

# EC-Declaration of Conformity

**Manufacturer:**

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**Product:** Electro Surgery Cables & Accessories

*Electrosurgical Disposable Grounding Plate Cables  
Electrosurgical Bipolar Cables, Electrosurgical Monopolar Cables  
Electrosurgical Bipolar Adaptors  
Electrosurgical Disposable Grounding Plates*

**Models :** RDC-XX Series  
ESU-BP/XXX Series, ESU-MP/XXXX Series  
ESU-ADP/XX Series  
FMT-MX and FMT-CXX Series

**Classification:** Class I Medical Device

We herewith declare that the above mentioned products meet the Essential requirements and conforms to the Medical Device Directive 93/42/EEC.

**Standards:**

EN 60601-1-1: 2001	Medical electrical equipment, Part 1: General requirements for safety
EN 980: 2003	Graphical symbols for use in the labeling of medical devices
EN ISO 9001:2000	Quality management systems-Requirements
EN ISO 13485:2003	Medical devices - Quality management systems -Requirements for regulatory purposes
EN 1041:1998	Information supplied by the manufacturer with medical devices
EN 14971:2000	Medical devices - Application of risk management to medical devices
EN 10993-1:2003	Biological evaluation of medical devices Part 1: Evaluation and testing

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**Signature:**



**Name:** Filiz ERSOY

**Position:** Company Manager