



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.

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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,4.2 W,4.2LW 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 extension , 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

