]

3.2 biocompatibility

the ability to be in contact with a living system without producing an adverse effect

[Source: Pure and Applied Chemistry. 84 (2): 377–410. 2012. doi:10.1351/PAC-REC-10-12-04.ed, "Terminology for biorelated polymers and applications (IUPAC Recommendations 2012)]

3.3 blood-borne pathogen

Infectious bacterium, virus, or other disease-inducing microbe carried in blood or other body fluids.

[Source AAMI PB70:2012]

3.4 body fluid

Any liquid produced (secreted or excreted) by the body.

Note 1 to entry: For purposes of this document, body fluids include those liquids potentially infected with bloodborne pathogens, including, but not limited to, blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.

[Source AAMI PB70:2012]

3.5 cfu (colony forming unit)

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.

[Source EN 13795-1:2019]

3.6 cleanliness

freedom from unwanted foreign matter

Note 1 to entry: Such matter can be micro-organisms, organic residues or particulate matter.

[Source EN 13795-1:2019]

3.7 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'.

[Source EN 13795-1:2019]

3.8 critical area

Area of protective apparel, including surgical gowns and surgical drapes where direct contact with blood, body fluids, and other potentially infectious materials (OPIMs) is most likely to occur.

[Source: AAMI PB70;2012 - modified]

3.9 dry microbial penetration

ability of microorganisms to penetrate through material in dry conditions.

3.10 infective agent

micro-organism that has been shown to potentially cause infections

3.11 surgical procedure

surgical intervention performed by a surgical team

[Source: EN 13795-1:2019].

3.12 isolation gown

item of protective apparel used to protect health care personnel, patients and environment from the transfer of microorganisms, particles, and body fluids

[Source AAMI PB70:2012, modified]

3.13 less critical product area

product area where direct contact with blood, body fluids, and OPIMs is less likely to occur.

[Source: EN 13795-1:2019 - modified].

3.14 liquid penetration

migration of liquid(s) through the material

Note 1 to entry: liquid penetration is also called strikethrough.

[Source: EN 13795-1:2019- modified].

3.15 manufacturer

natural or legal person with responsibility for the design, manufacture, packaging, and/or labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

[Source: EN 13795-1:2019].

Note 1 to entry: a re-processor is considered as manufacturer of the product.

Note 2 to entry: In different parts of the world, different sets of regulatory frameworks may apply for these products and for the manufacturers.

3.16 Surgical gown

Gown used to protect the patient, the wearer, or the environment during the peri-operative process within the operating room and PACU.

Note 1 to entry: Medical gowns include surgical gowns. However, some types of medical gowns, e.g. Isolation gowns, are not intended to be used as surgical gowns.

3.17 microbial penetration

migration of micro-organisms, including viruses, from one side of a material through to the other.

[Source: EN 13795-1:2019 - modified].

3.18 particle release

particle release of fiber fragments and other particles during mechanical stress.

[Source: EN 13795-1:2019 - modified].

3.19 performance level

discrete standard defined to classify products according to the performance requirements of this document.

[Source: EN 13795-1:2019].

3.20 Processor / reprocessor

natural or legal person who processes products so that their performance complies with the requirements of this document.

[Source: EN 13795-1:2019].

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 2017/745). References in EN 13795 / ISO 20384 to 'processors' include 'reprocessors' and to 'processing' include 'reprocessing'.

3.21 *protective apparel*

item of clothing that is specifically designed and constructed for the purpose of isolating all or part of the body from a potential (biological) hazard or isolating the external environment from contamination by the wearer of the clothing.

Note 1 to entry: Examples of protective apparel include isolation gowns, decontamination garments, aprons, and sleeve protectors.

Note 2 to entry: Protective apparel includes also hoods, not being caps used operating rooms to cover head and facial hair, and protective shoe covers.

[Source: AAMI PB70;2012]

3.22 reusable product

product intended by the manufacturer to be reprocessed and reused.

[Source: EN 13795-1:2019].

3.23 single-use product

product intended to be used only once.

3.24 sterile field

area created by sterile surgical drape, gown, equipment cover material.

3.25 surgical drape

a covering for the patient for the prevention of transfer of infective agents.

