



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
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-MT-06.

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: Medical Chair
Model: See Annex
GMDN: 34833
Basic UDI-DI: 697885897mcr007VJ
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: *Diana Shan* Date: 2 June, 2021

Position: GM

Place: Anhui/China



Annex

Product Name	Model	GMDN	Basic UDI-DI
Medical Chair	D19,D20,D24,D25,D19A,D19B,D20A,D20B, D24A,D24B,D25A,D25B,D25,D26,D5,D5-1,D5-2,D5-3, D6,D6-1,D6-2,D6-3,D8,D8-1,D8-2,D8-3,D9,D9-1,D9-2, D9-3,D10,D10-1,D10-2,D10-3,D11,D11-1,D11-2,D11-3, D12,D12-1,D12-2,D12-3,D21,D22,D23,D21A,D21B,D21C, D21D, D22A,D22B,D22C,D22D,D23A,D23B,D23C,D23D, D7 D7-A D7-B D7-C D7-D D7-E,D7-F, D7-G,D7-H,D7-I, D7-J, D7-K,D7-L,D7-M,D7-N,D7-P	34833	697885897 mcr007VJ

Signature:

Date: 2 June, 2021

Position: GM

Place: Anhui/China

