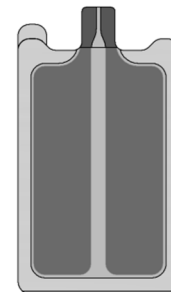


### Skintact® Electrosurgical Neutral Electrode

RS25

Code: 59333



#### PRODUCT

|                                |                                        |
|--------------------------------|----------------------------------------|
| Characteristics                | disposabel, self adhesive, non-sterile |
| Type                           | split                                  |
| Shelf Life                     | 36 Mon                                 |
| Storing Conditions (min./max.) | +5°C (41°F) / +30°C (86°F)             |
| Patient Target group           | Adult (> 15 kg / > 33 lbs)             |

#### STANDARD PACKAGING

|                                                              |     |
|--------------------------------------------------------------|-----|
| Pieces / Pouch                                               | 1   |
| Pieces / Box                                                 | 50  |
| Pieces / Case                                                | 600 |
| Duplex Label on Pouch                                        | yes |
| Lot number and expiration date on every pouch, box and case. |     |

#### CLASSIFICATION AND STANDARDS

|                                               |           |
|-----------------------------------------------|-----------|
| Classification (REG(EU) 2017/745, Annex VIII) | Class IIb |
| Classification (21 CFR 878.4400)              | Class II  |
| CMDR SOR/98-282                               | Class II  |

#### DIMENSIONS PACKAGING

|                   |                 |
|-------------------|-----------------|
| Pouch (L/W) [mm]  | 280 / 175       |
| Box (L/W/H) [mm]  | 282 / 185 / 141 |
| Case (L/W/H) [mm] | 395 / 595 / 455 |

#### BIOCOMPATIBILITY

|                |      |
|----------------|------|
| ISO 10993-1 ff | pass |
|----------------|------|

#### PERFORMANCE

|               |      |
|---------------|------|
| IEC 60601-2-2 | pass |
|---------------|------|

#### MATERIAL PACKAGING

|       |                        |
|-------|------------------------|
| Pouch | Paper / Aluminium / PE |
| Box   | Cardboard              |
| Case  | Cardboard              |

#### MATERIALS

|                  |                  |
|------------------|------------------|
| Carrier Material | Foam             |
| Adhesive         | Polyacrylate     |
| Conductive Layer | Aluminium        |
| Gel              | Hydrogel         |
| Protective Cover | Siliconized Foil |

#### ENVIRONMENTAL INFORMATION

|                                     |     |
|-------------------------------------|-----|
| Compliance with RoHS Directive      | yes |
| Compliance with REACH Regulation    | yes |
| Not made with natural rubber latex. |     |

#### DIMENSIONS

|                                   |            |
|-----------------------------------|------------|
| Electrode Size L/W [cm] (approx.) | 20 / 11    |
| Adhesive Area [cm²] (approx.)     | 190        |
| Conductive Area [cm²] (approx.)   | 118        |
| Gel Thickness [mm]                | 0.5 ± 0.05 |