3.26 equipment cover

a device intended to be used as sterile or non-sterile cover for equipment.

Note 1 to entry: For instance, instrument table, C-arms, camera covers, etc.

3.27 surgical gown

a device intended to be worn during surgical procedures to protect both the patient and the wearer from the transfer of microorganisms, body fluids, and particulate matter.

[Source AAMI PB70:2012 - modified]

3.28 synthetic blood

mixture of red dye/surfactant, thickening agent, and distilled water having a surface tension and viscosity representative of blood and some other body fluids and the color of blood.

[Source AAMI PB70:2012 - modified]

3.29 *wet microbial penetration*

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

[Source: EN 13795-1:2019 - modified].

Products mentioned and used within the scope of this document may be regarded as medical devices as well as/or personal protective equipment in different parts of the world, and different sets of regulatory frameworks may apply for these products and for the manufacturers.

Note 1 to entry: The first intended use of surgical gowns and surgical drapes is to protect the patient where the first intended use of protective apparel is to protect the user.

The list below is always included after each option:

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
term
text of the definition

Note 1 to entry: Text of the note.

[SOURCE: …]

3.2
term
text of the definition

4 General requirements

4.1 General

Products within the scope of this document shall meet all the requirements specified in this document, when tested according to this document throughout their useful life.

If the manufacturer does not specify product areas, all areas shall meet at least level 1 performance requirements with exception of isolation gowns which will meet level 0 requirements.

4.2 Manufacturing and processing requirements and documentation

The manufacturer/processor shall establish a formal quality management system including requirements for the product development, design, production, testing, packaging, labelling, distribution and provision of related services. The quality management system shall include a risk management procedure where inputs for product realization shall include the outputs from risk management.

For reusable products, processing and life-cycle control shall be included in the quality management system.

The requirements of this document shall be met and documented that the fitness for the intended purpose has been established for each use, both for single-use and reusable medical devices.

A quality system such as ISO 13485 is recommended. For processing of reusable products ISO 13485 may be applied in accordance with EN 14065 (Convener: AAMI ST 65 to be added as applicable?).

NOTE ISO 13485 specifies requirements for a quality management system enabling an organization to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. However, as the primary objective of ISO 13485 is to facilitate harmonized medical device regulatory requirements for quality management systems, it includes some particular requirements for medical devices but also excludes some of the requirements of ISO 9001 that are not appropriate as regulatory requirements. Because of the exclusions, organizations whose quality management systems conform to ISO 13485 cannot claim conformity to ISO 9001 unless their quality management systems conform to all the requirements of ISO 9001.

NOTE 2 For packaging for terminally sterilized medical devices is referred to the ISO 11607 series.

A clinical evaluation for surgical drapes and gowns shall be carried out. The performance of the full draping and gowning system shall be considered in order 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.

4.3 Barrier properties

The classification of multiple-use products shall be based on their performance at the end of the labelled use-life (i.e., at the end of the simulated life cycle performance).

The classification of the product shall indicate the performance of the critical zone component having the lowest barrier performance. The performance of seams between and within critical zones shall meet the requirements of this document. The performance of seams between critical and less critical zones shall meet at least the requirements of the adjacent less critical zone.

4.4 Biocompatibility

The manufacturer shall complete the evaluation of the products according to ISO 10993-1, determine the applicable toxicology testing regime, and report the results of testing and evaluation according to the applicable parts of the ISO 10993 series.

5 Performance requirements

To comply with this document, products shall meet all the requirements specified in Table 1, when tested according to this Document throughout their useful life.

