

Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment —

Part 2: Test methods

The European Standard EN 13795-2:2004 has the status of a
British Standard

ICS 11.140

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- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 10, an inside back cover and a back cover.

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Amendments issued since publication

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 6 December 2004

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ISBN 0 580 44954 8

Amd. No.	Date	Comments

English version

Surgical drapes, gowns and clean air suits, used as medical
devices for patients, clinical staff and equipment - Part 2: Test
methods

Champs chirurgicaux, casques et tenues de blocs, utilisés
comme dispositifs médicaux, pour les patients, le
personnel médical et les équipements - Partie 2: Méthodes
d'essai

Operationsabdecktücher, -mäntel und Rein-Luft-Kleidung
zur Verwendung als Medizinprodukte für Patienten,
Klinikpersonal und Geräte - Teil 2: Prüfverfahren

This European Standard was approved by CEN on 15 October 2004.

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Foreword

This document (EN 13795-2:2004) has been prepared by Technical Committee CEN/TC 205 "Non-active medical devices", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2005, and conflicting national standards shall be withdrawn at the latest by May 2005.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

EN 13795 is expected to consist of the following parts under the general title "*Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment*":

Part 1: *General requirements for manufacturers, processors and products*

Part 2: *Test methods*

Part 3: *Performance requirements*

Originally EN 13795 was also to include Part 3: *Test method for resistance to dry microbial penetration* and Part 4: *Test method for resistance to wet microbial penetration*. However, it has been decided that these parts will now be developed by the Vienna Agreement/CEN lead route in conjunction with ISO/TC 94/SC 13. As a result, what was to have been EN 13795-3 is published as EN ISO 22612 *Clothing for protection against infectious agents – Test method for resistance to dry microbial penetration*, what was to have been EN 13795-4 will be published as EN 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/DIS 22610:2004)* and what was to have been EN 13795-5 will be published as EN 13795-3.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

General requirements for surgical drapes, gowns and clean air suits, used as medical devices, for patients clinical staff and equipment are specified in EN 13795-1. In this respect, EN 13795-1 specifies the relevant characteristics to be evaluated for products covered by this document.

NOTE For more information on products which are either included or not included in this document, refer to EN 13795-1.

The EN 13795 series of European Standards, together with EN ISO 22610 and EN ISO 22612, is intended to assist the communication between users, manufacturers and third party verifiers with regard to material or product characteristics. It focuses on relevant Essential Requirements arising from the Medical Device Directive 93/42/EEC. The general requirements and guidance in EN 13795-1 are expected to be of help to manufacturers, test houses and users when designing, processing, assessing and selecting products. It is the intention of EN 13795 to ensure the same level of safety from single-use and reusable surgical clothing and drapes throughout their useful life.

1 Scope

This EN 13795-2 specifies test methods for evaluating characteristics of surgical drapes, gowns and clean air suits.

NOTE 1 Test methods are specified by referring to a standard test method and, if necessary, specifying amendments to adapt the test method for the purpose of this document.

NOTE 2 EN 13795-2 does not cover a test method for evaluating adhesion for fixation for the purpose of wound isolation as there is no suitable test method for adhesion to human skin available at present. For more information on adhesion for fixation for the purpose of wound isolation see EN 13795-1: 2002, Annex B.

2 Normative references

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.

EN 1174-1, *Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 1: Requirements.*

EN 1174-2: 1996, *Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 2: Guidance.*

EN 1174-3, *Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 3: Guide to the methods for validation of microbiological techniques.*

EN 13795-1: 2002, *Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Part 1: General requirements for manufacturers, processors and products.*

EN 20139, *Textiles — Standard atmospheres for conditioning and testing (ISO 139:1973).*

EN 20811, *Textiles - Determination of resistance to water penetration — Hydrostatic pressure test.*

EN 29073-3, *Textiles — Test methods for nonwovens — Part 3: Determination of tensile strength and elongation.*

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

prEN 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/DIS 22610:2004).*

EN ISO 22612, *Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration (ISO 22612:2004).*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 13795-1:2002 and the following apply.

3.1

cfu (colony forming unit)

unit by which the culturable number of microorganisms is expressed

NOTE The culturable number is the number of microorganisms, single cells or aggregates, able to form colonies on a solid nutrient medium.

