

EC-Declaration of Conformity

Manufacturer:

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Product: Reusable and Disposable NIBP Cuffs, NIBP Hoses

Reference Numbers:

FMT-SX, FMT-SX/BPYY-Z (Reusable Cuff with bladder /Single tube/ X (size): 1, 2, 3, 4, 4L, 5, 6; YY variable: 00 to 99; Z variable: -, H, P)
FMT-DX, FMT-DX/BPYYYY (Reusable Cuff with bladder /Double tube/ X (size): 1, 2, 3, 4, 4L, 5, 6; YYYYY variable: 0000 to 9999)
FMT-SBX, FMT-SBX/BPYY-Z (Reusable Cuff without bladder /Single tube/ X (size): 1, 2, 3, 4, 4L, 5, 6; YY variable: 00 to 99; Z variable: -, H, P)
FMT-DBX, FMT-DBX/BPYYYY (Reusable Cuff without bladder /Double tube/ X (size): 1, 2, 3, 4, 4L, 5, 6; YYYYY variable: 0000 to 9999)
FMT-DSX, FMT-DSXS, FMT-DSXT, FMT-DSX/BPYY-Z, FMT-DSXS/BPYY-Z, FMT-DSXT/BPYY-Z (Single Patient Use Cuff /Single tube/ X: sizes, 1 to 13; YY variable: 00 to 99; Z variable: -, H, P)
FMT-DDX, FMT-DDXS, FMT-DDXT, FMT-DDX/BPYYYY, FMT-DDXS/BPYYYY, FMT-DDXT/BPYYYY (Single Patient Use Cuff /Double tube/ X: sizes, 1 to 13; YYYYY variable: 0000 to 9999)
FMT-ASX, FMT-ASX/BPYY-Z (ABPM Cuff / X (size): 3, 4, 5; YY variable: 00 to 99; Z variable: -, H, P)
SBPXX/BPXX-Z (Single Line Hose, 3.0 m) (XX variable: 00 to 99; Z variable: -, H, P)
DBPXXXX/BPXXXX (Double Line Hose, 3.0 m) (XXXX variable: 00 to 99 or 0000 to 9999)
CEBPXX/BPXX-Z (Coiled Extendable Hoses) (XX variable: 00 to 99; Z variable: -, H, P)

Classification: Class I Medical Device, Annex IX Rule 1

Conformity Assessment Procedure: Ek VII

GMDN Codes: 34978, 37326

We herewith declare that the above mentioned products meet the Essential requirements and conforms to the Medical Device Directive 93/42/EEC.

Standards:

EN 60601-1:2006	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 81060-1:2012	Non-invasive sphygmomanometers - Part 1: Requirements and test methods or non-automated measurement type
EN 1060-3:1997+A2:2009	Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electromechanical blood pressure measuring systems
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices
EN 62366-1:2015	Medical devices - Application of usability engineering to medical devices
EN ISO 9001:2015	Quality management systems-Requirements
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes

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Signature:



Name: Filiz ERSOY
Position: Company Manager