Table 1 — Surgical gowns and drapes

Characteristic	Clause	Test method	Unit	ID 1 (MD)	ID 2 (MD)	Performance levels to pass			
				Inside	*Outside*	0	1	2	3
Resistance to microbial penetration — Dry	A.2	ISO 22612	CFU			N.A.	Req.	Req.	Req.
Resistance to microbial penetration — Wet	A.2	ISO 22610	% penetration			N.A.	Req.	Req.	Req.
Resistance to water penetration - Impact penetration test	A.3.2	ISO 18695	g			Req.	N.A.	N.A.	N.A.
Resistance to water penetration - Impact penetration test - Hydrostatic pressure test	A.3.3	ISO 18695 ISO 811	g cm			N.A.	Req Req	Req Req	? ?
Liquid penetration - Resistance to Synthetic blood[a]	A.3.4	ISO 16603	kPa			N.A.	N.A.	Req.	Req.
	A.3.4	ASTM F1670	kPa			N.A.	N.A.	Req.	Req.
Liquid penetration - Resistance to bacteriophage Phi-X174; surgical gown[b]	A.3.5	ISO 16604	KPa			N.A.	N.A.	N.A.	Pass
	A.3.5	ASTM F1671	KPa			N.A.	N.A.	N.A.	Pass
Cleanliness microbial / Bioburden	A.4	ISO 11737-1	CFU/ 100 cm^2			N.A.	Req.	Req.	Req.
Particle release	A.5	ISO 9073-10	$\log_{10}$ (lint count)			N.A.	Req.	Req.	Req.
Bursting strength — Dry[c]	A.6	ISO 13938-1	kPa			N.A.	Req.	Req.	Req.
Bursting strength — Wet[c]	A.6	ISO 13938-1	kPa			N.A.	Req.	Req.	Req.
Tensile strength — Dry	A.7	ISO 9073-3	N			Req.	Req.	Req.	Req.
Tensile strength — Wet	A.7	ISO 9073-3	N			Req.	Req.	Req.	Req.

5.1 [Subclause autonumber]

6 Information to be supplied with the product

6.1 General

Technical literature shall be provided by the manufacturer upon request. This literature shall contain detailed information on the performance of a product in each level.

NOTE This information may take the form of a graphical representation of the product showing the level of barrier performance of each component, a narrative description of the level of barrier performance of each component, or both.

6.2 Labelling

The products shall be prominently labelled stating the level of barrier performance for each relevant performance area on that product, as determined in accordance with this document.

Each product or package containing surgical gowns, isolation gowns, other items of protective apparel, having a critical area shall be prominently labelled identifying the areas with different performance levels and the performance level of the relevant area(s), using one of the two options mentioned below.

1. A so-called 'long hand description', identifying the critical area and the corresponding performance level.

2. Every product is labelled, identifying the critical area and the corresponding performance level, in the shipping papers, instructions for use and/or the product(s) package using the following designation system.

    - Less critical area; indication of the performance level LC0, LC1, LC2, or LC3, according to Table 1

    - Critical area; indication of the performance level: CA1, CA2, or CA3, according to Table 1.

Each product having areas that do not meet at least the requirements for Level '0' barrier performance shall be prominently labelled with a warning stating “Partially Non-Protective”.

NOTE Additional labelling requirements may be used as e.g. FDA labelling requirements applicable to all medical devices.

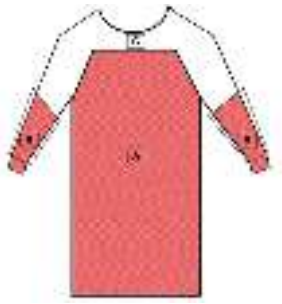

Figure 1 — Example of a medical gown with designation

Key

— A, Critical Area; C1

— B, Critical Area; C2

— C, Less critical Area; L2

6.3 Education

The manufacturer may provide technical information and/or training explaining the performance level classification system and its implications for the end-user. Thereafter, the end-user is responsible for making judicious selections of products according to (a) the performance level of the product and (b) the anticipated degree of exposure of health care personnel to blood, body fluids, and OPIM during a given procedure or activity.

6.4 Information on critical and less critical areas

The manufacturer or processor shall differentiate between the critical and less critical areas of the product, if applicable, and identify the different areas (6.1). In addition to this, information shall be provided according to the legal requirements.

EXAMPLE For the European legal requirements is referred to the ~~*Europe Medical Device Directive 93/42/EEC*~~ / Medical Device Regulation 2017/745.

A certificate stating that the product meets the minimum performance requirements of this document shall be supplied upon request. The manufacturer shall provide efficient labelling and information about intended use of the product or product system. The labelling shall include information on the performance level of the product (6.2.2).

NOTE In different parts of the world, different sets of regulatory frameworks may apply for these products and for the manufacturers.

