NISSHA
MEDICAL TECHNOLOGIES




# Swaromed

1023-SWARO-V30-300-3600

Reference: **1023**

Wet Gel

30 Electrodes / Pouch
3600 Electrodes / Case

## APPLICATION

For: 72 Hours

Short- and Long-term Monitoring

## PRODUCT INFORMATION

| | |
|---|---|
| **Shape** | Circular |
| **Size (excl. grip)** | 2.2 in / 55 mm |
| **Sensor (Eyelet) Diameter** | 0.3 in / 8 mm |
| **Substrate Thickness (adapter excluded)** | 0.04 in / 1 mm |
| **Total Product Surface Area** | 3.68 $in^2$ / 2376 $mm^2$ |
| **Gel Area** | 0.39 $in^2$ / 254 $mm^2$ |
| **Adhesive Area** | 3.29 $in^2$ / 2122 $mm^2$ |
| **Integrated Lead Wire (length / color)** | N/A |

## MATERIALS

| | |
|---|---|
| **Substrate Material** | Polyethylene Foam |
| **Adhesive** | Medical grade pressure sensitive adhesive |
| **Gel Type** | Wet Gel |
| **Foam (Sponge) Material** | Synthetic foam - Open Cell |
| **Release Liner** | PETP Film |
| **Sensor Polymer** | Glass-filled ABS - Ag/AgCl Coated |
| **Adaptor / Connector (Stud)** | Stainless Steel |
| **Integrated Lead Wire Jacketing** | N/A |
| **Integrated Lead Wire Cord** | N/A |

## ELECTRICAL PERFORMANCE (ANSI/AAMI EC 12)

| | |
|---|---|
| **ACZ impedance** (before defib simulation) **@10 Hz** | < 300 Ohm |
| **DC Offset Voltage** (before defib simulation) | < 1 mV |
| **SDR Slope** (remaining potential after defib) **@ 30 Sec int.** | < 0.2 mV/sec |
| **ACZ impedance repeat** (after defib simulation) | < 150 Ohm |
| **COIIN** (combined offset instability and inner noise) | 22 µV |
| **Bias Current Tolerance** (DC offset voltage after DC loading) | < 1.7 mV |

## FEATURES

| | |
|---|---|
| **MR Conditional** | No |
| **X-ray Translucence** | No |
| **Integrated Abrader** | No |
| **Repositionability** | No |

## PACKAGING

| | |
|---|---|
| **Product Packaging Material** | Foil/PET/AL/PE |
| **Resealable Pouch** | No |
| **Product Packaging Size (L x W)** | 10.2 x 7.9 in<br>26 x 20 cm |
| **Department Packaging - Box ( L x W)** | 10.4 x 8.1 x 5.1 in<br>26.5 x 20.5 x 13 cm |
| **Transport Packaging - Carton (L x W)** | 21.5 x 16.7 x 16.3 in<br>54.5 x 42.5 x 41.5 cm |

## BIOCOMPATIBILITY

| | |
|---|---|
| **ISO 10993** | Yes |
| **Latex Free** | Yes |

## ENVIRONMENTAL

| | |
|---|---|
| **Halogenated Hydrocarbon Content (e.g. PVC)** | None |
| **Phthalate Derivatives Content (e.g. DEHP)** | None |
| **RoHS Compliant** | Yes |
| **REACH Compliant** | Yes |

## SHELF LIFE

| | |
|---|---|
| **Product Shelf Life** (in accordance with storage guidelines) | 36 Months |

## REGULATORY STATUS

**CE marked according to EU MDR 2017/745**

**Reorder Part Number: 6000607C**

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Disclaimer: The information presented is believed to be reliable concerning the subject matter covered. The final determination of the accuracy or completeness of any information, and the suitability of the product for the use contemplated, is the responsibility of the user.

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