



**Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3**

Certificate Number: 1984-MDD-13-200

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

**METKO MEDİKAL VE TIBBİ CİHAZLAR
DIŞ TİCARET LİMİTED ŞİRKETİ**

İvedik OSB Ağaç İşleri San. Sitesi 1354. Cadde 1358. Sokak No:9 06378
Yenimahalle Ankara Turkey

Product	Type	Model	Class
Sterile Disposable Pressure Transducer	TKBT-XXX	TKBT-103 TKBT-203	IIb

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa Meyer for details. This certificate is valid until 03 March 2019.

Report Number: M.3393.04
Date of first issue: 08 January 2013
Date of last issue: 04 March 2014
Revision Number : 01

Kiwa Meyer Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number : 1984.

04 March 2014, Istanbul, Turkey

Head of Notified Body

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* Certificates without seal are invalid.

Certificate



EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-10-075

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

**METKO MEDİKAL VE TIBBİ CİHAZLAR
DIŞ TİCARET LİMİTED ŞİRKETİ**

İvedik OSB Ağaç İşleri San. Sitesi 1354. Cadde 1358. Sokak No:9 06378
Yenimahalle Ankara Turkey

Products: Temperature Probes, Pulse Oximetry (SpO2) Sensors

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa Meyer for details. This certificate is valid until 26 November 2017.

Report Number: M.3393.05
Date of first issue: 23 December 2010
Revision Number: 04
Date of last issue: 27 November 2014

27 November 2014, Istanbul, Turkey

Head of Notified Body

Certificate



Enclosure of the EC Certificate:

**Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II.3**

Certificate Number: 1984-MDD-10-075, Revision Number: 04

Concerned medical devices;

Product Name: Temperature Probes, Class: IIb

Model Numbers:

FMT400/AOR, FMT400/POR, FMT400/AS, FMT400/AOR-15, FMT400/POR-15,
FMT400/AS-15, FMT400/AOR-A, FMT400/POR-A, FMT400/AS-A, FMT400/AOR-
A15, FMT400/POR-A15, FMT400/AS-A15, FMT400/AOR/XX, FMT400/POR/XX,
FMT400/AS/XX, FMT400/AOR/XX-15, FMT400/POR/XX-15, FMT400/AS/XX-15,
FMT400/AOR/XX-A, FMT400/POR/XX-A, FMT400/AS/XX-A, FMT400/AOR/XX-
A15, FMT400/POR/XX-A15, FMT400/AS/XX-A15

(XX variable: BLT, EDN, GE, HP, MND, S, SW, Z)

FMT400/AOR-DX, FMT400/AS-DX, FMT400/OXY-X, FMT-INC/SDX

(X variable: -, 2, 3, 4)

FMT-INC/X (X variable: A, AA, S, SA, SFP, SGR, SIS, SND, SND2, SND3, SO, SO2, SRS,
SAD)

FMT-AFT/XX (XX variable: A1, A2, A3, A4, A5)

Product Name: Pulse Oximetry (SpO2) Sensors, Class: IIb

Model Numbers:

FMT-RAF/XXX, FMT-RAFB/XXX, FMT-RPF/XXX, FMT-RYS/XXX, FMT-RAS/XXX,
FMT-RASB/XXX, FMT-REC/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,
FMT-DVF/XXX

(XXX variable: AT-L, BCI, BCI-L, BCI-LR, BLT-LR, BRC-L, BYS-L, CNC-LR, CHC-LR, CRT,
CRT-L, CRT-LL, CSI, DGC-L, DLP, DLW-L, DTS, DTS-L, DTX, DTX-L, DXT, DXT-L, END-LR,
GLD-LL, GLD-LR, GOX-L, GTG-LR, HPB-L, HPS-L, INV-L, KNT-L, LHM, MEK, MEK-L,
MEK-LD, MEK-LH, MEM-L, MRQ-L, MMH-L, MND-L, MNM-L, MSM-L, NTG, NTG-L,
NTG-LR, NKN, NKN-L, NKN-LC, NLC, NLC-L, NLO, NLO-L, NVM, NVM-L, NON, NON-L,
OHM-L, OHM-S, OXN, OXY, PLS, PLS-L, RGB-LR, PLC, PLC-L, PLM-LR, PRN-LR, SHA-L,
SPL-L, SIE-L, SW-L, UTS-L, TRS-L)

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27 November 2014, Istanbul, Turkey

Head of Notified Body

Certificate