Annex A
(normative)

Test methods and conformance

A.1 General

Testing shall be performed on the finished product. If the product is intended to be used after sterilization, testing shall be carried out on products after sterilization with the exception of microbial cleanliness. Testing shall include potential weak spots based on a risk assessment carried out by the manufacturer, e.g. seams and tie attachments not described in Clause 4.3.

Test specimens shall be taken from different products from the same lot. If multiple tests must be performed (e.g., the critical zone consists of more than one component, such as the base material, a seam, and a point of attachment), then test specimens for each component may be taken from the same product.

If the test area of the finished product is too small to perform the test a representative sample of the same material may be used. The representative sample shall be treated in the same way as the finished product.

During manufacture and processing, testing shall be carried out in within a formal quality system.

All test results and test conditions shall be recorded.

If a test method in this document is used for quality control or to support broad product claims concerning the properties of materials used in protective clothing, proper statistical design and analysis of lager data sets than those specified in the test methods should be performed. Examples of acceptable sampling plans are found in references such as ISO 2859-1 and AAMI PB70.

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 ISO 9001 and ISO 13485 contain requirements for suitable quality systems. Additional requirements may be specified by a country or a region.

NOTE 3 Other, alternative, test methods for monitoring may be used, provided that they address the same characteristic, are validated and comparable or correlating results can be obtained.

A.2 Resistance to dry and wet microbial penetration

The determination resistance to dry and wet microbial penetration applies to all products specified in this document, excluding products used for equipment covering.

The resistance to dry microbial penetration shall be determined on 10 test specimens according to EN ISO 22612. The arithmetic mean of the 10 results shall at least meet the requirements for the relevant performance level as specified in Table 1.

For evaluation of the resistance to wet microbial penetration the product shall be tested according to ISO 22610. Report mean percentage of penetration. The mean result shall meet at least the requirement for the relevant performance level as specified in Table 1.

Any antimicrobial treatment of the product shall be reported as this may significantly influence the results.

A.3 Resistance to liquid penetration

A.3.1 General

The determination of resistance to liquid penetration applies to all products specified in this document. The determination of resistance to liquid penetration shall be carried out using the test method(s) for the relevant level as specified in Table 1. If the direction of the liquid penetration through the product to be tested is not specified in the relevant test standard, the direction of test shall be indicated by the manufacturer and reported.

If, in the design of the product, different materials are specified at separate locations, either inside or outside of the critical zones, specimens shall be selected from each location.

Test specimens shall be taken from different products from the same lot. If multiple tests must be performed (e.g., the critical zone consists of more than one component, such as the base material, a seam, and a point of attachment), then test specimens for each component may be taken from the same product.

NOTE Simulating the critical design and construction features of the product is acceptable if it can be demonstrated that the simulated products are representative of actual production.

A.3.1.1 Resistance to liquid penetration according to ISO 18695; Impact penetration test

The determination of the resistance to liquid penetration according to ISO 18695 applies only to performance level 'zero' products (Table 1).

The resistance to liquid penetration according to ISO 18695 shall be determined on at least 3 test specimens.

Report the individual results and mean percentage of penetration. All individual results and the mean result shall meet at least the requirements for the relevant performance level 'zero' as specified in Table 1.

NOTE When materials and components are tested according to ISO 18695, it is important to position the test specimens the same way every time. Seams should be centered and extend down the full length of the specimen; any points of attachment should be positioned in the center of the specimen.

A.3.1.2 Resistance to liquid penetration according to ISO 811; Hydrostatic pressure test

The resistance to water penetration liquid according to ISO 811, Hydrostatic pressure test, shall be determined using at least 5 specimens and applying the following test conditions and supplementary instructions;

- the test area shall be 100 cm^2;
- the rate of increase of water pressure shall be (10 ± 0,5) cm/min;
- the side of the product in contact with the test liquid shall be the outer side,
- a support screen may be applied. A piece of netting, 20 cm x 20 cm, with approximately 3 cm diameter holes may be used as fabric support. If a net support is used this shall be reported.
- For highly stretchable material the test is finished after the requirement value + 10% has been reached

Report the individual results and mean percentage of penetration. All individual results shall meet at least the requirements for the relevant performance level as specified in Table 1.

