




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	Rollators
Product and trade name	
GMDN code	37951:Basic Walker,Foldable 31110:Walking Aid
UMDNS code	14393,Walkers 17980,Walker/Chairs,Wheeled
Single Registration Nuber(SRN)	DIMDI register#00311668
Basic UDI-DI	Rollaror RU4011:6973134780152
Risk class of the device	Class I
Common Specification(CS) references	Rollator,Walker with wheels,Walker/Chairs with wheeled, Rollator with Seat,Foldable Rollator with Seat
Intended purpose (GMDN definition)	An all-or partially-wheeled mobility aid in the form of a Waist-high, foldable or non-foldable framework with Handgrips and four or three legs designed to provide a stable support to a person with a disability,a geriatric or an infirm Person when standing or ambulating;it may also be used During rehabilitation, it is constructed of lightweight metal, Plastic,and rubber materials in the shape of a mobile support Structure which the user holds and pushes in front of them as They walk.It is foldable or non-foldable and includes a Braking mechanism;it may be width-adjustable and some types may include a seat on which the user can rest.
Conformity assèssment procedure performed and identification of the certificates issued by notified body, if applicable	Quality Management Syster 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

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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 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 1985:1999 Walking aids-Requirements and test methods
- EN ISO 11199-2:2005 Walking aids manipulated by both arms-Requirements and test methods-PART 2: Rollators

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, 52844 China,
(Manufacturer's name/ Registered address)

Hongmei Tian/General Manager
(Name/Function)


(Legal Signature)

June 24, 2020
(Date of issue)