FELIX MEDICAL FABRICS

EN 13795
UNDERSTANDING THE EUROPEAN STANDARD
SURGICAL GOWNS, DRAPES AND CLEAN AIR SUITS

INTRODUCTION

European Standard EN 13795 aims to establish requirements for surgical drapes, gowns and clean air suits used as medical devices for patients, clinical staff and equipment.

Felix sees EN 13795 as a vital advancement towards improved safety and protection of people and has therefore strongly supported the drafting efforts of the text. It is Felix"s intention to further contribute to the education and information dissemination across the healthcare profession in matters related to this important Standard.

This booklet provides healthcare professionals, medical devices manufacturers and administrators with up to date information on the EN 13795 Standard and its relationship to other European legislation in the field of medical devices. It also describes the implications of the Standard for the daily work practices of healthcare workers in Europe.

THE CONTEXT OF THE EUROPEAN STANDARD EN 13795

In 1998, the European Committee for Standardization (CEN) and its Technical Committee 205 Non-active Medical Devices received a mandate from the European Commission to establish a harmonized European Standard EN 13795 for surgical gowns, drapes and clean air suits. This brochure introduces the reader to the results of that work.

THE SCOPE OF THE NEW STANDARD WAS DEFINED AS FOLLOWS

This Standard specifies information to be supplied to users and third party verifiers in addition to the usual labelling of Medical Devices concerning manufacturing and processing requirements. It gives general guidance on the characteristics of single-use and re-usable surgical gowns, surgical drapes and clean air suits used as medical devices for patients, clinical staff and equipment. It is intended to prevent the transmission of infectious agents between patients and clinical staff during surgical and other invasive procedures.

ENHANCING THE MEDICAL DEVICE DIRECTIVE

EN 13795 closes the missing technical link to compliance with the regulations of the European Council Directive 93/42/EEC that is often referred to as Medical Device Directive (MDD). The Medical Device Directive was published in 1993 and became mandatory in all European and EFTA countries in 1998 superseding prior existing national legislation. MDD applies to all medical devices and describes the essential requirements in a broad manner.

The essential requirements regulate the design and construction of medical devices and clarify key parameters for ensuring that medical devices will not compromise the safety and health of patients and healthcare professionals. These parameters include the conditions for their safe use, storage, transport and labelling as well as for their chemical, microbiological and physical properties. Each device is classified as Class I, Class II or Class III depending on its intended purpose and its associated risks. Class I covers non-invasive devices such as surgical gowns, drapes and clean air suits. Classes II and III deal with devices that bear a higher risk potential for patients and healthcare workers.

Medical devices that comply with the provisions of the Medical Devices Directive will receive the CE mark as the visible indication to users that the device can be safely used and provides the correct level of protection.

The new Standard defines the essential requirements for surgical gowns, drapes and clean air suits. The European Standard EN 13795 consists of 3 separate parts.

PART I GENERAL REQUIREMENTS FOR MANUFACTURERS, PROCESSORS AND PRODUCTS - EN 13795-1

Part I defines the general requirements for the design, processing, assessment and selection of products. The objective is to ensure the same level of safety from single-use and re-usable surgical clothing and drapes **throughout their entire useful life**.

PART II TEST METHODS - EN 13795-2

Part II of the standard describes the test methods to be used to evaluate the product characteristics indicated in Part I.

PART III PERFORMANCE REQUIREMENT AND PERFORMANCE LEVEL - EN 13795-3

A Performance Requirements matrix divides covered products into standard performance and high performance classes. The matrix is then subdivided into critical and less critical product areas.

High performance products shall be used for surgical interventions with a high infection risk due to the length or intensity of the surgical intervention.

Critical product areas are defined as product areas that are more likely to be involved in the transfer of infectious agents to or from a wound, such as the front or sleeves of a surgical gown.

In the case of surgical gowns and drapes, labelling of products put on the market shall include a clear indication of critical and less critical product areas, as designed by the manufacturer.

The European Standard does not provide any recommendation for the end user as to which product shall be used for a specific surgical intervention.

For this, the healthcare provider needs to perform a risk assessment for the surgical intervention in question and can request guidance for this from his provider of surgical gowns and drapes.

PART I - EN 13795-1 GENERAL REQUIREMENTS FOR MANUFACTURERS, PROCESSORS AND PRODUCTS

INFORMATION TO BE SUPPLIED BY MANUFACTURER OR PROCESSOR OF THE PRODUCTS - EN 13795-1

TABLE 1 CHARACTERISTICS TO BE EVALUATED IN SURGICAL GOWNS

Characteristic
Resistance to microbial penetration – dry
Resistance to microbial penetration – wet
Cleanliness – microbial
Cleanliness – particulate matter
Linting
Resistance to liquid penetration
Bursting strength – dry
Bursting strength – wet
Tensile strength – dry
Tensile strength – wet

TABLE 2 CHARACTERISTICS TO BE EVALUATED IN SURGICAL DRAPES

Characteristic
Resistance to microbial penetration – dry
Resistance to microbial penetration – wet
Cleanliness – microbial
Cleanliness – particulate matter
Linting
Resistance to liquid penetration
Bursting strength – dry
Bursting strength – wet
Tensile strength – dry
Tensile strength – wet
Adhesion for fixation for the purpose of wound isolation