Kommentiert [jrb1]: Why individual when others are averages?

NOTE 1 As some nonwovens, such as a melt-blown fabric, exhibit low tensile strength, a nylon web or net screen may be used to support the sample. This simulates the effect of a bonded laminate and prevents the weight of the water from tearing or stretching the material. Nylon netting may be obtained from a local fabric store. See ISO 9073-16.

NOTE 2 When materials and components are tested according to ISO 811, it is important to position the test specimens the same way every time. Seams should be centered across the width of the specimen. Any points of attachment should be positioned in the center of the specimen.

A.3.1.3 Resistance to liquid penetration according to ISO 16603; Test method using synthetic blood

The determination of the resistance to liquid penetration applies to all performance level 3 critical zone components of medical gowns and surgical drapes.

The selection of the test method and procedure, ISO 16603 (procedure A, B, C, or D) or ASTM F1670, shall be made based on the task analysis and on the degree of exposure anticipated.

The resistance to liquid penetration according to ISO 16603 shall be determined using the pressure/time sequence according to the procedure chosen.

The resistance to liquid penetration according to ASTM F1670 shall be determined using the pressure/time sequence as stated in the standard.

For both ISO 16603 and ASTM F1670 a retaining screen may be used to support the specimen (method B). If method B is used the type of retaining screen shall be specified.

The resistance to liquid penetration shall be determined using three specimens taken randomly from each material, composite, area (in the case of heterogeneous design), or other condition.

Report the individual results, including which standard (ISO 16603 or ASTM F1670) and procedure (A, B, C, or D) has been used in the testing. All individual results shall pass the test (Table 1). Any evidence of appearance of synthetic blood or wetness for a test specimen constitutes failure.

A.3.1.4 Resistance to liquid penetration according to ISO 16604; Test method using Phi-X 174 bacteriophage

The determination of the resistance to liquid penetration, using bacteriophage Phi X174, applies to all performance level 3 critical zone components of surgical gowns, isolation gowns, or other protective apparel products.

The selection of the test method and procedure, ISO 16604 (procedure A, B, C, or D) or ASTM F1671, shall be made based on the task analysis and on the degree of exposure anticipated.

The resistance to liquid penetration according to ISO 16604 shall be determined using the pressure/time sequence according to the procedure chosen.

The resistance to liquid penetration according to ASTM F1671 shall be determined using the pressure/time sequence as stated in the standard.

For both ISO 16604 and ASTM F1671 a retaining screen may be used to support the specimen (method B). If method B is used the type of retaining screen shall be specified.

The resistance to liquid penetration, using bacteriophage Phi X174, shall be determined using three specimens taken randomly from each material, composite, area (in the case of heterogeneous design), or other condition.

Protective clothing materials incorporating an impervious layer between two fabric layers may give rise to false positive failures due to wicking effects at the edges. In this case, the edges of the test specimens shall be sealed to prevent "wicking" modes of failure using an adhesive, para-film, paraffin wax, or adhesive-backed foam prior to testing. Only the edges of the test specimens shall be sealed, leaving the center 57 mm area open for testing. Do not allow sealants to intrude, block, or occlude the structure of the test specimen in the test area, as this may compromise the test procedure. Choose sealants and sealing methods that are compatible with the protective clothing materials.

Report the individual results, including which procedure (A, B, C, or D) has been used in the testing. All individual results shall pass the test (Table 1). Any evidence of viral penetration for a test specimen constitutes failure.

NOTE 1 When qualifying the integrity of materials, supporting broad product claims, or using the test as a quality control and assurance procedure, the test should be modified for larger data sets with proper statistical design and analysis.

NOTE 2 False positives can be minimized by following standard microbiological regimes and proper aseptic techniques. If test results are in doubt, repeat the test using statistically valid sample methods.

A.3.2 Cleanliness microbial / bioburden

The determination of Cleanliness microbial/bioburden applies to all products within the scope of this document.

For evaluation of cleanliness, microbial, the product shall be tested according to ISO 11737-1 using at least 5 specimens and applying the stomaching method.

