EU Declaration of Conformity

The following description for the medical device,

Device information	*Description*
Registered trade name and address	*WU'S Tech Co., Ltd.* *No. 225, Yuanpeir St., Hsinchu City, Taiwan, R.O.C.* *Tel:+886-3-5382105*
Authorized representative	*Y. Sung Handelsvertretung* *Toulouser Allee 9, 40211 Düsseldorf, Germany*
Common device name	*Power Assist Drive Unit*
Product and trade name	
GMDN code	*42805: Power assisted conversion kit*
Manufacturer SRN	*EUDAMED register TW-MF-000011590*
Authorized representative SRN	*EUDAMED register DE-AR-000005142*
Basic UDI-DI	*471987290PS3860JF*
Model	*PS-HA (PS-HA, PS-HAD, PS-HAS, PS-PA, PS-PAD),* ***V-Mobil***
Risk class of the device	*Class I*
Intended purpose (GMDN definition)	*The Wheelchair attachment is intended as a mobility aid that attaches to a Manual Wheelchair to assist in Propulsion of the wheelchair.* *The PS-HAS is designed as an aid to a wheelchair attendant providing power to aid pushing in otherwise strenuous situations such as up steep hills, etc.*

that is covered by the present declaration is in conformity with the Medical Device **Regulation 2017/745/EU** as amended by **2020/561/EU** and, if applicable, with any other relevant Union legislation that provides for the issuing of this EU declaration of conformity. The device is in conformity with conformity assessment procedure for **Class I devices** that should be carried out, as a general rule, under the sole responsibility of manufacturers in view of the low level of vulnerability associated with such devices. Thus, manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing an EU declaration of conformity referred to in Article 19 "EC declaration of conformity" after drawing up the technical documentation set out in Annexes II and III of the **Regulation**.

For the evaluation regarding Class I device **(**Risk class in accordance with the Rule 1 set out in Annex VIII of the **Regulation**), the following harmonized standards are applied:

- *EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes*
- *EN ISO 14971:2019 Medical devices－Application of Risk Management*
- *EN ISO 15223-1:2021 Medical device – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements*

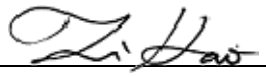
  EN 60601-1:2006＋A11:2011＋A1:2013＋A12:2014 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- *EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- *Directive 2011/65/EU & Directive (EU) 2015/863*
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The following Union authorized representative is stated to the declaration:

Y. Sung Handelsvertretung
Toulouser Allee 9, 40211 Düsseldorf, Germany
(Company name / Registered place of business)

The following person is exclusively responsible for the compliance of declaration:

WU'S Tech Co., Ltd.
No. 225, Yuanpeir St., Hsinchu City, Taiwan, R.O.C.
(Manufacturer's name/ Registered address)

Tim Kao / Vice President  *May 31, 2023*

(Name/Function) (Legal Signature) (Date of issue)