

# EC-Declaration of Conformity

## Manufacturer:

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## Authorized European Representative:

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**Product:** Adaptor & Extension Cable for Pulse Oximetry (SpO<sub>2</sub>) Sensors  
Adaptor & Extension Cable for Medical Temperature Probes

**Models:** **AEC-5XXX** Series Pulse Oximetry (SpO<sub>2</sub>) Adaptor & Extension Cables  
**FMT400/AEC-XX** Series Temperature Probe Adaptor & Extension Cables

**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

**Date of issue:** 03.10.2005

**Signature:**



**Name:** Filiz ERSOY

**Position:** Company Manager