MEYSA TIBBİ CİHAZLAR SAN. ve TİC. A.Ş.
O. S. B. 16.Cad. No :73 Melikgazi / KAYSERİ / TÜRKİYE
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CE

DECLARATION OF CONFORMITY

IN accordance with 93/42/EC Medical Devices Directive of the Council of European Union, whose purpose is providing conformity of laws, directives and administrative of documents of member countries in respect to Medical Device;

Name and Address of the Company: MEYSA TIBBİ CİHAZLAR SAN VE TİC A.S.
Tel: +90 352 5013 16 6 **Fax:** +90 352 503 16 61
Place and Address of Manufacture: OSB. 16.Cad No:73 Melikgazi Kayseri / TURKEY
Applied Directives: 93/42/EC- Medical Devices Directive
Classification and Annex Applied: Product is subject to Medical Devices Directive Class 1. Applied.
Name of Product and Types:

Patient and ICU Beds: PIONEER CLW, CL, 4.3PLUS, 4.2CARE, 4.1 TREND, 3.1 , 2,DUO 2, PRIMITIVE 1,2,3
Stretchers: MOVEE 2.0 NW, DYNAMIC 3.0 ,DYNAMIC 2.0, DYNAMIC 1.0 ,MOVEE VERSUS, HYDRAULIC SHOWER STRETCHER
Gynecological Ex. Table: MOTHERCARE 2, MOTHERCARE 3
Pediatric Bed: JUNIOR 4, 3, 2, JUNIOR
Delivery Bed : SUNRISE
Chair: DONEE 01 , 02, 03
IV Stand: MIP 100, MIP 101
Armchair Bed: Relaxia 01,02,03,04,05
Examination Table: Diagno 01,02,03
Patient Transport : Hercules
Trolley: Tena 01, Tena 02, Tena 03, Tena 04, Emergency Trolley
Patient Bed Side Cabinets: SERA 1,2,3,4,5,6,7,8,9,10,11,12
Patient Overbed Table: MIRACH 1,2,3,4,5
Baby cots : NICE 01,02
Mattress : Smooth ST , 01 , 02 , FX 01 , FX 02 , FX 03
Wardrobe : Bien 01 , 02 , Beta 01 , 02, Bona 01 , 02
Accessories : Lifting pole, iv pole, A4 sheet holder, oxygen bottle holder , urine bag basket , defibrillator tray, nurse control, hand control , length extention , traction frame,

Declaration;

Our company manufactures the products stated above in accordance with the requirements of the current EN 980-1996/A1 (Graphs and Symbols Used on labels) EN 1401 (Information provided with the Product by Manufacturer) ISO 13485:2003 Medical Devices Quality Management System.

Used Standards;

The mentioned products are complying with the requirements of the following **standards**; EN 60601-1:2006/A1:2013 EN 60601-1-2:2007 EN 60601-1-6:2010, IEC60601-2-38, EN 60601-2-52: 1-2010

The products described above were subjected to initial type experiments by Manufacturer and factory manufacture control was carried out by regular tests.

Date of Issue 01.01.2023 General Manager

MEYSA TIBBİ CİHAZLAR SAN. ve TİC. A.Ş. OSB 16. Cad. KAYSERİ Tel: 0352 503 16 61

Digitally signed by Grabazei Alexandru
Date: 2023.09.23 22:11:45 EEST
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