



## EU Declaration of Conformity

The following description for the medical device,

Device information	Description
Registered trade name and address	<i>WU'S Tech (Vietnam) Co., Ltd. No. 31, VSIP II, Road 6, Hoa Phu Ward City, Binh Duong Province, Vietnam +84-650-3628201</i>
Authorized representative	<i>Y. Sung Handelsvertretung Duesselthaler Str. 24, 40211 Duesseldorf Germany</i>
Common device name	<i>Electrical Scooters</i>
Product and trade name	
UMDNS code	<i>17733, Scooters, Powered</i>
GMDN code	<i>45684: Assistive scooter, electric-motor-driven</i>
Single Registration Number (SRN)	<i>DIMDI register # 00314156</i>
Basic UDI-DI	<i>Model: WT-M4J, Electrical Scooter Basic UDI-DI: 471987290WT3800M3</i>
Risk class of the device	<i>Class I</i>
Intended purpose (GMDN definition)	<i>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.</i>
Conformity assessment procedure performed and identification of the certificates issued by notified body, if applicable	<i>Quality Management System ISO 13485:2016 by DNV GL ISO 9001:2015 by DNV GL</i>
Name and identification number of the notified body, if applicable	<i>ISO 13485, Certificate Number: 217113-2017-AQ-RGC-NA-PS Rev. 2.0 ISO 9001, NQA Certificate Number: 00003-2018-AQ-YWN-TAF</i>

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 14971:2012 Medical devices –Application of Risk Management*
- *EN ISO 15223-1:2016 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
- *EN 60601-1:2006 + AC:2010 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- *EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- *EN 62366-1:2015 Medical devices Part 1-- Application of usability engineering to medical devices*
- *2011/65/EU*
- *ISO 7176 series Requirements and test methods for Wheelchairs and Scooters*

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The following Union authorized representative is stated to the declaration:

*Y. Sung Handelsvertretung*

*Duesselthaler Str. 24, 40211 Duesseldorf Germany*

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(Company name / Registered place of business)

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

*WU'S Tech (Vietnam) Co., Ltd.*

*No. 31, VSIP II, Road 6, Hoa Phu Ward City . Binh Duong Province, Vietnam*

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(Manufacturer's name/ Registered address)

*Tim Kao / Vice President*

(Name/Function)

(Legal Signature)

*December 27, 2020*

(Date of issue)