

evercare[®] XP Clean Air Suit

REF: 260110, 260111, 260112, 260113, 260114, 260115, 260116, 260210, 260211, 260212, 260213, 260214, 260215, 260216

evercare[®] XP Clean Air Suits for single-use contribute to maintaining the operation room air clean and improve the hospital's infection control. Made of low linting material and a comfortable design. A two-piece suit with shirt and pants packed separately for individual fit.

Key Features:

- ▶ Complies to EN13795 for clean air suits
- ▶ Breathable material with low particle release and with resistance to microbial penetration
- ▶ Cuffs in sleeves and legs, shirt has elastic band in waist
- ▶ Pants have tie-band in waist for individual adjustment
- ▶ 3 pockets on shirt, 2 on pants
- ▶ Anti-static
- ▶ Single-use
- ▶ Available in sizes XS-XXXL



REF	DESCRIPTION	SIZE	PACK COUNT bag/carton
260110	XP Clean Air Suit, Shirt, with cuffs, blue	XS	1/30
260111	XP Clean Air Suit, Shirt, with cuffs, blue	S	1/30
260112	XP Clean Air Suit, Shirt, with cuffs, blue	M	1/30
260113	XP Clean Air Suit, Shirt, with cuffs, blue	L	1/30
260114	XP Clean Air Suit, Shirt, with cuffs, blue	XL	1/30
260115	XP Clean Air Suit, Shirt, with cuffs, blue	XXL	1/30
260116	XP Clean Air Suit, Shirt, with cuffs, blue	XXXL	1/30
260210	XP Clean Air Suit, Pants, with cuffs, blue	XS	1/30
260211	XP Clean Air Suit, Pants, with cuffs, blue	S	1/30
260212	XP Clean Air Suit, Pants, with cuffs, blue	M	1/30
260213	XP Clean Air Suit, Pants, with cuffs, blue	L	1/30
260214	XP Clean Air Suit, Pants, with cuffs, blue	XL	1/30
260215	XP Clean Air Suit, Pants, with cuffs, blue	XXL	1/30
260216	XP Clean Air Suit, Pants, with cuffs, blue	XXXL	1/30

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:	EN ISO 10993-5, EN ISO 10993-10
Compliance with legal requirements:	Medical Devices Directive 93/42/EEC, Class I
Compliance with product standards:	EN 13795-2 for Clean Air Suits
Quality standards:	EN ISO 13485
Label information and packaging compliance:	EN ISO 15223-1, EN 1041

Material

Product Part	Raw Material & Characteristic
Body, sleeve, pocket, collar, belt	PP SSMMS nonwoven, antistatic white
Buttons	POM, white
Cuffs	PES, white
Elastic band	Synthetic rubber, natural latex free
Washing label	99% Nylon & 1% calcium carbonate
Sewing thread	PES, white

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	N/A	N/A
Transport Carton	Carton, TCF quality	380 x 297 x 240
Packing Tape	Transparent, PVC-free	N/A

Barcodes

REF	Single Pack	Dispenser	Transport Carton
260110	N/A	N/A	 6 438129 523003
260111	N/A	N/A	 6 438129 523010
260112	N/A	N/A	 6 438129 523027
260113	N/A	N/A	 6 438129 523034
260114	N/A	N/A	 6 438129 523041
260115	N/A	N/A	 6 438129 523058
260116	N/A	N/A	 6 438129 523065
260210	N/A	N/A	 6 438129 523072
260211	N/A	N/A	 6 438129 523089
260212	N/A	N/A	 6 438129 523096

260213	N/A	N/A	 6 438129 523102
260214	N/A	N/A	 6 438129 523119
260215	N/A	N/A	 6 438129 523126
260216	N/A	N/A	 6 438129 523133



OneMed Group Oy
 Address: Metsäläntie 20
 Postal Address: P.O. Box 10
 FI-00321 Helsinki, Finland
 Phone +358 20 786 6800
 www.onemed.com
 Domicile Helsinki
 Business ID 2039640-1