Note: in some cases, the non-destructible method mentioned in ISO 11737-1 may be preferred.

Report the individual results and mean percentage of penetration. All individual results shall meet at least the requirements for the relevant performance level as specified in Table 1.

NOTE ISO 11737-1 does not provide a fixed test method but specifies requirements for test methods and test mechanisms. The different test methods ISO 11737-1 provide comparable results. For further information on the stomacher method is referred to ISO 11737-1.

A.3.3 Particle release

The determination of particle release applies to all products within the scope of this document.

The particle release of the product shall be determined according to EN ISO 9073-10 using at least 10 specimens, 5 for each side of the material. If the test equipment is located in a laminar flow hood the laminar flow during the test shall be validated.

The coefficient of linting shall be calculated for particles in the size range 3 µm to 25 µm.

Report the individual results and mean percentage of penetration. All individual results shall meet at least the requirements for the relevant performance level as specified in Table 1.

NOTE 1 Particles in the size range 3 µm to 25 µm are considered to be capable of carrying bacteria.

A.3.4 Bursting strength in dry and wet state

The determination bursting strength applies to all products within the scope of this document. The direction of the product to be tested shall be indicated by the manufacturer and reported.

The bursting strength test, in dry and wet state, shall be determined according to ISO 13938-1 using at least 5 test specimens for each state.

For highly stretchable material the test is finished after the requirement value + 10% has been reached or if the measurement capability of the instrument is exceeded.

Report the individual results and mean percentage of penetration. All individual results shall meet at least the requirements for the relevant performance level as specified in Table 1.

NOTE 1 When testing some nonwovens that exhibit low tensile strength, such as a melt-blown fabric, a nylon web or net screen may be used to support the sample. This would simulate the effect of a bonded laminate and prevent the weight of the water from tearing or stretching the material. The use of the nylon support should be agreed upon by all parties and all parties should be fully aware of its effects. The test in this document is normally done with the use of the nylon support. Nylon netting may be obtained from a local fabric store. See ISO 9073-16.

Kommentiert [SS2]: I don't think this is appropriate for this testing?

The preparation of samples for wet state testing shall be performed according to ISO 9073-3. The test conditions shall be reported.

The pressure measured at first break shall be reported. The lowest value is reported if both sides of the products are relevant.

Report the individual results and mean pressure measured at first break. All individual results shall meet at least the requirements for the relevant performance level as specified in Table 1.

NOTE 2 If testing of both sides of material lead to different results, both sides should be tested, and the results should be recorded.

Kommentiert [SS3]: How do you know this is the case unless you test the material on both sides?

A.3.5 Tensile strength in dry and wet state

The determination of the tensile strength applies to all products within the scope of this document.

The determination of the tensile strength shall be carried out according to ISO 9073-3, in wet and dry state and both in longitudinal and in lateral directions, using 5 specimens for each state and each direction.

The maximum force measured shall be reported. If laminated materials show two break points when tested, the maximum force at second break shall be reported.

Report the individual results and mean tensile strength for both states and both directions. All individual results shall meet at least the requirements for the relevant performance level as specified in Table 1.

A.4 Test report

The test report shall include the following information

a) a reference to this International Document;

b) all details necessary for complete identification of the sample;

c) the test methods carried out;

d) all results as specified for the relevant test methods carried out;

e) the date of the test.

Annex B
(informative)

Classification of surgical gowns and drapes

The structure for the classification of surgical gowns and drapes is based on the following considerations:

- Surgical gowns and drapes are categorized into four levels according to their performance, as shown in Figure 1. This classification reflects the different performance levels necessary on the one hand (and the possible special location of critical and less critical areas) of the product.
- For each classification, reference is made to a specific set of requirements.
- Critical area properties are those properties which are considered critical for the intended application of the product.
- Less critical area properties are those properties which are considered less critical for the intended application of the product.

