TUNG KENG ENTERPRISE CO., LTD.
No. 1, Lane 160, Sec. 2, Tan-Fu Road, Tan-Tzu Dist.,
Taichung City, Taiwan
Tel: +886-4-25321000 Fax: +886-4-25325000
Website: www.dkcity.com

EU Declaration of Conformity

The following description for the medical device,

Device information	***Description***
Registered trade name and address	*Tung Keng Enterprise Co., Ltd.* *No. 1, Lane 160, Sec. 2, Tan-Fu Road, Tan-Tzu Dist., Taichung City, Taiwan*
Authorized representative	*Y. Sung Handelsvertretung* *Toulouser Allee 9, Düsseldorf, Nordrhein-Westfalen 40211, Germany*
Common device name	*Electrically Powered Wheelchair*
Product and trade name	DK CITY
UMDNS code	***16214**, Wheelchairs, Powered*
GMDN code	***45880**: Wheelchair, electric-motor-driven, occupant-controlled*
Single Registration Number (SRN)	*TW-MF-000012340*
Basic UDI-DI	*471988454JoyRider3B*
Risk class of the device	*Class I*
Intended purpose (GMDN definition)	*A wheeled personal mobility device that incorporates a seat-support system for a person with a disability or a person without the full capacity to walk (not bariatric) designed to be propelled by power from one or more electric motor(s). The electronic control of speed and direction are performed by the occupant of the device. The device cannot be folded or readily dismantled for transport.*
Conformity assessment procedure performed and identification of the certificates issued by notified body, if applicable	*Quality Management System* *ISO 13485:2016 by CISQ* *ISO 9001:2015 by UKAS*
Name and identification number of the notified body, if applicable	*ISO 13485, Certificate Number:* *9124.TNGK* *ISO 9001, NQA Certificate Number:* *TW005573*

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Version V1.2

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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 the Rule 1 set out in Annex VIII ot the **Regulation**), the following international standards are applied:

- *EN 1041:2008 Information supplied by the manufacturer of medical devices*
- *ISO 7176 series Requirements and test methods for Wheelchairs and Scooters*
- *ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*
- *EN 12184:2014 Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods*
- *EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes*
- *ISO 14971:2019 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*
- *IEC 62133:2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*
- *EN 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices*

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The following Union authorized representative is stated to the declaration:

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

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

Tung Keng Enterprise Co., Ltd.
No. 1, Lane 160, Sec. 2, Tan-Fu Road, Tan-Tzu Dist., Taichung City, Taiwan
(Manufacturer's name / Registered address)

Frank Huang / General Manager		Mar 2, 2023
(Name / Function)	(Legal Signature)	(Date of issue)

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