3.2

product

surgical gown, surgical drape including equipment covering and clean air suit

4 Testing requirements

4.1 General

If the product is to be used after sterilization, the test shall be performed on products after sterilization with the exception of cleanliness – microbial.

Testing shall include potential weak spots.

4.2 Atmospheres for conditioning and testing

Where the standard test methods do not specify the atmosphere for pre-conditioning, conditioning and testing, the specifications of EN 20139 shall be applied.

Prior to testing, the samples shall be conditioned in the relaxed state.

5 Test methods

5.1 Test method for evaluation of cleanliness – microbial

For evaluation of cleanliness – microbial, product shall be tested according to the standards of EN 1174–1, EN 1174-2 and EN 1174-3, using a stomaching method in accordance with 5.2.4.2 of EN 1174-2:1996.

NOTE The standards of the EN 1174 series do not provide a fixed test method but specify requirements for test methods and test mechanisms. The requirements of the EN 1174 series are such that different test methods developed in accordance with EN 1174-1: 1996, 5.2.4.2 provide comparable results.

The result shall be expressed as cfu/100 cm².

5.2 Test method for evaluation of cleanliness – particulate matter

For estimation of cleanliness - particulate matter, product shall be tested according to ISO 9073-10.

NOTE 1 ISO 9073-10 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.

The following specific amendments apply for the purpose of this document for estimation of cleanliness – particulate matter:

NOTE 2 This procedure cannot distinguish between particulate matter and linting for this time period and includes both.

a) Particle counts for the size range 3µm to 25µm shall be calculated.

NOTE 3 Particles of this size range are considered to be capable of carrying microorganisms.

- b) Particle counts from time steps 30 s, 60 s and 90 s shall be added together for the calculation of particulate matter PM:

$$PM = C_{30} + C_{60} + C_{90}$$

The result of the test shall be reported as the index for particulate matter (IPM) expressed as \log_{10} of particulate matter: $IPM = \log_{10} PM$."

5.3 Test method for evaluation of linting

For evaluation of linting product shall be tested according to ISO 9073-10.

NOTE 1 ISO 9073-10 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.

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.

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

5.4 Test method for evaluation of resistance to liquid penetration

For evaluation of resistance to liquid penetration product shall be tested according to EN 20811.

The following specific amendments to the procedure in EN 20811 apply for the purpose of EN 13795-2:

- a) The test area shall be 100 cm²;
- b) The rate of increase of water pressure shall be $(10 \pm 0,5)$ cm/min;
- c) The side of the product in contact with the test liquid shall be the outer side.

5.5 Test method for evaluation of bursting strength in dry and wet state

For evaluation of bursting strength, product shall be tested according to EN ISO 13938-1. The preparation of samples for wet state testing shall be performed according to EN 29073-3.

NOTE 1 The test conditions should be specified in the test report.

NOTE 2 If there are differences in the test results of both sides of material, both sides should be tested and the results should be recorded.

5.6 Test method for evaluation of tensile strength in dry and wet state

For evaluation of tensile strength, product shall be tested according to EN 29073-3 in the wet and dry states both in longitudinal and in lateral directions.

5.7 Test methods for evaluation of liquid control

If absorption is a factor claimed by the manufacturer in order to have liquid control then evaluation is recommended as follows:

- a) Distilled or deionised water shall be used as test liquid.
- b) Results shall be reported in %RO (run off) and in retention percentages given as follows:
 $\%Retention = 100 - \%RO$.
 $\%Retention$ is thus the amount of liquid retained by the material.

NOTE Liquid control can be achieved by several mechanisms. 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.

5.8 Test method for evaluation of resistance to dry microbial penetration

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

5.9 Test method for evaluation of resistance to wet microbial penetration

For evaluation of resistance to wet microbial penetration the product shall be tested according to prEN ISO 22610.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC Medical devices

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC Medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.1, 5.1, 5.2, 5.3, 5.4, 5.7	7, 8	EN 13795-2 is intended to be used in conjunction with EN 13795-1 and prEN 13795-3
5.5, 5.6	4, 5	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Bibliography

- [1] ISO 9073-11, *Textiles — Test methods for nonwovens — Part 11: Run-off.*
- [2] ISO 9073-12, *Textiles — Test methods for nonwovens — Part 12: Demand absorbency.*

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