

**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 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

