

evercare® Visitor overall, universal

REF: 2704 and 2705

evercare® Visitor overall Universal Size small & big a comfortable single-use visitor overall with cuffs on neck, arms and legs. Zipper closure with tape sealing for extra protection. This product is specially designed for persons that need to enter the operating theatre during an operation. For instance parents can join their children to provide support and comfort. It can also provide a good alternative clothing to other visitors like relatives, students or different kind of health care workers that need to be present during operations. The overall is made of SMS material and fulfills the EN Standard 13795 for clean air suits. A Clean Air Suits grant a certain level of protection towards bacterial penetration, which makes it more suitable for this type of application.

Key Features:

- ▶ Complies to EN13795 for Clean Air Suit.
- ▶ Specially designed with cuffs in arms, neck and ankles
- ▶ Tape to cover the Zipper-lock to provide better protection to bacteria
- ▶ Available in 2 sizes to cover most fits: Universal Small & Universal Big



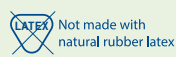
REF	DESCRIPTION	SIZE	PACK COUNT dispenser/carton
2704	Visitor overall, universal, blue	Small	10/30
2705	Visitor overall, universal, blue	Big	10/30

Sales Unit: Transport Carton

Technical Summary

Regulations

The product complies with legal requirements for medical devices



REACH regulation:

The product(s) covered by this data sheet does(do) not contain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), including any of the Substances of Very High Concern (SVHC) as listed in the latest available version of the Candidate List published by European Chemicals Agency (ECHA).

Biological evaluation:

ISO 10993-5, ISO 10993-10

Compliance with legal requirements:

Medical Devices Directive 93/42/EEC, Class I

Compliance with product standards:

Complies with EN 13795 for clean air suits

Quality standards:

ISO 13485

Label information and packaging compliance:

EN ISO 15223-1, and EN 1041

Material

Product Part	Raw Material & Characteristic
Body, sleeves	PP SMMS nonwoven, antistatic, blue
Cuffs	PES, white
Sewing thread	PES, white
Elastic rubber band	Synthetic rubber, natural latex free
Zipper	Nylon with one metal zipper handle
Double adhesive tape / silicone paper	PET film and bi-axially oriented polypropylene, pressure-sensitive adhesive + silicone paper

Warnings and Recommendations

Warnings:

The product is single use. If reused performance of product may deteriorate, cross contamination may occur

Storage Recommendation

Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone.

Disposal Recommendation

Dispose in accordance with local regulations

Shelf Life 5 Years

Packing Information

Package	Material	Size (L x W x H) mm
Single Pack	PE-bag	300 x 480
Dispenser Pack	PE-bag	680 x 850
Transport Carton	Carton, TCF or ECF quality	406 x 254 x 520
Packing Tape	Transparent, PVC-free	N/A

Barcodes

REF	Single Pack	Dispenser	Transport Carton
2704	N/A	 6 438129 323436	 6 438129 523430
2705	N/A	 6 438129 318203	 6 438129 518207

ONEMED

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