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 1041:2008+A1:2013
EN ISO 15223-1: 2016
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 60601-1-2:2015
EN 60601-2-52:2010/A1:2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-MT-01.

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: Electric Hospital Bed

Model: See Annex

GMDN: 34870

Basic UDI-DI: 697885897ehb003Q9

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: Dilong Shan Date: 2 June 2021

Position: GM Place: Anhui/China

Annex

Product Name	Model	GMDN	Basic UDI-DI
Electric Hospital Bed	DHC-IV(FG05),DHC-IV(FG06),DHC-IV(FG07),DHC-IV(FG08), DHC-IV(FG09),DHC-IV(FG10),DHC-IV(FP07),DHC-III(FP05), DHC-III(FH12),DHC-III(FM05),DHC-III(FM04),DHC-III(FM03), DHC-II(FO03),DHC-III(FP04),DHC-III(FP05A),DHC-II(FS-01), DHC-II(FS-02),DHC-II(FS-03),DHC-II(FA-05),DHC-II(FA-05-1), FA-1,FA-2,FA-3,FA-4,FA-5,DHC-II(FE01),DHC-III(FE01), FB-1,FC-1,FD-1,DHC-II(FH01),DHC-II(FH02),DHC-II(FH03), DHC-II(FH04),DHC-II(FH05),DHC-II(FH06),DHC-II(FH07), DHC-II(FK02),DHC-II(FK03),DHC-II(FK04),DHC-II(FK05), FH05,FH06,FH07,FH08,FH09,FH10,A1,A2	34870	697885897 ehb003Q9

Signature:

Date: 2 June, 2021

Position: GM

Place: Anhui/China