TABLE 3 CHARACTERISTICS TO BE EVALUATED IN CLEAN AIR SUITS

Characteristic
Resistance to microbial penetration – dry
Cleanliness – microbial
Cleanliness – particulate matter
Linting
Bursting strength – dry
Tensile strength – dry

GENERAL REQUIREMENTS

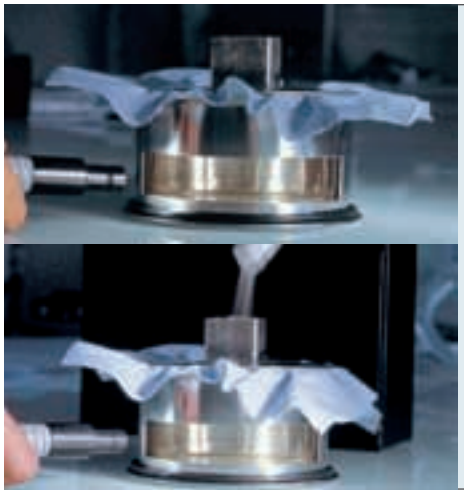
The manufacturer or processor must:

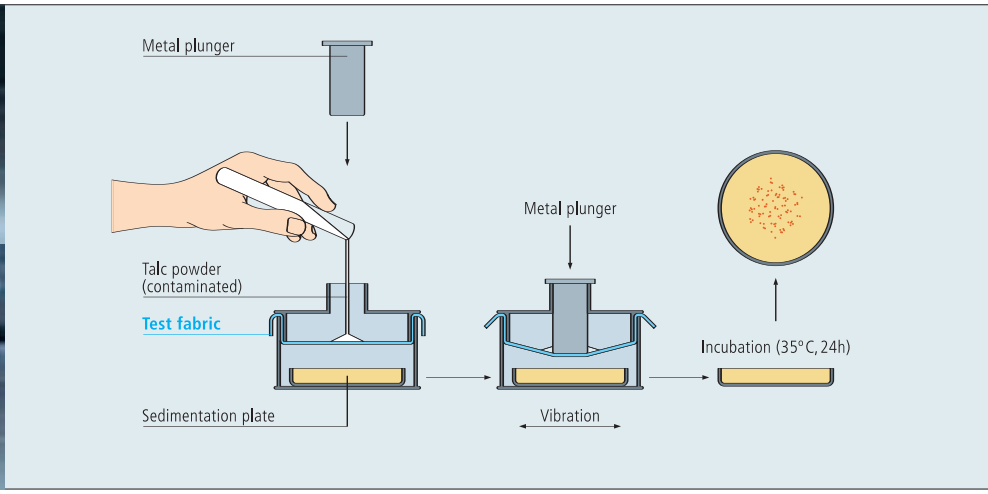
- for re-usable devices: provide information on the appropriate process to allow re-use (cleaning, disinfection, packaging, sterilization methods) including number of re-uses and any restriction to the re-use
- for sterile devices: provide instructions for sterilization methods
- differentiate between critical and less critical areas on the device, where appropriate, as well as physical identification of these areas
- upon request, reference test methods used, and corresponding test results (see Tables 1, 2, and 3), differentiating critical and less critical areas with appropriate rationale for the differentiation
- use validated manufacturing and processing procedures

General product requirements:

- it shall be possible to demonstrate that the product requirements of EN 13795 are met (see Tables 4, 5 and 6), and test results shall be recorded and retained
- the finished product (after sterilization if appropriate) shall be tested prior to commercialization
- during manufacturing and processing, testing shall be done according to the requirements of the manufacturer's or processor's quality system

TEST OF RESISTANCE TO MICROBIAL DRY PENETRATION - EN ISO 22612





The test method is designed to determine the ability of materials to resist penetration of particles carrying micro-organisms under dry fabric conditions.

The method establishes the quantity of micro-organisms that can penetrate through the test material being carried on talcum powder.

Test results are expressed in CFU (colony forming units) that were observed on the agar plate.

Performance requirements

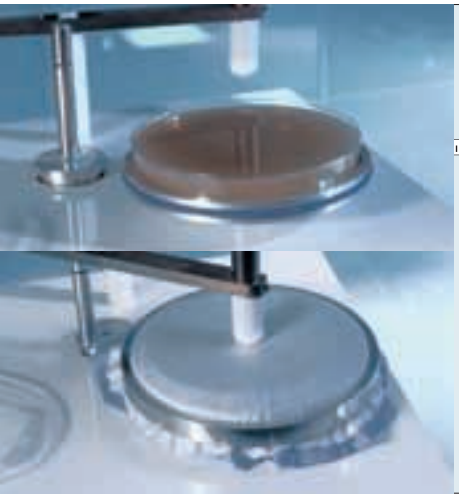
Unit	Surgical gowns				Surgical drapes				Clean air suits
	Standard Performance		High Performance		Standard Performance		High Performance		Requirement[e]
	critical area	less critical area	critical area	less critical area	critical area	less critical area	critical area	less critical area	
Log_{10} (CFU)	N/A	≤ 2 [a,c]	N/A	≤ 2 [a,c]	N/A	≤ 2 [a,c]	N/A	≤ 2 [a,c]	≤ 2 [a,c]

