

BLAYCO®

Sterile single use hand control
electrosurgical pencil with 70mm
blade electrode

References

MB-100: with cable 3m length
MB-100/5: with cable 5m length

CE 0197

Date

December 2011

Specification N.

ETP/026/11

**TECHNICAL
SPECIFICATIONS****Materials**

- Plastic casing: Polypropylene / ABS
- Activation switches (CUT & COAG): Polypropylene / ABS
- Moldet socket: PVC
- Connecting wire: PVC
- Banana plugs: Brass
- Probe holder: Brass
- Included 70mm blade electrode:
 - Blade: Stainless steel AISI 303
 - Collar material: HIPS/PP
- Printed circuit board
- Sterile pouch:
 - Cellulose, medical grade
 - Film PET/Polyethylene

**Main dimensional properties**

- Banana plugs: 3 x Ø4.0mm ±0.2mm
- Wire length:
 - MB-100: 300 ±15cm
 - MB-100/5: 500 ±15cm
- Total electrode length: 70 ±1mm
- Diameter of the electrode: 2.35 ±0.03mm
- Electrode insert: hexagonal

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

**IEC 60601-2-2 and
ANSI/AAMI HF 18 tests**

(High-frequency voltage rating of 5kV peak)

- Cable leakage current
- Cable dielectric withstand, high frequency (6kV peak)
- Cable dielectric withstand, mains frequency (6kV peak, 60Hz)
- Cable strain relief
- Handpiece dielectric withstand, high frequency (6kV peak)
- Handpiece dielectric withstand, mains frequency (6kV peak, 60Hz)
- Handpiece resistance to ingress of liquids
- Handpiece retention of removable electrode

Conclusion: electrical requirements are met

Sterilization and expiry date

- Sterility: Ethylene oxide
- Shelf life: 3 years

Packaging

- Cardboard boxes containing 50 units

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