

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: Pulse Oximetry (SpO2) Sensors

Models: FMT-RAF/XXX, FMT-RPF/XXX, FMT- RYS/XXX, FMT-RAS/XXX,
FMT-RPS/XXX, FMT-RIS/XXX, FMT-RNS/XXX, FMT-RWS/XXX
FMT-DAF/XXX, FMT-DPF/XXX, FMT-DIF/XXX, FMT-DNF/XXX Series

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
EN ISO 9919:2005	Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use

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