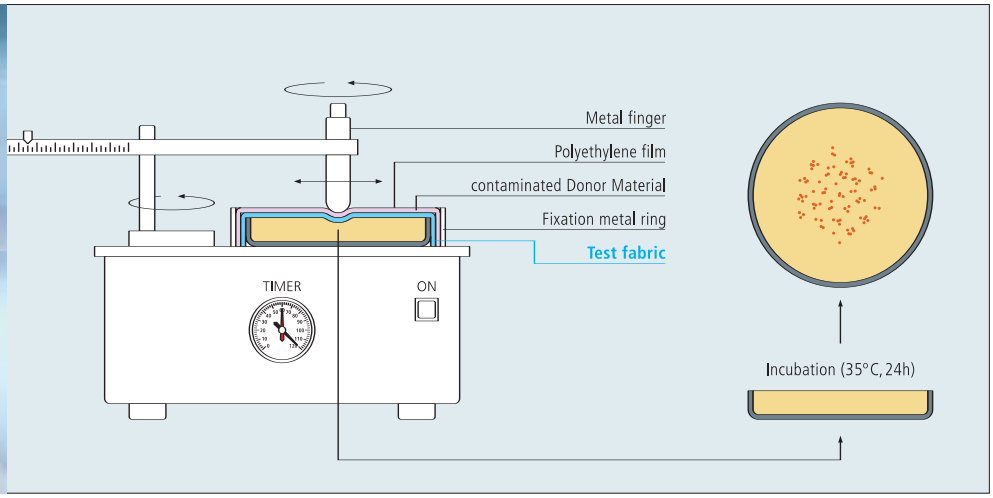
a Test conditions: challenge concentration 10^8 CFU/g talc. and 30 minutes vibration time.

c For the purpose of this standard, log_{10} CFU ≤ 2 means maximum 300 CFU.

e Performance requirements apply for all product areas of clean air suits, as clean air suits should be used in addition to surgical gowns and not as a substitute.

TEST OF RESISTANCE TO MICROBIAL WET PENETRATION - EN ISO 22610





The purpose of this test is to evaluate the ability of fabrics to resist microbial penetration under conditions of liquid pooling on the fabric and mechanical stress.

Test results are expressed in BI “Barrier Index”.

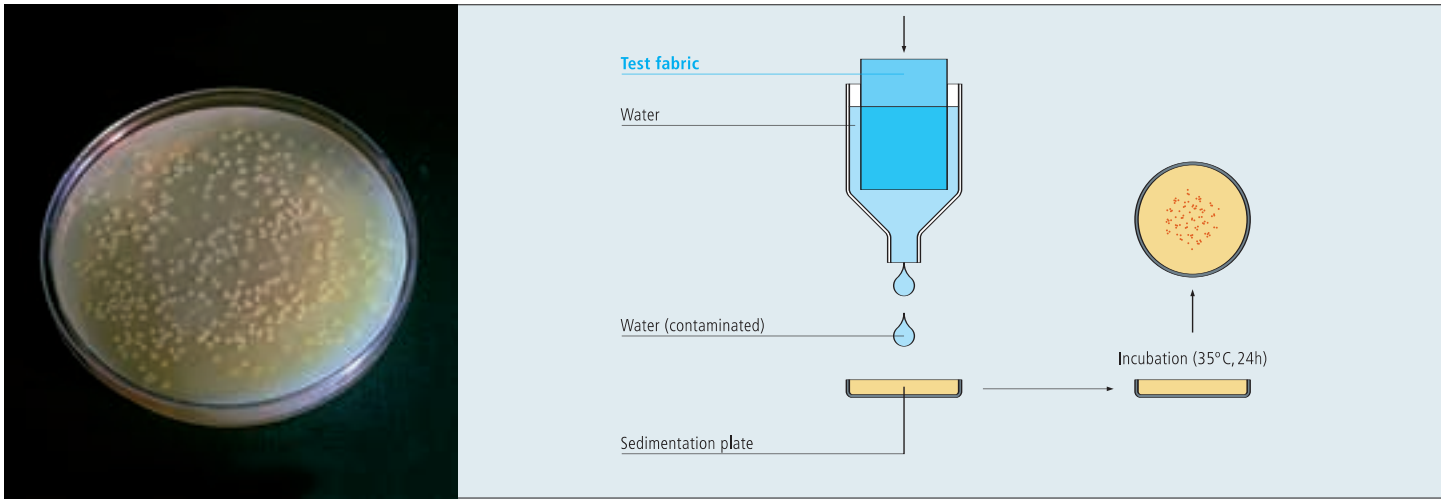
Performance requirements

	Surgical gowns				Surgical drapes				Clean air suits
Unit	Standard Performance		High Performance		Standard Performance		High Performance		Requirement
	critical area	less critical area	critical area	less critical area	critical area	less critical area	critical area	less critical area	
BI	≥ 2,8[b]	N/A	6,0[b,d]	N/A	≥ 2,8[b]	N/A	6,0[b,d]	N/A	N/A

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

d BI = 6,0 for the purpose of this standard means: no penetration. BI = 6,0 is the maximum achievable value.

