

EC-Declaration of Conformity

Manufacturer:

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Product: Reusable and Disposable NIBP Cuffs, NIBP Hoses

Models : **FMT-S/X** (Reusable Cuff with bladder /Single tube/ X: sizes, 1 to 6)
FMT- D/X (Reusable Cuff with bladder /Double tube/ X: sizes, 1 to 6)
FMT-SB/X (Reusable Cuff without bladder /Single tube/ X: sizes, 1 to 6)
FMT- DB/X (Reusable Cuff without bladder /Double tube/ X: sizes, 1 to 6)
FMT-DS/X (Disposable Neonatal Cuff /Single tube/ X: sizes, 1 to 5)
FMT-DD/X (Disposable Neonatal Cuff /Double tube/ X: sizes, 1 to 5)
SBPXXXX (Single Line Hose, 3.0 m)
DBPXXXX/BPXXXX (Double Line Hose, 3.0 m)

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:

EN60601-1-1:2000	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 1060-1:1995	Non-Invasive Sphygmomanometers Part 1: General Requirements
EN 1060-2:1995	Non-Invasive Sphygmomanometers Part 2: Supplementary Requirements for medical sphygmomanometers
EN 10993-1:2003	Biological evaluation of medical devices Part 1: Evaluation and testing

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Signature:



Name: Filiz ERSOY

Position: Company Manager