



Surgical/Medical Masks, Gowns & Drapes Quality & Compliance

In a hospital environment, health staff's clothes provide a safety barrier for both patients and themselves. Gowns, drapes and masks are made of medical textiles which must comply with certain standards to ensure safety of a product in concordance with its specified use.

Product and regulatory scenario

Surgical/Medical Masks

Surgical and medical masks are designed to cover the mouth and nose providing a barrier to minimize the direct transmission of infective agents from the wearer to others, or vice versa. There are different kinds of surgical masks: Type I, Type II and Type IIR (in Europe according to Directive 93/42/EEC to be replaced by Regulation (EU) 2017/745¹); Level 1, Level 2, Level 3 and Level 4 (in US according to FDA requirements) and class 1, class 2 and class 3 (splash/ fluid resistant) in India according to IS 16289. Surgical and medical masks are classified as medical devices.

Surgical Gowns and Drapes

Surgical gowns and drapes are commonly used in healthcare facilities during surgical procedures and/or to prevent the transfer of infective agents. These products are made of non-woven fabric and provide a protective barrier. Both surgical gowns and drapes are classified as medical devices and are

categorised according to their barrier protection levels.

- Surgical gowns are used by many people in healthcare and provide a barrier by covering important areas from the shoulders to the knees and wrists.
- Surgical drapes are used in the operating room to protect the patient, clinicians, and medical equipment.

Eurofins can support medical textile suppliers to ensure the functionality, as well as compliance with relevant safety standards, of these products.

Service scope

Surgical Clothing and Drapes

Part 1: Surgical Drapes and Gowns

- Europe/EN 13795-1
- US/ASTM F2407-6
- ANSI/AAMI PB70

Part 2: Clean Air Suits

- Europe/EN 13795-2

Medical textiles

- India/IS 16289 Surgical face mask
- India/IS 17423 Coveralls

¹ The Commission adopted a proposal on 3 April 2020 to postpone the application date of the Medical Devices Regulation (MDR) for one year as from 26 May 2020.

Part 1: Surgical Drapes and Gowns

US (ASTM F2407-6)	
Characteristic	Test method
Tensile Strength	ASTM D5034, ASTM D1682
Tear resistance	ASTM D5587(woven), ASTM D5587 (non woven), ASTM D1424
Seam Strength	ASTM D751 (stretch woven or knit)
Fabric weight	ASTM D3776-20
Lint Generation	ISO 9073 Part 10
Water vapor trans- mission (breathability)	ASTM F1868 Part B, ASTM D6701 (nonwoven), ASTM D737-75
Safety testing	Flammability 16 CR Part 1610
ANSI/AAMI PB70:2012 describes liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (4 levels of barrier performance).	

Part 2: Clean Air Suits

Europe (EN 13795-1)	
Characteristic	Test method
Microbial penetration – Dry	EN ISO 22612
Microbial penetration – Wet	EN ISO 22610
Cleanliness microbial / Bioburden	EN ISO 17737-1
Particle release	EN ISO 9073-10
Liquid penetration	EN ISO 811
Bursting strength – Dry	EN ISO 13938-1
Bursting strength – Wet	EN ISO 13938-1
Tensile strength – Dry	EN 29073-3
Tensile strength – Wet	EN 29073-3

Medical Face Masks

Europe / US (EN 14683:2019 / ASTM F2100-19)	
Characteristic	Test method
Barrier testing	Bacterial filtration efficiency (BFE), EN 14683 (Annex B) / ASTM F2101
	Particle Filtration Efficiency (PFE), ASTM F2299
	Splash resistance pressure (or Synthetic Blood), ISO 22609 / ASTM F1862
Physical testing	Differential pressure, EN 14683 (Annex C)
Safety testing	Microbial cleanliness (bioburden, ref. ISO 11737-1)
	Biocompatibility (ISO 19993 series)
	Flammability 16 CR Part 1610

Medical Textiles

India	
Standard	Test requirements
IS 16289 Surgical mask (Class 1, Class 2, Class 3)	Bacterial filtration efficiency (IS 16288) Differential pressure Splash resistance Sub-micron particulate filtration efficiency Fluid/splash resistance
IS 17423 Coveralls	Blood resistance (IS 16546/ ISO 16603)

Eurofins provides high standard quality assurance and control services throughout the supply chain. Our laboratories are ISO/IEC17025:2017 accredited for Bacterial Filtration Efficiency testing (BFE), differential pressure (breathability) and resistance to synthetic blood splashes, delivering precise, reliable and accurate testing results to our customers for ISO and ASTM test methods.

On-site inspections and audits

Assessing the manufacturing site before launching mass production and checking the products' quality prior to shipment are key parts of the quality control process, to ensure that the production was carried out according to the quality standards and expectations of destination markets.

Quality Assurance and Control throughout the Supply Chain

Whichever your role in the supply chain you need to safeguard the reputation of your brand and/or that of your client.

From supplier's assessment, R&D support, regulatory guidance, supply chain mapping, all the way through compliance and bespoke testing, QC inspections and down to failure analysis or market surveillance, we cover every need of your product's quality journey.