TEST OF MICROBIAL CLEANLINESS EN 1174



Microbial cleanliness determines the bioburden, meaning the number of viable micro-organisms on the product.

Microbial cleanliness is especially important to achieve sterilization and a sterilization assurance level of 10^{-6} as is required to label a product as sterile.

For products that are not sold as sterile, the test method allows assessment of their potential for microbial contamination.

The test results are expressed in a decimal logarithm of CFU (colony forming units) per plate. Lower numbers indicate a better cleanliness.

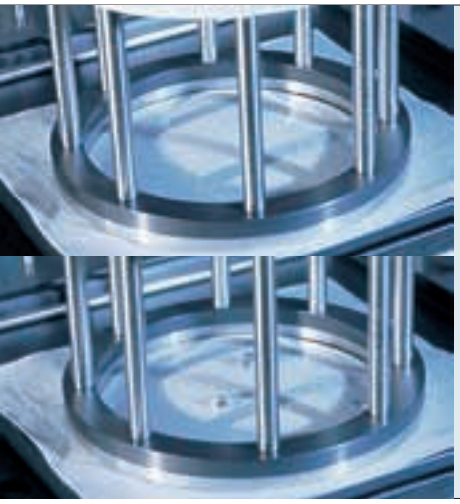
Performance requirements

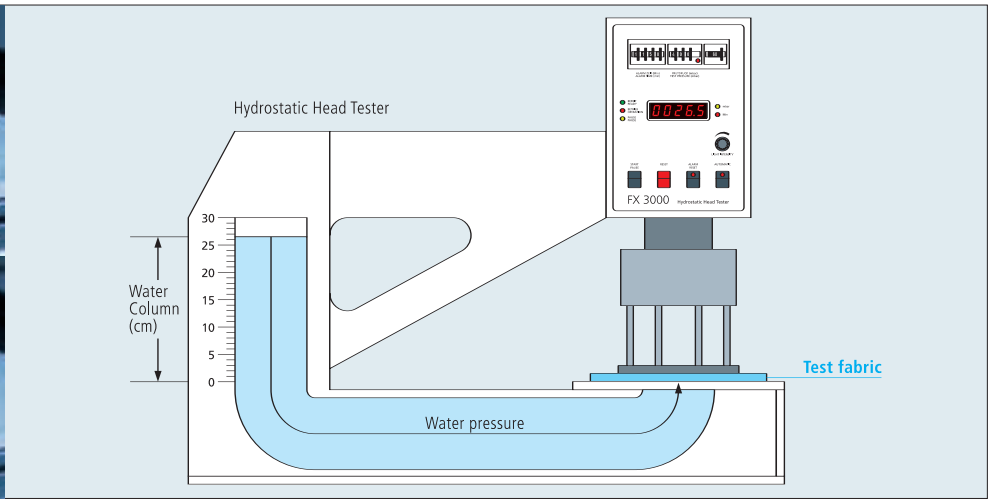
	Surgical gowns				Surgical drapes				Clean air suits
Unit	Standard Performance		High Performance		Standard Performance		High Performance		Requirement[e]
	critical area	less critical area	critical area	less critical area	critical area	less critical area	critical area	less critical area	
Log_{10} (CFU/dm²)	≤ 2[c]	≤ 2[c]	≤ 2[c]	≤ 2[c]	≤ 2[c]	≤ 2[c]	≤ 2[c]	≤ 2[c]	≤ 2[c]

c For the purpose of this standard, log_{10} CFU ≤ 2 means maximum 300 CFU.

e Performance requirements apply for all product areas of clean air suits, as clean air suits should be used in addition to surgical gowns and not as a substitute.

TEST OF RESISTANCE TO LIQUID PENETRATION - EN 20811





This test method evaluates the behaviour of the fabric structure under increasing hydrostatic pressure. When sufficient pressure is applied, water will penetrate the fabric and liquid strike-through occurs.

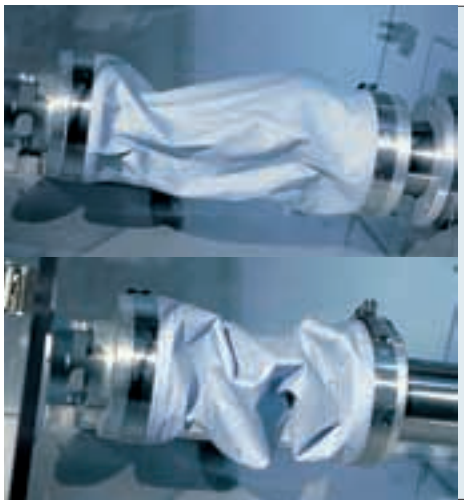
Protection against contamination due to liquid penetrating surgical garments is of critical importance for both staff and patients.