NOTE critical / less-critical area to be specified by the manufacturer

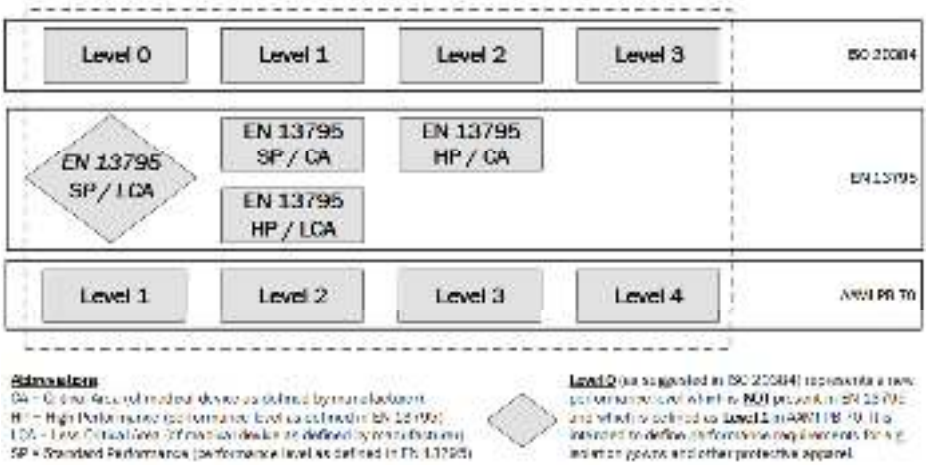

Figure A.1 — Relation EN 13795 - AAMI PB70 and Classification of surgical gowns, drapes

NOTE 1 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 2 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.

NOTE 3 Level '0' are supportive articles/apparel with basic protective characteristics, not intended to be used as medical device.

Annex C
(informative)

Rationales

[ATTENTION: this section originates from EN 13795-1:2019 with kind permission from CEN/TC 205/WG 14]

C.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.

C.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 XXX CFU (Table 1) 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.

C.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 x µm to xx µm has been chosen based on the opinion that particles smaller than x µm are too small to carry microorganisms, and particles larger than xx 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*".

C.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 xx cm, xx cm, xx cm and xx cm H_2O (Table 1) 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 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 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 WG 14 to only allow a 10 cm/min rate of rise when testing to compliance for this document.

C.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 (Table 1) are based on manufacturer's experience of products deemed to be clinically suitable in the market place.

C.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 (Table 1) are based on manufacturer's experience of products deemed to be clinically suitable in the market place.

Table 1 has 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.

C.7 Resistance to microbial penetration – dry

Dry bacterial penetration EN ISO 22612 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 ≤ XXX CFU (Table 1) appears to be partially based on the results of the BIOBAR project[1)] 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 Table 1 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 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.

1) 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.

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.

C.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. 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.

C.9 Labelling

The Medical Device Directive 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 13 of Annex I (Essential Requirements) of the Medical Device Directive the experts found no or only very little need to further specify the Essential Requirements in this document.

C.10 Treatment of results

The Median, M_d, was chosen as the preferred 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 Table 1. More simply, for PR_{min}, for five replicates the highest four shall pass and for 10 replicates the highest eight shall pass. The method for determining L_q and U_q in A.3 gives the statistical justification for this.

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.

EN 13795:2023 Amendments to above text:

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 Table 1);

— $U_q \leq PR_{max}$ (see Table 1); 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 D
(informative)

Information on further characteristic

[ATTENTION: this section originates from EN 13795-1:2019 with kind permission from CEN/TC 205/WG 14]

D.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.

D.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.

D.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.

D.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 essential requirements of Directive 93/42/EEC on Medical Devices or basic health and safety requirements of the Directive 89/686/EEC on Personal Protective Equipment regarding flammability of surgical gowns and drapes.

D.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, WG14 note the following:

a) There are three potential risks from ESD:

   1. ESD damage to equipment;
   2. ESD ignition of flammable anaesthetic agents;
   3. 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 E
(informative)

Guidance to users for selecting products

[ATTENTION: this section originates from EN 13795-1:2019 with kind permission from CEN/TC 205/WG 14]

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 Table 1.

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 has 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.

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[ATTENTION: this section originates from ISO WD 20384, 2019-03, Hangzhou]

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[3] AATCC TM127: Water Resistance — Hydrostatic Pressure Test

[ATTENTION: this section originates from EN 13795-1:2019 with kind permission from CEN/TC 205/WG 14]

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

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

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