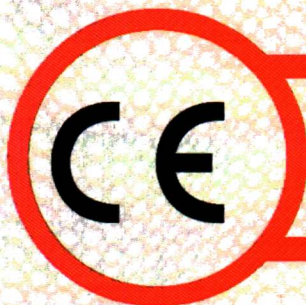




DECLARATION OF CONFORMITY

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
EN 62366-1:2015

Remark

*The declaration of conformity is valid in connection
with the release technical document
CE/MDR-Y122127-02.*

*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: Kunshan Hi-Fortune Health Products Co., Ltd
Address: #625 Juxiang Rd, Zhangpu Town, Kunshan
City, Jiangsu, CHINA
SRN: CN-MF-000035403

Product Information

Name: Electrically powered wheelchair
Model: HP358E, HP358EA, HP202, HP201, HP200,
HP458E, EY07, EY18, P15, P55, HP203, HP204,
HP205, HP206, HP207, HP208, HP209, HP210,
HP211, HP212
EMDN: Y122127
Basic UDI-DI: 697385259Ewheelchair95
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:

Position: GM

Date:

20/6 2023

Place: Kunshan/China