

EC Declaration of Conformity

Medical Device Regulation (MDR) EU 2017/745

We, Soletek GmbH, Feldheider Str. 62-64, 40699 Erkrath, Germany, as the authorized representative, declare under our sole responsibility that the following medical devices:

Product Name	Model Number	Variant	EAN/UDI-1D
Rolektro ERS-6 Li	35000	Li Lithium	4251293537766
Sanamobil ERS-6 Li	34826	Li Lithium	4251293537506
Libremo ERS-6 Li	35147	Li Lithium	4251293539067
Maximus ERS-6 Li	35148	Li Lithium	4251293539074

Manufacturer:

NINGBO SHENCHIMA VEHICLE INDUSTRY CO., LTD
No. 199 Xingci 3# Road, Hangzhou Bay New Zone
Cixi, Ningbo City
Zhejiang Province, China

Testing Laboratory:

Shanghai Global Testing Services Co. Ltd.
Floor 2nd, Building D-1, No. 128, Shenfu Road, Minhang District, Shanghai, China
Test-Report-No.: TMG24101662991
Date of Issue: October 21th, 2024

MDR Certificate:

Verification No.: ICR Polska/VC/HS241075 / S/N: 010973
Date of review: 21.10.2024
Expiration date: 20.10.2029

Intended purpose:

The electric mobility scooters are intended for the transportation of individuals with restricted mobility in indoor and outdoor environments. They can be operated with one hand, and foot function is not required. The vehicle is therefore particularly suitable for people with the indication of only having the right hand or the left hand available. It is also suitable for people with mobility handicaps.

Risk class:

Class I in accordance with Regulation (EU) 2017/745 on medical devices.

List of European Union Harmonized Standards which these products apply:

Standard	Version	Name of document
EN 12184	2022	Electric wheelchairs and mobility scooters for indoor and outdoor use - Requirements and test methods.
EN ISO 15223-1	2021	Symbols for use in the labelling devices Medical device - Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements.
EN ISO 20417	2021	Information supplied by the manufacturer of medical devices.
EN ISO 14971	2019+A11:2021	Medical devices - Application of risk management to medical devices.

Conformity assessment procedure:


Conformity assessment in accordance with Annex X of Regulation (EU) 2017/745 on medical devices


Declaration:

The above-mentioned medical devices comply with the essential requirements of Regulation (EU) 2017/745 on medical devices and the standards listed above.

We declare that the technical documentation required by Annex II of Regulation (EU) 2017/745 for the above-mentioned medical devices is available and that a proper conformity assessment has been carried out.

Erkrath, Februar 19th, 2025


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Head of Purchase


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