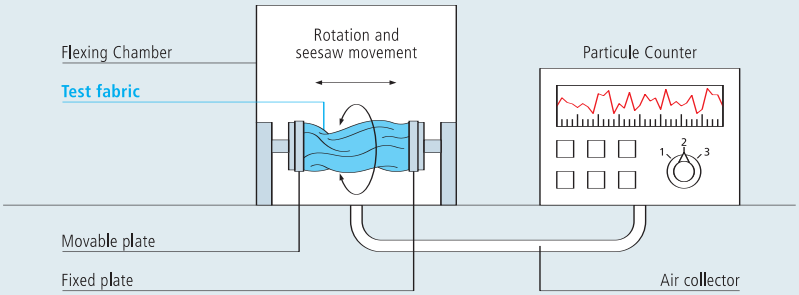
Test results are expressed in water column (cm) and higher values indicate a better resistance.

Performance requirements

	Surgical gowns				Surgical drapes				Clean air suits
Unit	Standard Performance		High Performance		Standard Performance		High Performance		Requirement
	critical area	less critical area	critical area	less critical area	critical area	less critical area	critical area	less critical area	
cm H_2O	≥ 20	≥ 10	≥ 100	≥ 10	≥ 30	≥ 10	≥ 100	≥ 10	N/A

TEST FOR LINTING AND CLEANLINESS-PARTICULATE MATTER - ISO 9073-10





The same piece of equipment is used to measure linting and cleanliness - particulate matter, and the respective indexes result from the same test method. The device measures the number of particles in the size range between 3 to 25 microns that are released from the product while subjected to predefined cyclic torsional and axial efforts. Cleanliness particulate matter emphasizes rapid release of particles whereas linting is a measure of a longer-term particle reserve in the product.

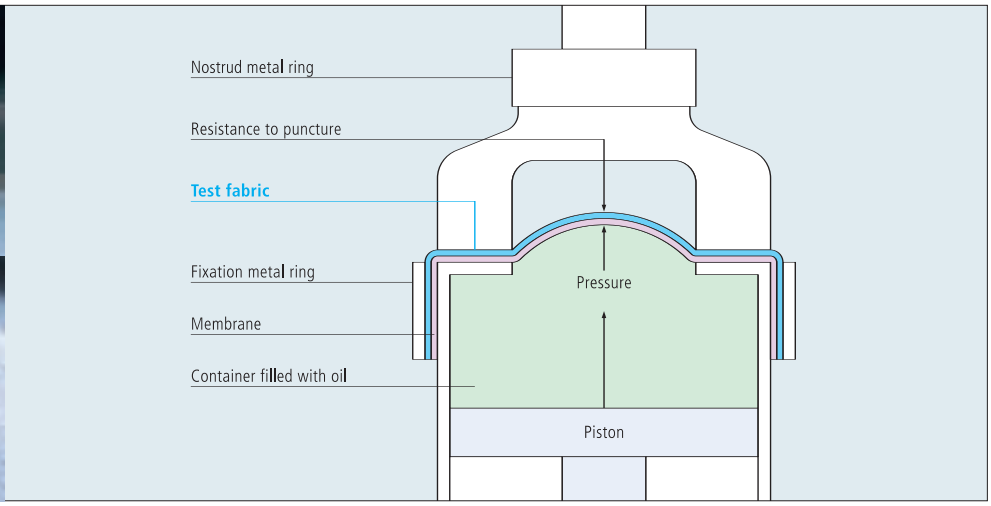
The test method simulates the effort being put into the fabric during medical staff practice exercise. Particles in the size range between 3 and 25 microns are considered capable of transporting infectious agents, and are therefore characterized.

Performance requirements

Unit	Surgical gowns				Surgical drapes				Clean air suits
	Standard Performance		High Performance		Standard Performance		High Performance		Requirement[e]
	critical area	less critical area	critical area	less critical area	critical area	less critical area	critical area	less critical area	
IPM	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5
Log_{10} (lint count)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0

e Performance requirements apply for all product areas of clean air suits, as clean air suits should be used in addition to surgical gowns and not as a substitute.

TEST OF BURSTING STRENGTH EN ISO 13938



This test measures the resistance of a fabric to burst or puncture.

Some areas of surgical garments may be subject to burst or puncture stress during use in the operating theatre. For example, the surgeon's elbow or instruments used in the operation may cause damage by exerting pressure on small areas of the fabric.

