EU Declaration of Conformity

Manufacturer:
MERITS HEALTH PRODUCTS CO., LTD.
NO. 18, JINGKE RD., NANTUN DISTRICT,
40852 TAICHUNG CITY, TAIWAN

whose single Authorized Representative:
MedNet EC-REP GmbH
Borkstrasse 10, 48163 Münster, Germany

We, the manufacturer, herewith declare under our sole responsibility that the products

Electrically Powered wheelchairs
Model No.: P113 S/N : XXXX
Trade Names: Kompas, Yoyo
(including system components and accessories)
*UMDNS-Code:***41637***; GMDN-Code/Preferred Terms:* **41637** / Wheelchair, occupant, electric drive/steer, collapsible
Intended Purpose: This device is intended to provide mobility to adult persons limited to a sitting position and capable to operate a few simple controls.

The classification is made in accordance with ***MDR (EU) 2017/745, Annex VIII*** *Section 4, 4.1, rule 1,"All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies" &* ***Section 6, 6.5, rule 13, "All other active devices are classified as class I.".*** It bears the mark

CE

To which this declaration relates is in conformity with the standard(s) or common specification or other normative document(s) specified in the Annex on the following pages.

Compliance of the designated product with the MDR (EU) 2017/745 has been assessed.

following the provision of Regulation: EU Medical Device Regulation [MDR (EU) 2017/745] ANNEX II (Technical documentation), ANNEX III (Technical documentation on post-market surveillance), and including an assessment of the technical documentation; RoHS 2 of Directive 2011/65/EC

This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

MERITS HEALTH PRODUCTS CO., LTD.

MERITS HEALTHCARE INDUSTRIES (SUZHOU) CO., LTD. 美利驰医疗器械(苏州)有限公司

Taichung, Taiwan
2020/11/06
Place , date

York Lee
Supervisor of R&D Dept.
Legally binding signature, Function

York Lee
2020.11.6

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DOC-P02-00

ANNEX A:

All devices carry the CE mark. The applied conformity assessment procedure is carried out according to EU Medical Device Regulation [MDR (EU) 2017/745] ANNEX II (Technical documentation), ANNEX III (Technical documentation on post-market surveillance), and including an assessment of the technical documentation; RoHS 2 of Directive 2011/65/EC.

Comply with following Standards:

Document No.	Description	Note
EN 12184:2014	Technical systems and aids for disabled or handicapped persons, Wheelchairs.	
ISO 7176-21:2009	Wheelchairs - Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers	
EN ISO 14971:2012	Medical devices -- Application of risk management to medical devices	
IEC 62304:2006	Medical device software-Software life cycle processes	
EN 62366 : 2008	Medical devices. Application of usability Engineering to medical devices	
EN ISO 10993-1:2009 (ISO 10993-1:2003)	Biological evaluation of medical devices – Part 1: Evaluation and testing	
EN ISO 10993-5:2009 (ISO 10993-5:2009)	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	
ISO 10993-10:2002/ Amd1:2006	Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity	
EN ISO 13485:2016 /AC:2016	Medical device-Quality management systems-Requirements for regulatory purposes	

ANNEX B:

P113AUDGIDB	04714379294477	Electrically Powered wheelchairs
P113AUBGIDB	04714379294484	Electrically Powered wheelchairs