



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971:2019
EN ISO 15223-1:2016
ISO 10993-1:2018
EN ISO 10993-5:2009
EN ISO 10993-10:2010
EN 1041:2008+A1:2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-MT-04.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: HEFEI MT MEDICAL CO., LTD.

Address: Shangze Business Center, Economic Development Zone, Hefei, Anhui, China.

Product Information

Name: Manual Hospital Bed

Model: See Annex

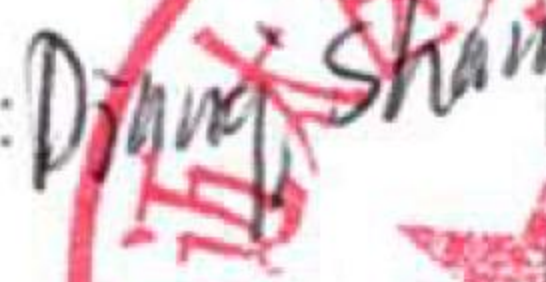
GMDN: 34873

Basic UDI-DI: 697885897mhb002TF

Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:  Date: 2 June, 2021

Position: GM

Place: Anhui/China



Annex

Product Name	Model	GMDN	Basic UDI-DI
Manual Hospital Bed	FN-1,FN-2,FN-3,FO-1,FO-2,FO-6,FO-6-1,FO-7,FO-7-1,FO-8,FO-8-H,FO-8-1,FO-9,FO-9-H,FO-9-1,FP03,FP-2,FP-1,FP-6,FP-6-1,FP-7,FP-7-1,FP-8,FP-8-H,FP-8-1,FP-9,FP-9-H,FP-9-1,FA-6,FA-7,FA-8,FA-8-H,FA-9,FE-2,FE-3,FE-4,FE-5,FE-6,FE-2,FE-3,FE-4,FB-2,FB-3,FB-4,FC-2,FC-3,FC-4,FC-5,FE-1,FE-2,FE-3,FE-4,FE-5,FE-6,FE-7,FE-8,FE-9,FE-10,FE-11,FE-12,FE-13,FE-14,FE-15,FE-16,FE-17,A20,A21,A22,A23,A24,A25,A26,A27,A28,A29,A30,A31,A32,A33,A34,A35,A36,A37,A38,A39,Z-01,Z-02,Z-03,FA-Z,FA,ZM-A,A37-1,A37-2,A37-3,A37-4,A37-5,A37-6,A39-1P,A39-1D,A39-1S,A39D,A39-2P,A39-2D,A39-2S,A39-3,FI-1,A26,A27,A28,A29,A30,A31,A32,A33,A34,A35,A36,A37,A38,A39,A37-1,Z-01,Z-02,FA-Z,Z-03,A39D,A39-1P,A39-2S,A39A,A39B,A39D,A39-1P,A39-2S,A39-3,FI-1,A3,A4,A5,A6,A7,A8,A9,A10,A11,A12,A13,A14,A15,A16,A17,A18,A19,FJ,FJ-2,FJ-1,FJ-3,FJ-4,FJ-5,FA-8-M,A41,A42,A43,A44,A44-1,A44-2,A44-3,A44-4,A44-5,A44-6,D4,D4-1,D4-2,D4-3,A45,A45-1,A46,A47,A48,A49,A50,D14,D15,D17,D18,D14A,D14B,D15A,D15B,D17A,D17B,D18A,D18B	34873	697885897 mhb002TF

Signature:

Date: 2 June, 2021

Position: GM

Place: Anhui/China

