EU Declaration of Conformity

The following description for the medical device,

Device information	Description
Registered trade name and address	Lerado Zhongshan Peaceful Cove Business Trading Co., Ltd. No.26, Guangfu Road. Dongsheng Town, Zhongshan Ctry, Guangdong Province, 528414, China Tel:+86-760-23372447
Authorized representative	Y. Sung Handelsvertretung Duesselthaler Str. 24,40211 Duesseldorf Germany
Common device name	Strollers
Product and trade name	LERADO Excel Elise Travel Buggy Mobiquip Elise XL stroller
UMDNS code	18139,Strollers
Basic UDI-DI	Stroller MK1000:6973134780121
Risk class of the device	Class I
Intended purpose (GMDN definition)	A wheeled personal mobility device designed for transporting persons(not bariatric)over a short distance and generally limited to indoor use or use outdoors over smooth paved surfaces. It has small wheels that the occupant cannot use for propulsion and incorporates a simple seat-support system for a person with a disability or a person without the full capacity to walk. It will also include footrests to keep the occupant's feet raised from the ground .It is typically used in hospitals, airports, and railway stations. Also known as a transportation chair or transit wheelchair, it may be disassembled or folded for transport.
Conformity assessment procedure performed and identification of the certificates issued by notified body, if applicable	Quality Management System ISO 13485:2016 by NQA ISO 9001:2015 by NQA
Name and identification number of the notified body, if applicable	ISO 13485,NQA Certificate Number: 49451 ISO 9001, NQA Certificate Number: 41344

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

Issued date: June 24. 2020
Version: V1.0

LERADO

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 I 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 62366-1: 2015 Medical devices Part 1--Application of usability engineering to medical devices
-EN 12182: 2012 Assistive products for persons with disability-General requirements and test methods

---

The following Union authorized representative is stated to the declaration:

Y. Sung Handelsvertretung
Duesselthaler Str. 24. 40211 Duesseldorf Germany
(Company name/Registered place of business)

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

Lerado Zhongshan Peaceful Cove Business Trading Co., Ltd.
No. 26. Guangfu Road. Dongsheng Town, Zhongshan City, Guangdong Province, 528414 China,
(Manufacturer's name/ Registered address)

Hongmei Tian/General Manager — June24, 2020
(Name/Function) (Legal Signature) (Date of issue)

Issued date: June 24. 2020
Version: V1.0