

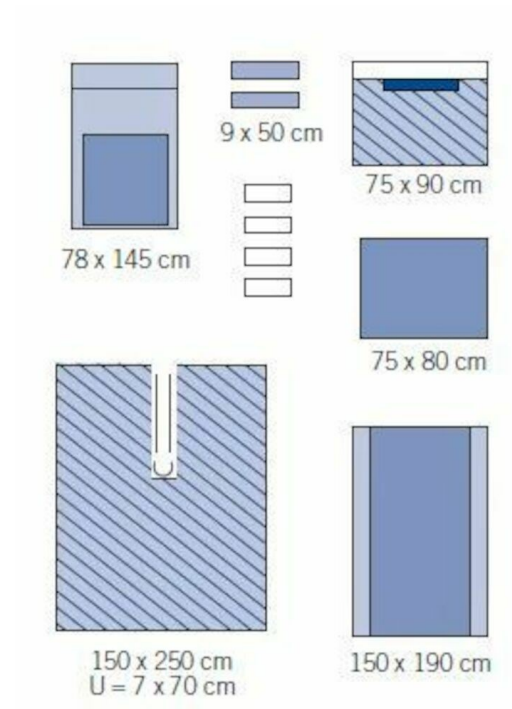
evercare[®] ENT set

REF: 1238-03

evercare[®] ENT set, sterile is a versatile and practical set for operations of the ear/nose/throat area. Non-reinforced drape for comfortability.

Key Features

- ▶ Absorbent patch
- ▶ Adhesive OP Tape
- ▶ Main drape complies to EN 13795-1 High performance critical product area requirements



REF	DESCRIPTION	SIZE	Pack Count dispenser/carton
1238-03	ENT set, sterile	See Material table	5 / 10

Sales Unit: Transport Carton

Regulations

The product complies with legal requirements for medical devices. EO sterilized according to valid version of ISO 11135 standard.



REACH regulation:

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).

Biological evaluation:

EN ISO 10993-01
EN ISO 10993-5
EN ISO 10993-7
EN ISO 10993-10

Compliance with legal requirements:

Medical Device Regulation (EU) 2017/745, MDR class Is

Compliance with product standards:

EN13795-1

Quality standards:

EN ISO 13485

Label information and packaging compliance:

EN ISO 15223-1, EN ISO 20417, EN ISO 11607-1

Material

Product Part	Raw Material & Characteristics
4 Hand towels	30 x 34 cm, Pulp, natural white, thread reinforced
1 Mayo cover	78 x 145 cm, Laminate: PP nonwoven/PE film/PE-film, blue
2 Adhesive Op-tapes	9 x 50 cm, Nonwoven polyester, blue, adhesive coated
1 Adhesive drape	75 x 90 cm, Laminate: blue PP nonwoven/blue PE film/white PP nonwoven, absorbent patch 15 x 50 cm blue PET nonwoven
1 Utility drape	75 x 80 cm, Laminate: PP nonwoven/PE film, blue
1 Adhesive split sheet	150 x 250 cm, Laminate: blue PP nonwoven/blue PE film/white PP nonwoven, split 7 x 70 cm
1 Instrument table cover	150 x 190 cm, Laminate: PP nonwoven/PE film, blue

Warnings & Recommendations

Warnings	The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur. Do not use if package is damaged.
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	Medical grade paper, PE/PET film	420 x 603
Dispenser Pack	TCF or ECF quality	485 x 285 x 287
Transport Carton	TCF or ECF quality	500 x 310 x 590
Packing Tape	Transparent	N/A

Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
1238-03	06438129119879	06438129319873	06438129519877

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.