

TECHNICAL DATA SHEET

Disposable Electrosurgical Pencil



Product :

DENA Sterile electrosurgical pencil

CE 0477

Materials

- Handle cover: ABS.
- Electrode connector: Copper.
- Printed circuit: PCB.
- Activation switches CUT & COAG.
- Connector mould: ABS.
- Connector pins: Brass.
- Cable: Copper coating with PVC.
- Blade electrode 70mm:
 - Electrode body: 304 stainless steel

- Sterile pouch:
 - Cellulose, medical grade.
 - Film PET/Polyethylene.

Main dimensional properties

- Banana plugs: 3 x $\varnothing 4.0$ mm ± 0.2 mm.
- Wire length:
 - MB-100: 300 ± 15 cm.
 - MB-100/5: 500 ± 15 cm.
- Total electrode length: 70 ± 1 mm.
- Diameter of the electrode: 2.36 ± 0.03 mm.
- Electrode insert: hexagonal.

Other properties

Electrical assays EN 60601-2-2

- (High-frequency voltage rating of 5kV peak)
- Cable leakage current.
- Cable dielectric withstand, high frequency (6 kV peak).
- Cable dielectric withstand, mains frequency (6 kV peak, 60 Hz).
- Cable strain relief.
- Handpiece dielectric withstand, high frequency (6 kV peak).
- Handpiece dielectric withstand, mains frequency (6 kV peak, 60 Hz).
- Handpiece retention of removable electrode.

Conclusion: electrical requirements are met.

Biocompatibility

- ISO 10993-5: No cytotoxic.
- ISO 10993-10: no sensitizing, negative intracutaneous irritation test.
- ISO 10993-11: no pyrogen presence, negative systemic injection test.
- ISO 10993-4: negative haemolysis test.

Conclusion: product is biocompatible.

Sterilization and expiry date

- Sterility: Ethylene oxide.
- Shelf life: 3 years.

Storage and maintenance

- Keep protected from direct sunlight / the outside.
- Keep in a dry place.
- Temperature limitation: 5-45°C.
- Single use product.
- No maintenance required.

Packaging

- Cardboard boxes containing 100 units.

REGULATORY INFORMATION

D.G.DENA guarantees that this product is in conformity with **Directive 93/42/EEC** and that it has been manufactured following the directives of the Quality Assurance System certified as **ISO 13485**.

This product is classified as:

- **Class IIb** sterile product according to Annex IX of Directive 93/42/EEC, rule 9.
- GMDN code: 61869. Open-surgery electrosurgical handpiece/electrode, monopolar, single-use.