

SPECIFICATION SPN145/2

Re-usable Cleanroom Garments

This Specification replaces
SPN145/1.1

Copy Number

Effective

19/02/20

Summary of Significant Changes

Update of 'Applicable Documents'

Purpose

To specify the requirements for re-usable cleanroom garments.

Definitions

BTTG - British Textile Testing Group

ITT -Institute for Textile Technology

ISO – International Standards Organisation

Applicable Documents

[ESD1](#) - Current edition of the Guidelines for the Blood Transfusion Services in the United Kingdom (Red Book).

EU Guidelines to Good Manufacturing Practice (GMP) for Medicinal Products for Human and Veterinary Use.

EU Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

IEST-RP-CC-003.3 Garment System Considerations for Cleanrooms and other Controlled Environments.

International Standard ISO 14644-5. Cleanrooms and associated controlled environments Part 5: Operations.

Directions given under the Human Tissue Act 2004 implementing the Human Tissue (Quality and Safety for Human Application) Regulations 2018. Human Tissue Authority.

[MPD363](#) - Cleanroom Gowning

[SPN146](#) - Cleanroom Garment Laundering

[SPN148](#) - Cleanroom Garment Sterilisation

[SPN149](#) - Cleanroom Changing Rooms

[SPN150](#) - Cleanroom Garment Components

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Requirements

These requirements are based on guidance given in:

- **EU Guidelines to Good Manufacturing Practice (GMP) for Medicinal Products for Human and Veterinary Use**
- International Standard ISO 14644-5
- IEST-RP-CC-003.3
- EU Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
- Directions given under the Human Tissue Act 2004 implementing the Human Tissue (Quality and Safety for Human Application) Regulations 2018. Human Tissue Authority
- Guidelines for the Blood Transfusion Services in the United Kingdom (Red Book).

(See applicable documents.)

1. **Material.** Generally 100% polyester made to a cleanroom quality specification. A validation document preferably from an independent test house such as BTTG (British Textile Testing Group) or ITT (Institute for Textile Technology), must be available showing test results for the fabric after 50 wash cycles. Test data showing textile performance after 50 sterilisation cycles would also be advisable, if available.

The supplier must be able to provide the following information either upon request or through supplier audit:

- a) Fabric manufacturers' name
- b) Fabric product name and product code
- c) Particle retention/barrier properties for 0.5 µm and 5.0 µm particle sizes
- d) Air permeability result
- e) Water vapour diffusion result.

These properties must meet the following criteria.

Parameter	Particle Size	Acceptable Range
Particle Retention	0.5µm and greater	*75 -95%
Particle Retention	5.0µm and greater	*90 -98%
Air Permeability	N/A	30 - 35 l/m ² /second
Water Vapour Diffusion	N/A	20 - 30 g/m ² /hour

*BTTG (British Textile Testing Group Method)

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2. The textile must include a static dissipative thread woven into the fabric in a grid pattern of 6 mm grid width or less.
3. Fabric performance will deteriorate with age, wear, laundry and sterilisation. The fabric must be monitored to detect degradation. A specification regarding the maximum number of wash, wear, sterilise cycles after which a garment is discarded and replaced must be provided by the supplier or laundry service.
4. Construction. Raw fabric edges must be sealed, covered or interlocked to prevent fraying and particle generation. Sewing methods at the seams must prevent fibre production and retain particles. The seams may be bound, sealed, taped, tunnel or double stitched to maintain the particle barrier.
5. Accessories such as boot soles, zippers, tapes, buckles, fasteners and closures must be non-shedding and capable of withstanding a given number of wash, wear and sterilisation cycles specified by the manufacturers.
6. Personal Clothing: for more details see Cleanroom Garment Components [SPN150](#).
 - a) Coverall. Closures at wrists and high collar or integral hood. Covered full length front zipper, with a fabric cover in front and behind the zipper. No pockets, clean lines avoiding loops, darts and accessories which may become particle traps.

A good fit with room to move must be ensured by trying garments prior to purchase.
 - b) Hood if separate from the coverall. Open face hood with full cape for tucking inside coverall. Adjustment at back of the head for fit and comfort.
 - c) High Overboots. Knee length overboots with non-slip soles and fastenings at the knee and foot to ensure a safe comfortable fit.
 - d) Coat. Long length coat with covered zipper, closures at wrist and high collar.
7. Colour. Light colours are preferable to show up soiling e.g. white, light blue, light green.
8. Frequency of Change.

Refer to [SPN146](#) and [MPD363](#) for gowning requirements.

Grade A and B. Change on entry. New decontaminated (laundered) sterile garments are required for each entry in to a grade A/B cleanroom.

Grade C and D Optional, can be reused for a maximum period of one week.
Storage of garments between use must prevent cross contamination and soiling.

9. Garments must be laundered and sterilised according to specifications [SPN146](#) and [SPN148](#).