

4560-164 Guilhufe, Penafiel - Portugal

Ref: **489-005**

Product Specification

Brand:

STERILE EO



DRQ 14/21 REV.00 2020/09/08

| Description: FOR |
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| Final dimensions: | 13 cm |
|------------------------------|--------------------------------------|
| Composition: | Colourant, Reinforced Polypropylene. |
| Latex: | Free |
| PVC: | Free |
| Re use: | No |
| CMR: | Free |
| Endocrine Disruptors: | Free |
| Colour: | blue |
| Sterilization method: | Ethylene Oxide |
| Shelf life: | 60 months |
| CFU/g | N.A. |
| Sterility Assur. Level_SAL | ≤10^-6 |



| Nr and Revision Date: | 31 2021/08/24 | |
|-----------------------|---|---|
| CE Class: | Ila | |
| CE mark: | CE1639 | |
| Compliance with: | MDD 93/42/EEC amended by 2007/47/EC | |
| | EN_ISO10993-1.09_AC.10 ; EN_ISO_10993- | 18.2009 ; EN_ISO_10993-18_2020 ; EN_ISO_10993-1- |
| | 2020 ; EN_ISO_14971_2019 ; EN_ISO_1522 | 23-1.2021 ;EN_ISO 20417_2021 ;ISTA Standard 2A ; |
| | ICH Q1A (2003) ; ASTM D4332_01 ; ASTM [| D4169 ; EN_ISO_11607_1 2020 ; EN_ISO_11607- |
| | 2.2020 ; EN_ISO_14971_2019_A11 ; ISO_2 | 759.2014 ; ISO_3037_2013 ; |
| | EN_ISO_11135.2014_A1.2019 ; CEN_ISO_TS | S_16775_2021 ; EN_ISO_13485.2016 ; |
| | EN_ISO_13485.2016_AC18 ; EN 556-1.2001_ | _AC.2006 ; ISO_11135.2014 ; EN_ISO_11607_1 2017 ; |
| | EN_ISO_11607-2.2017 ; ISO_TS_16775.2014 | 1 ; ASTM_F1980_16 ; ISO_14644-1.2015 ; ISO_14644- |
| | 5_2004 ; ISO_14698_1_2003 ; EN_ISO_149 | 71.2012 ; EN_ISO_15223-1.2016 ; |
| Applicable norms: | EN_1041.2008_A1.2013 ; | |
| GMDN: | 62489 - Dressing/utility forceps, tweezers-li | ke, single use |

| Level | | | Туре | Dimension | Stamp | Labels |
|------------|---|-----|-------------------------|---------------|-------|---------|
| 223 PAP | 1 | 1 | Flexible peel-open pack | 80x190mm | | |
| 213 PAP | 2 | 35 | Folding box | 78x193x360mm | | labeled |
| 20) PAP | 3 | 560 | Carton box | 786x386x321mm | | labeled |

| Basic UDI | 56056221206002JN | |
|-----------|-------------------------------------|--|
| | EAN 1th level/nivel:05605622229539 | |
| | EAN 2th level/nivel:05605622429533 | |
| | EAN Carton Box/Caixa:05605622029535 | |

| | The device is intended to be used on a single patient during one single procedure to prevent risks from | |
|------------------|---|--|
| Important Notes: | contamination, including possible infections, and/or functional damage. | |

| Store in a dry place at room temperature and protect from sunlight. The product has a good stability and therefore, normal conditions of medical devices storage shall apply. |
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| No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste. |
| For grasping and to hold and stabilize tissues. For holding swabs for absorption during surgery or woundcare procedures or for skin disinfection procedures- |
| Any modification of the product as presented or any use out of its intended use are not of the manufacturer responsibility. |

Weight (gr) of packing material used in 100 pcs

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ISSUED BY: Quality Management Department, 2022/09/15

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