

EC-Declaration of Conformity

Manufacturer:

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Authorized European Representative:

Name : Medset Medizintechnik GmbH.
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Product: Medical Temperature Probes

Models: FMT400/AOR/XX-X, FMT400/AS/XX-X, FMT400/AOR/XX-AXX Series,
FMT-INC/XX, FMT400/AOR-DXX, FMT400/AS-DXX Series, FMT-INC/SDX

Classification: Class II b Medical Device, Rule 10

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

Notified Body: ORKI - Hungary
(INSTITUTE FOR HOSPITAL AND MEDICAL ENGINEERING)

CE-Mark:  1011

Number of Certificate: 5-413-200-0411

Start of CE Mark: 19.11.2004

Date of issue: 03.10.2005

Signature:



Name: Filiz ERSOY

Position: Company Manager