

EC-Declaration of Conformity

Manufacturer:

Name : METKO Medikal ve Tıbbi Cihazlar Dış Ticaret Ltd. Şti.
Address : ATB İş Merkezi E - Blok No: 137 06370 Yenimahalle - Ankara \ Turkey
Tel : + 90 312 387 12 46 (pbx)
Fax : + 90 312 387 12 51
E-mail : metko @metkold.com
Web : www.metkold.com

Authorized European Representative:

Name : Medset Medizintechnik GmbH.
Address : P.O. Box 800 103 D-21001 Hamburg \ Germany
Tel : 0049 40 724 822- 0
Fax : 0049 40 725 822-11
E-mail : info@medset.com
Web : www.medset.com

Product: ECG Suction & Clamp Electrodes
ECG Adaptors for Cables and Leadwires

Models: SE1, SE2 ECG Suction Electrodes
CEAI1, CEAI2, CEEA1, CEEA2 ECG Clamp Electrodes
BS3, BS4, BG3, BG4, BA4B, BA4R ECG Adaptors

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:

| | |
|-------------------|--|
| EN60601-1-1: 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 |

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Signature:



Name: Filiz ERSOY

Position: Company Manager