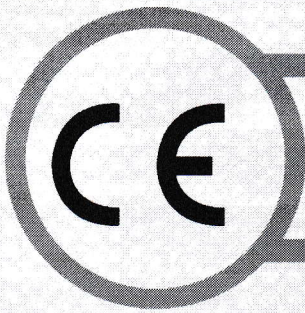




DECLARATION OF CONFORMITY

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
EN ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN 12184:2014

Remark

The declaration of conformity is valid in connection with the release technical document CE-MDR-TCF01.
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

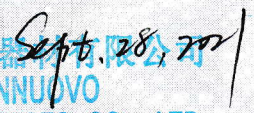
Name: Zhejiang Innovo Rehabilitation Devices Co.,Ltd.
Address: No.196 Industy Road, Hengdian Movie Zone, Dongyang, Zhejiang, China
SRN: CN-MF-000008727

Product Information

Name: Mobility Scooter
Model: W3331,W3431,W3433,N3458,N3458A,N3458C,W3331D,W3431A,W3431B,W3431D,W3433D,W3433E,W3435,W3451,W3459,W3463,W3463A.
GMDN: 45684
Basic UDI-DI: 697076597MS001NQ
Intended purpose: The product is intended to provide transportation for disabled.
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:  Date: 
ZHEJIANG INNUOVO
REHABILITATION DEVICES CO., LTD

Position: GM

Place: Zhejiang/China