



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- 07.

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 Trolley
Model: See annex
GMDN: 35597
Basic UDI-DI: /
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.

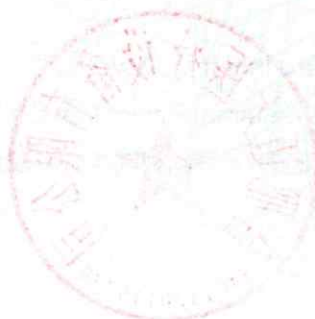
Signature: *Dong, Shan* Date: 2 June, 2021

Position: GM

Place: Anhui/China

Annex

Product Name	Model	GMDN	Basic UDI-DI
Medical Trolley	CQ-02, CM-02, CF-02, CF-06, CQ-06, CM-06, CS-06, CZ-06, CB-06, MWT-1, CQ-08, CF-08, CM-08, CQ-10, CM-10, CF-10, CS-10, CZ-10, CB-10, MWT-10, CQ-11, CM-11, CF-11, CS-11, CZ-11, CB-11, MWT-11, CQ-12, CM-12, CF-12, CS-12, CZ-12, CB-12, MWT-12, CQ-13, CM-13, CF-13, CS-13, CZ-13, CB-13, MWT-13, MWT-4A, MWT-4B, CF-04, CZ-04A, CZ-04B, CZ-04C, CF-09, MWT-5A, MWT-5B, CZ-05A, CZ-05B, CZ-05C, CM-05, CF-05A, CF-05B, CQ-03, CM-03, CS-03, CZ-03, CM-07, CQ-07, MWT-7, CB-02, CB-07, CB-03, CB-04, CF-07, CF-09, CS-08, CH-02, CH-04, CH-03, CH-06, CZ-08, CY-01, CY-03, CY-02, CY-04, CY-05, CY-06, CY-07, CY-08, CY-09, CY-10, CY-11, CY-12, CY-13, CY-14, CY-15, CY-16, CY-17, CY-18, CY-19, CY-20, CY-21, CY-22, CY-3, B11, B12, B13, B14, B15, B16, B17, B18, B19, B20, B21, B22, B23, B24, B25, B26, B27, B28, B29, B30, B9, B10, B8, CR-01, CR-02, B10-2, CR-03, B10-3, B7-4, B7-2, B7-3, B7-5, B7-6, B7-7, B7-8, B31, B32, B33, B34, B35, B36, B37, B37-1, B38, B39, B40, B41, B42, B43, B44, B45, B46, B47, B48, B49, B50, B51, B52, B53, B54, B55, B56, B57, B58, B59, B60, B61, B62, B63, B64, B65, B66, B67, B68, B69, B70, B71, B72, B73, C55, C56, C57, C58, C59, C55A, C55B, C57A, C57B, C59A, C59B, D13, D13A, D13B, D13C, D14, D14A, D14B, D14C, D15, D15A, D15B, D15C, D16, D16A, D16B, D16C	35597	/



Signature:

Position: GM

Date: 2 June, 2021

Place: Anhui/China