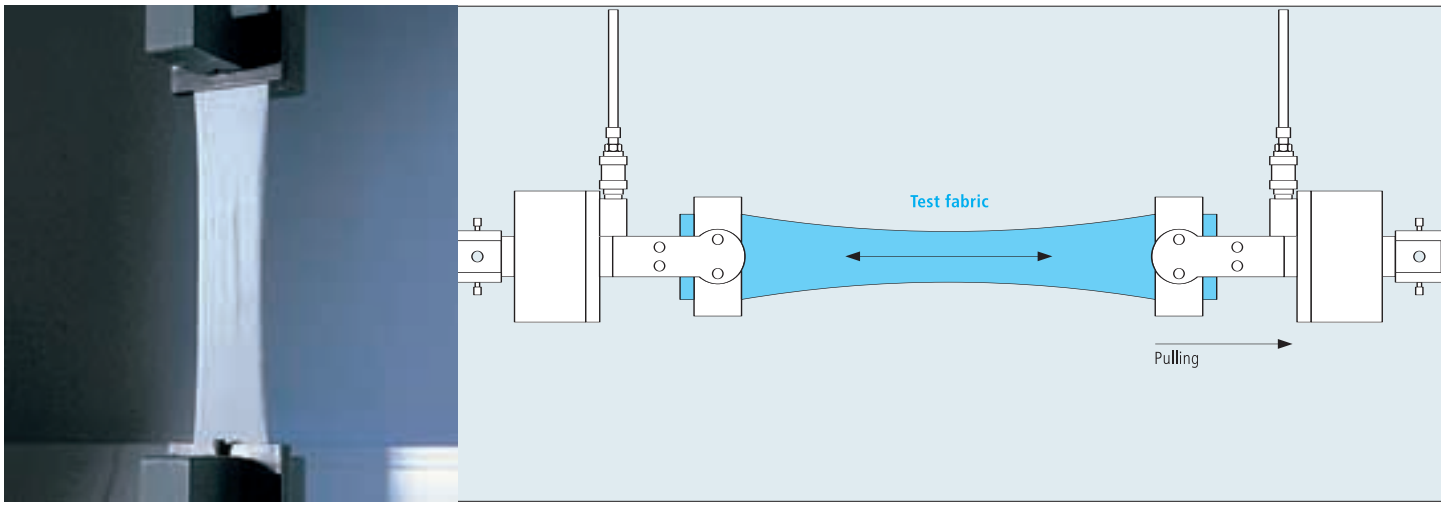
Test results are expressed in Kilopascal and higher numbers indicate a higher resistance.

Performance requirements

Unit	Surgical gowns				Surgical drapes				Clean air suits
	Standard Performance		High Performance		Standard Performance		High Performance		Requirement[e]
	critical area	less critical area	critical area	less critical area	critical area	less critical area	critical area	less critical area	
Dry kPa	≥ 40	≥ 40	≥ 40	≥ 40	≥ 40	≥ 40	≥ 40	≥ 40	≥ 40
Wet kPa	≥ 40	N/A	≥ 40	N/A	≥ 40	N/A	≥ 40	N/A	N/A

e Performance requirements apply for all product areas of clean air suits, as clean air suits should be used in addition to surgical gowns and not as a substitute.

TEST OF TENSILE STRENGTH EN 29073-3



This test method measures the ability of a fabric to withstand elongation - induced stresses.

This type of stress occurs naturally during normal wear situations. Minimum requirements ensure that the device will perform satisfactorily, without mechanical failure.

Test results are expressed in Newton and higher numbers stand for a better fabric strength.

Performance requirements

	Surgical gowns				Surgical drapes				Clean air suits
Unit	Standard Performance		High Performance		Standard Performance		High Performance		Requirement[e]
	critical area	less critical area	critical area	less critical area	critical area	less critical area	critical area	less critical area	
Dry N	≥ 20	≥ 20	≥ 20	≥ 20	≥ 15	≥ 15	≥ 20	≥ 20	≥ 20
Wet N	≥ 20	N/A	≥ 20	N/A	≥ 15	N/A	≥ 20	N/A	N/A

e Performance requirements apply for all product areas of clean air suits, as clean air suits should be used in addition to surgical gowns and not as a substitute.

PART III - PERFORMANCE REQUIREMENTS AND PERFORMANCE LEVELS - EN 13795-3

TABLE 4
PERFORMANCE REQUIREMENTS FOR SURGICAL GOWNS

PERFORMANCE REQUIREMENTS FOR SURGICAL GOWNS

Characteristic	Unit	Standard Performance		High Performance	
		critical area	less critical area	critical area	less critical area
Resistance to microbial penetration – dry	Log_{10} (CFU)	N/A	≤ 2 [a,c]	N/A	≤ 2 [a,c]
Resistance to microbial penetration – wet	BI	≥ 2,8 [b]	N/A	6,0 [b,d]	N/A
Cleanliness – microbial	Log_{10} (CFU/dm²)	≤ 2 [c]	≤ 2 [c]	≤ 2 [c]	≤ 2 [c]
Cleanliness – particulate matter	IPM	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5
Linting	Log_{10} (lint count)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0
Resistance to liquid penetration	cm H_2O	≥ 20	≥ 10	≥ 100	≥ 10
Bursting strength – dry	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength – wet	kPa	≥ 40	N/A	≥ 40	N/A
Tensile strength – dry	N	≥ 20	≥ 20	≥ 20	≥ 20
Tensile strength – wet	N	≥ 20	N/A	≥ 20	N/A

a Test conditions: challenge concentration 10^8 CFU/g talc. and 30 minutes vibration time.

