

CE marked

KENDALL[™] ECG Electrodes Product Data Sheet

Covidien[™] H135SG



CE Mark according to MDD 93/42/EEC

| 1. Basic Product Information | |
|--|---------------------|
| Shape / size (incl. grip) | Round / 43 x 35 mm |
| Total product surface (incl. grip) | 1182 mm² |
| Gel area | 254 mm ² |
| Adhesive area | 708 mm² |
| Sensor area | 50 mm ² |
| Product thickness (adapter excluded) | 1 mm |
| Adapter | Stud |
| Integrated lead wire (length / colour) | |

Ref. Code: 31.1355.21

| 2. Materials Information | | | | | |
|---|--|---|--------------------------------|--|--|
| Backing material | | F | Polyethylene foam (PE), white | | |
| Adhesive characteristics | | Medical grade acrylic-based pressure sensitive adhesive | | | |
| Gel characteristics | | Conductive and adhesive acrylic-based hydrogel | | | |
| Supporting / back label | | Polypropylene film (PP), transparent | | | |
| Release liner | | PE/Pa | per/PE, both sides siliconized | | |
| Sensor | | | Polymer Ag/AgCl coated | | |
| Adapter / connector | | | Stainless steel | | |
| Integrated lead wire jacketing | | | | | |
| Integrated lead wire cord | | | | | |
| 3. Electrical Characteristics (ANSI/AAMI | EC 12, average measu | red before packaging) | | | |
| ACZ I impedance (before defibrillation simulat | ion) | | 200 Ohm | | |
| DC offset voltage (before defibrillation simulat | offset voltage (before defibrillation simulation) 0.2 | | <i>0.2</i> mV | | |
| SDR (remaining potential after defibrillation sim | (remaining potential after defibrillation simulation) 11 | | 11 mV | | |
| Slope (potential decline after defibrillation simul | | | 0.2 mV/s | | |
| COIIN (combined offset instability and inner no | OIIN (combined offset instability and inner noise) | | 4 μV | | |
| Bias current tolerance (DC offset voltage after | r DC loading) | | 6 mV | | |
| 4. Special Features | | | | | |
| MRI compatibility (≤ 3T) | | | no | | |
| X-ray translucence | | | no | | |
| Peel off resistance, max. (from PE foil, 180 °, | 50 mm/min, ASTM D1876 | 5) | 4 N | | |
| Integrated abrader | | | no | | |
| Repositionability | | | no | | |
| 5. Packaging | L x W x H (mm) | Content (electrodes) | Material | | |
| Product packaging (pouch) | 200 x 180 | 50 | Paper / PE / Alu / PE | | |
| Department packaging (box) | 194 x 194 x 240 | 500 | Paper cardboard | | |
| Transport packaging (carton) | 600 x 400 x 510 | 6000 | Paper cardboard | | |
| 6. Biocompatibility | | | | | |
| Test acc. to DIN ISO 10993 | | | passed | | |
| LATEX content | | | no | | |
| 7. Environment (detailed information relat | ed to product and packa | aging see "Environmental Dec | laration") | | |
| Halogenated hydrocarbon content (e.g. PV | (C) | | no | | |
| Phthalate derivatives content (e.g. DEHP) | | | no | | |
| RoHS directive | | | in compliance | | |
| 8. Shelf life | | | | | |
| Product shelf life in an intact, originally sea | led packaging | | 24 months @ 10 30 °C | | |
| 9. Legal Status | | | | | |