

## evercare<sup>®</sup> Visitor overall, universal

REF: 2705

evercare<sup>®</sup> Visitor overall Universal Size 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 EN13795-2 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 size Universal/Big



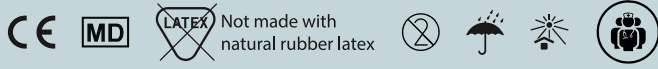
REF	DESCRIPTION	SIZE	PACK COUNT dispenser/carton
2705	Visitor overall, Blue	Universal/Big	10 / 30

Sales Unit: Transport Carton

# Technical Summary

## Regulations

The product complies with legal requirements for medical devices.



<b>REACH regulation:</b>	The products covered by this data sheet 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).
<b>Biological evaluation:</b>	EN ISO 10993-5 EN ISO 10993-10
<b>Compliance with legal requirements:</b>	Medical Device Regulation (EU) 2017/745, MDR class I
<b>Compliance with product standards:</b>	EN 13795-2 for Clean Air Suit
<b>Quality standards:</b>	EN ISO 13485
<b>Label information and packaging compliance:</b>	EN ISO 15223-1, EN ISO 20417

## Material

Product Part	Raw Material & Characteristics
Body, sleeves	PP SMS 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 & Recommendations

<b>Warnings</b>	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur.
<b>Storage Recommendation</b>	Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight, other intensive light sources and ozone.
<b>Disposal Recommendation</b>	Dispose in accordance with local regulations.
<b>Shelf Life</b>	5 Years

## Packing information

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

## Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
2705	N/A	06438129318203	06438129518207

Evercare Medical AB is a partner that enables better lives for patients, facilitates everyday life for healthcare employees and contributes to lower care costs. We strive to reduce the environmental impact and, together with our suppliers, to improve working conditions throughout the value chain.