



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-00000247

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 12184:2014
EN 60601-1:2006+A1:2013+
AC:2014+A12:2014 +A2:2020
EMC EN 60601-1-2:2015+A1:2020

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122124-02.

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 : MOBILITY SCOOTER
Model : KSM-901 KSM-902 KSM-903 KSM-905 KSM-906 KSM-907 KSM-908 KSM-909 KSM-910 KSM-920 KSM-930
EMDN : Y122124
GMDN: 45684
Basic UDI : 697614464MS01MX
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

