

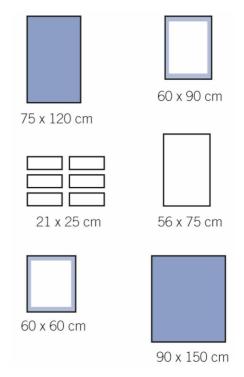
# evercare® Delivery set

REF: 1255-01

evercare<sup>®</sup> Delivery set, sterile is a disposable delivery set for vaginal deliveries.

# **Key Features**

▶ Main drape complies to EN 13795-1 High performance critical product area requirement



REF	DESCRIPTION	SIZE	
1255-01	Delivery set, sterile	See Material table	0/12

Sales Unit: Transport Carton

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### Regulations

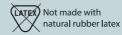
The product complies with legal requirements for medical devices. EO sterilized according to valid version of ISO 11135 standard.























**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).

EN ISO 10993-01 EN ISO 10993-5 **Biological evaluation:** 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	
1 Universal cover drape (for under the mother)	90 x 150 cm, Laminate: PP nonwoven/PE film, blue	
1 Utility drape (stitching sheet)	75x120 cm, PP nonwoven/PE film, blue	
1 Bed pad	$60\ x\ 90\ cm$ , Coverstock CV nonwoven white, fluff $100\ \%$ pulp white, PE-film green	
1 Absorbent sheet (baby sheet)	56x 75 cm, PP nonwoven, white	
6 Hand towels	21 x 25 cm, PP nonwoven, white	
1 Bed pad	60 x 60 cm, Coverstock CV nonwoven white, fluff 100 % pulp white, PE-film green	

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# Warnings & Recommendations

<b>Warnings</b> con	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 Recommendati	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	280 x 415
Dispenser Pack	TCF or ECF quality	
Transport Carton	TCF or ECF quality	545 x 310 x 246
Packing Tape	Transparent	N/A

#### Barcodes / UDI-DI

REF	Single Pack	Dispenser	Transport Carton
1255-01	06438129110272	06438129323658	06438129510270

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.