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

c For the purpose of this standard, log_{10} CFU ≤ 2 means maximum 300 CFU.

d BI = 6,0 for the purpose of this standard means: no penetration. BI = 6,0 is the maximum achievable value.

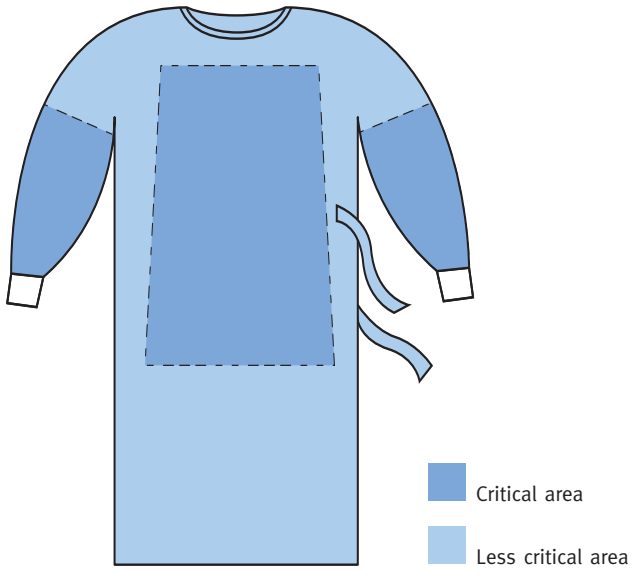


TABLE 5
PERFORMANCE REQUIREMENTS FOR SURGICAL DRAPES

PERFORMANCE REQUIREMENTS FOR SURGICAL DRAPES

Characteristic	Unit	Standard Performance		High Performance	
		critical area	less critical area	critical area	less critical area
Resistance to microbial penetration – dry	Log_{10} (CFU)	N/A	≤ 2 [a,c]	N/A	≤ 2 [a,c]
Resistance to microbial penetration – wet	BI	≥ 2,8 [b]	N/A	6,0 [b,d]	N/A
Cleanliness – microbial	Log_{10} (CFU/dm²)	≤ 2 [c]	≤ 2 [c]	≤ 2 [c]	≤ 2 [c]
Cleanliness – particulate matter	IPM	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5
Linting	Log_{10} (lint count)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0
Resistance to liquid penetration	cm H_2O	≥ 30	≥ 10	≥ 100	≥ 10
Bursting strength – dry	kPa	≥ 40	≥ 40	≥ 40	≥ 40
Bursting strength – wet	kPa	≥ 40	N/A	≥ 40	N/A
Tensile strength – dry	N	≥ 15	≥ 15	≥ 20	≥ 20
Tensile strength – wet	N	≥ 15	N/A	≥ 20	N/A

a Test conditions: challenge concentration 10^8 CFU/g talc. and 30 minutes vibration time.

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

c For the purpose of this standard, log_{10} CFU ≤ 2 means maximum 300 CFU.

d BI = 6,0 for the purpose of this standard means: no penetration. BI = 6,0 is the maximum achievable value.

