



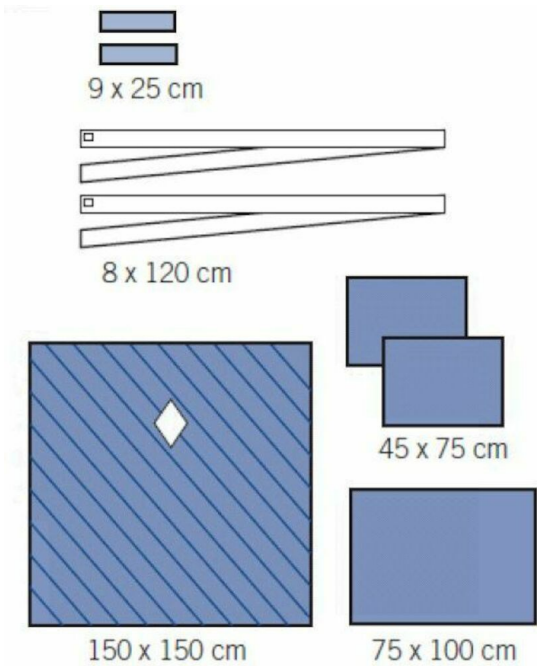
evercare<sup>®</sup> Dental set

REF: 1288-01

evercare<sup>®</sup> Dental set, sterile is a draping set for dental/oral surgery.

Key Features

- ▶ Tube covers
- ▶ Adhesive OP Tape
- ▶ Main drape complies to EN 13795-1 High performance critical product area requirement

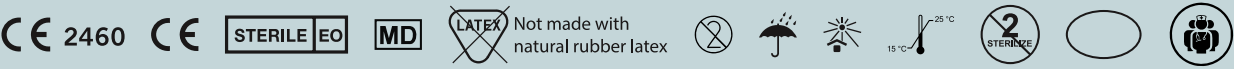


| REF     | DESCRIPTION         | SIZE               | Pack Count<br>dispenser/carton |
|---------|---------------------|--------------------|--------------------------------|
| 1288-01 | Dental set, sterile | See Material table | 9 / 36                         |

Sales Unit: Transport Carton

## Regulations

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



|                                                    |                                                                                                                                                                                                                                                                                                                     |
|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <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 10993-01<br>EN ISO 10993-5<br>EN ISO 10993-7<br>EN ISO 10993-10                                                                                                                                                                                                                                              |
| <b>Compliance with legal requirements:</b>         | Medical Device Regulation (EU) 2017/745, MDR class Is                                                                                                                                                                                                                                                               |
| <b>Compliance with product standards:</b>          | EN13795-1                                                                                                                                                                                                                                                                                                           |
| <b>Quality standards:</b>                          | EN ISO 13485                                                                                                                                                                                                                                                                                                        |
| <b>Label information and packaging compliance:</b> | EN ISO 15223-1, EN ISO 20417, EN ISO 11607-1                                                                                                                                                                                                                                                                        |

## Material

| Product Part                    | Raw Material & Characteristics                                                                        |
|---------------------------------|-------------------------------------------------------------------------------------------------------|
| <b>1 Dental drape</b>           | 150 x 150 cm, laminate: blue PP nonwoven/blue PE-film film/white pp nonwoven, diamond shaped aperture |
| <b>2 Adhesive Op-tape</b>       | 9 x 25 cm, Nonwoven polyester, blue, adhesive coated                                                  |
| <b>2 Tube covers</b>            | 8 x 120 cm, transparent polyethylene                                                                  |
| <b>2 Utility drapes</b>         | 45 x 75 cm, laminate: blue PP nonwoven/blue PE-film                                                   |
| <b>1 Instrument table cover</b> | 75 x 100 cm, PP nonwoven/polyethylene film laminate, blue                                             |

## Warnings & Recommendations

|                                |                                                                                                                                                             |
|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Warnings</b>                | The product is single use. If reused, the performance of product may deteriorate and cross contamination may occur.<br>Do not use if package is damaged.    |
| <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 |
|-------------------------|----------------------------------|-----------------------|
| <b>Single Pack</b>      | Medical grade paper, PE/PET film | 250 x 390             |
| <b>Dispenser Pack</b>   | TCF or ECF quality               | 285 x 242 x 287       |
| <b>Transport Carton</b> | TCF or ECF quality               | 500 x 310 x 590       |
| <b>Packing Tape</b>     | Transparent                      | N/A                   |

## Barcodes / UDI-DI

| REF            | Single Pack    | Dispenser      | Transport Carton |
|----------------|----------------|----------------|------------------|
| <b>1288-01</b> | 06438129117769 | 06438129317763 | 06438129517767   |

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.