CE EU Declaration of Conformity

The following description for the medical device,

Device information	***Description***
Registered trade name and address	*WU´S Tech (Vietnam) Co., Ltd.* *No. 31, VSIP II, Road 6, Thu Dau Mot City, Binh Duong Province, Vietnam* *+84-650-3628201*
Authorized representative	*Y. Sung Handelsvertretung* *Toulouser Allee 9, 40211 Düsseldorf, Germany*
Common device name	*Electrical Scooters*
Product and trade name	
GMDN code	*45684: Assistive scooter, electric-motor-driven*
Single Registration Number (SRN)	*EUDAMED register VN-MF-000011591*
Basic UDI-DI	*471987290WT3800M3*
Model:	*WT-M4JX (WT-M4JH8)* ***Bility S***
Risk class of the device	*Class I*
Intended purpose (GMDN definition)	*A battery-powered, electric-motor-driven mobility device designed to be operated by a person with a disability and consisting of a seat over two rear wheels, a platform for the feet, and handlebars in front to turn one or two steerable front wheels connected via a steering-column. The device is used to enhance the user's ability for self-transportation in the local environment and/or to promote the user's physical/recreational activities.*

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 62366-1:2015 Medical devices Part 1-- Application of usability engineering to medical devices*
- *Directive 2011/65/EU & Directive (EU) 2015/863*
- *ISO 7176 series Requirements and test methods for Wheelchairs and Scooters*

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 27, 2022*
(Name/Function)	(Legal Signature)	(Date of issue)