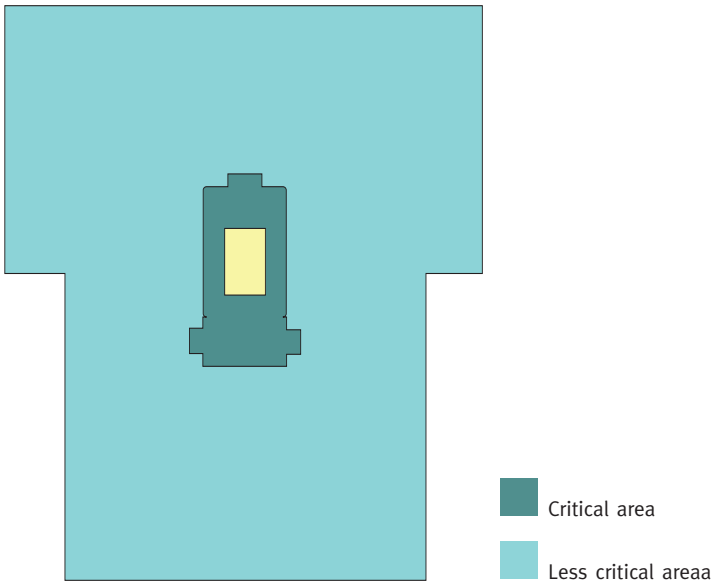


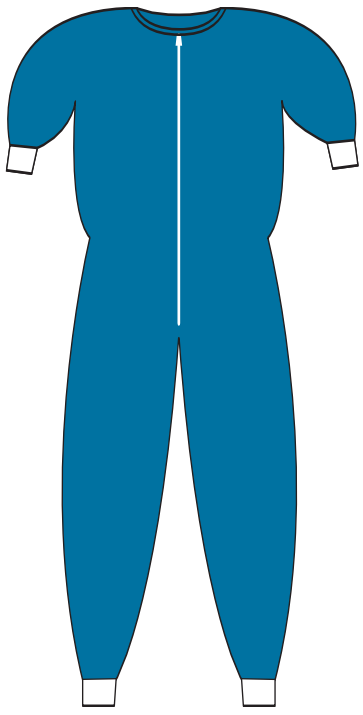
TABLE 6
PERFORMANCE REQUIREMENTS FOR CLEAN AIR SUITS

PERFORMANCE REQUIREMENTS FOR CLEAN AIR SUITS		
Characteristic	Unit	Requirement[e]
Resistance to microbial penetration – dry	Log_{10} (CFU)	≤ 2 [a,c]
Cleanliness – microbial	Log_{10} (CFU/dm^2)	≤ 2 [c]
Cleanliness – particulate matter	IPM	≤ 3,5
Linting	Log_{10} (lint count)	≤ 4,0
Bursting strength – dry	kPa	≥ 40
Tensile strength – dry	N	≥ 20

a Test conditions: challenge concentration 10^8 CFU/g talc. and 30 minutes vibration time.

c For the purpose of this standard, log_{10} CFU ≤ 2 means maximum 300 CFU.

e Performance requirements apply for all product areas of clean air suits, as clean air suits should be used in addition to surgical gowns and not as a substitute.



WHAT DOES EN 13795 MEAN FOR THE MEDICAL PROFESSION AND THE MEDICAL INDUSTRY?

Implementation of the European Standard on surgical gowns, drapes and clean air suits will cause a number of important changes in the best practice in the medical profession and medical industry. The materials and processes used to manufacture these products will now be considered as highly sophisticated protective systems. The new European Standard will provide industry-wide benchmarks, providing peace of mind to patients and healthcare professionals and valuable guidance to hospitals' purchasing departments, garment manufacturers, engineers and scientists active in the medical fabrics industry. The healthcare industry is now provided with a clear set of minimum requirements to be met by all products.

For the patient	greater protection and safety against post-operative infection
For the hospital	quality assurance, guidance in choice of product, compliance with EU regulations
For the nurse and surgeon	greater protection, peace of mind
For the garment manufacturer	quality assurance, defined qualification criteria
For the fabric manufacturer	quality assurance, defined qualification criteria, new goals for innovation

IMPORTANT IMPLICATIONS FOR THE HEALTHCARE INDUSTRY

What will be the impact of the new European Standard on the range of products currently on the market?

To meet the requirements of EN 13795, all manufacturers of surgical gowns and drapes, as well as suppliers of materials used in these applications, will have to operate quality control systems that will ensure consistent product quality. Re-usable or multi-patient products will need to be tested and certified by laundries as fit-for-use according to EN 13795 before being supplied for re-use in the operating theatre. Laundries will need to track usage and re-usage of surgical gowns and drapes so that the manufacturer's recommended lifetime limitations can be implemented.

WHAT ABOUT FELIX MEDICAL FABRICS

Felix welcomes the new European Standard and has actively participated in its development.

For two centuries, Felix has been a leader in scientific achievement and innovation. Felix Medical Fabrics is part of this strong tradition. Since the introduction by Felix of spunlaced fabric to the market more that a quarter of a century ago, Felix Medical Fabrics has grown to become the leading global supplier of nonwoven fabrics for the healthcare industry.

Today, Felix Medical Fabrics provides a family of innovative single-use operating room fabrics that go beyond increased protection and safety to offer improved comfort and control. These fabrics incorporate advances in technology and materials to help medical professionals stay cool and comfortable, move more freely and work in a protected environment.

FELIX DELIVERS EXCELLENCE

Felix Medical Fabrics goes beyond protection to help healthcare professionals stay comfortably in control. Our products not only meet, but also surpass the test requirements of the new Standard, confirming our position as the ideal partner for medical fabrics. Our commitment to excellence in every field of development and production ensures that we continue to set the standards for best practice in medical fabrics for the healthcare industry.

BEYOND EN 13795

The European medical fabrics industry can be proud of the new Standard, which is the result of lengthy and meticulous teamwork. It should be remembered however that the text is meant to set requirements for the safety and protection of patients and medical staff and, as such, is an excellent basis to judge minimum performance of gowns, drapes and clear air suits ... but just a basis. The industry, which already has the means to do so, needs to go beyond these minimum requirements.

INCREASED SAFETY

Adapted response to developing surgery techniques as well as to growing infection threats should also be taken into consideration when choosing the appropriate gown, drape or clean air suit. Other aspects, among them flammability, spark response and surface conductivity should also be kept in mind.

COMFORT

Notions such as comfort of the operating medical personnel and well-being of patients are factors that are not easy to quantify, but which do play an important role for a flawless intervention and for healing efficacy.

ENGINEERED TO USE

The gowns, drapes and clean air suits of tomorrow will likely be designed and engineered to fit the type of intervention, thus maximizing efficacy. Equally, they will match patient and healing process requirements for optimal recovery.

To respond to the highly demanding requirements of surgeons, nurses and patients of tomorrow, complexity of products will unavoidably increase. Flexibility of concurrent technologies at all levels will be a decisive factor in the development of the next generation of these medical devices.

REFERENCES

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
http://eur-lex.europa.eu

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