



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
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: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 60601-1-2:2015/A1:2021
EN 60601-1:2006/A2:2021
EN 12184: 2014

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122127-01.

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: NINGBO KS MEDICAL TECH CO.,LTD
Address: Building 1, No 462 Wenyuan road, Yinzhou district, Ningbo, China
SRN: CN-MF-000033670

Product Information

Name : ELECTRIC WHEELCHAIR
Model : KSM-601 KSM-602 KSM-603 KSM-605
KSM-606 KSM-607 KSM-608 KSM-609 KSM-610
KSM-501 KSM-502 KSM-503 KSM-505
KSM-506 KSM-507 KSM-508 KSM-509 KSM-510
KSM-301 KSM-302 KSM-303 KSM-305
EMDN : Y122127
GMDN : 40840
Basic UDI-DI : 697614464EW01LT
Classification: Class I, According to Rule 13, 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: Justin Wu Date: 2023-2-17

Position: GM Place: Ningbo/China

