

DRQ 14/21 REV.02 2024/09/20

Description: Spencer-Wells Forceps

| | |
|-----------------------------------|---------------------------|
| Final dimensions: | 18.5 cm |
| Composition: | High performance polymer. |
| Latex: | Free |
| PVC: | Free |
| Re use: | No |
| CMR: | Free |
| Endocrine Disruptors: | Free |
| Colour: | Grey |
| Sterilization method: | Ethylene Oxide |
| Shelf life: | 60 months |
| CFU/g | N.A. |
| Sterility Assur. Level_SAL | ≤10 ⁻⁶ |

STERILE EO



isento
Latex
free




isento
PVC
free



| | |
|------------------------------|-------------------|
| Nr and Revision Date: | 31 -- 2024/01/31 |
| CE Class: | Ila |
| CE mark: | CE1639 |
| Compliance with: | MDR (EU) 2017/745 |

ISTA Standard 2A ; ASTM D4169-22 ; EN ISO 14971:2019 ; EN ISO 11607-1:2020 ; EN ISO 20417:2021 ; EN ISO 11607-2:2020 ; EN ISO 10993-18:2020 ; EN ISO 10993-1:2020 ; EN ISO 15223-1:2021 ; EN ISO 14971:2019 A11:2021 ; ISO 2759:2014 ; ISO 3037:2013 ; EN ISO 11135:14 A1:2019-Not applicable ; CEN ISO TS 16775 2021 ; ISO TR 24971:2020 ; UDI FAQs ; EN ISO 13485:2016 ; EN ISO 13485:2016 AC:2018 ; EN 556-1:2001 AC:2006 ; ISO 11135:2014 ; ISO TS 16775:2014 ; ISO 14644-1:2015 ; ISO 14644-5:2004 ; ISO 14698-1:2003 ; EN ISO 13485:2016 A11:2021 ; EN ISO 10993-7:2008 ; ISO 10993-7:2008 Amd1 2019 ; ISO 11737-3:2023 ; ISO 10993-18:2020 AMD1:2022 ; EN ISO 11737-2:2020 ; EN ISO 11135:2014 ; EN 17141:2020 ; ISO 14698-2:2003 ; ISO 14644-2:2015 ; ISO 14644-3:2019 ; ASTM D7386-16 ; ASTM F1886/F1886M-16 ; ASTM F1929-15 ; ASTM F88/F88M-21 ; ASTM F1980-21 ; ISO TR 20416:2020 ; ISO 2859 1:1999 ; ISO 8601-1:2019 ; IEC 62366-1:2015 A1:2020 ; IEC TR 62366-2:2016 ;

| | |
|------------------------------|--|
| Applicable standards: | |
| GMDN: | 61478 - Surgical soft-tissue manipulation forceps, scissors-like, single-use |

| PACKING | | | | | |
|---|-------|------------------------|---------------|-------|---------|
| Level | Units | Type | Dimension | Stamp | Labels |
|  | 1 | 1 Rigid peel-open pack | 130x235mm | | |
|  | 2 | 26 Folding box | 238x133x212mm | | labeled |
|  | 3 | 104 Carton box | 553x250x223mm | | labeled |

| | |
|------------------|-------------------------------------|
| Basic UDI | 56056221203002HZ |
| | EAN 1th level/nivel:05605622248073 |
| | EAN 2th level/nivel:05605622448077 |
| | EAN Carton Box/Caixa:05605622048079 |

| | |
|-------------------------|---|
| Important Notes: | -These forceps are not intended for clamping or grasping the umbilical cord during a C-section. |
| Important Notes: | The device is intended to be used on a single patient during one single procedure to prevent risks from contamination, including possible infections, and/or functional damage. |

| | |
|-----------------------------|---|
| Storage instructions | 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. |
| Waste instructions | Dispose according to local laws rules, regulations and/or infection prevention standards for healthcare waste, to minimize potential risk of contamination, infection or pollution. |
| Intended purpose | For hemostasis/clamp vessels and/or grasping tissues. |

| | | |
|-------------------------------|---|------|
| Environment - Packaging waste | Weight (gr) of packing material used in 100 pcs | 2752 |
|-------------------------------|---|------|

ISSUED BY: Quality Management Department, 2024/11/21

CONFIDENTIAL: The information contained herein is confidential and belongs to Bastos Viegas, s.a. It is provided for specific purposes and in connection with established agreements. It is not permitted disclosure, reproduction, copying or distribution, in whole or in part, for other purposes or to any third parties.
