

# SPECIFICATION SPN147/2

## Cleanroom Undergarments

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This Specification replaces  
SPN147/1.1

Copy Number

Effective

19/02/20

### Summary of Significant Changes

Update of 'Applicable Documents'

Section 2. Style: Removal of the option for a short sleeved tee shirt and garments to include elasticated cuffs (CR42909).

Addition of requirement for cleanroom socks.

### Purpose

To provide a specification for cleanroom undergarments.

### Definitions

**GMP** - Good Manufacturing Practice

**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.

Advisory Committee on Dangerous Pathogens - Spongiform Encephalopathy Advisory Committee: Annex B, Transmissible Spongiform Encephalopathy Agents: Safe Working and prevention of infection.

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

[SPN146](#) - Cleanroom Garment Laundering

[SPN149](#) - Cleanroom Changing Rooms

## Cleanroom Undergarments

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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.](#)
- 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
- Advisory Committee on Dangerous Pathogens - Spongiform Encephalopathy Advisory Committee: Annex B
- Guidelines for the Blood Transfusion Services in the United Kingdom (Red Book)
- ISO 14644-5
- IEST-RP-CC-003.3.

(See Applicable Documents.)

#### 1. Material

- A durable non-shedding material with particle retention properties is advisable.
- Polyester is the preferred textile although polyester cotton undergarments may also be used.
- Polyester material when used as undergarments must be light and comfortable to wear to prevent a body temperature increase during long wearing periods or physical activity.
- Specialised polyester textiles based on sportswear fabrics are available in cleanroom undergarment style.

#### 2. Style

- Long sleeve top and trouser set to include elasticated cuffs.
- Cleanroom socks.

#### 3. Colour

- This is not important except the material must have a different appearance from the outer garments to distinguish undergarments when donning and disposal into separate undergarment laundry containers.

#### 4. Laundry requirements

- See "Cleanroom Garment Laundering" specification [SPN146](#).

#### 5. Frequency of change

- The frequency is not specified by GMP or ISO guidelines/standards, it is not a requirement to change undergarments upon each entry.
- In practice, a personalised undergarment set must be changed at a minimum weekly.

#### 6. Storage

- The undergarments, between uses, must be stored in facilities which are provided in the preliminary change area, see "Cleanroom Changing Rooms" [SPN149](#).