



EU DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745 -Article 19, Annex II and Annex III.

Manufacturer:

Company name: Anhui Longway Medical Technology Co., Ltd.
Address: No.59 Lingji Rd., Industrial Park, Mingguang City, Anhui Prov. China
Tel: +86 550 8021288
E-mail: sales@china-longway.com
Website: www.china-longway.com
SRN: CN-MF-000001292

Whose Authorized Representative:

Name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1c
Verd, 2595AA, The Hague, Netherlands.
E-mail: info@lotusnl.com
SRN: NL-AR-000000121

We, the manufacturer, herewith declare that the device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745.

Product Name	Manual Lifter		
Model	LW06101,LW06204A,LW06204B,LW06204C		
Intend use	The Manual Lifter is intended to lift and transfer disabled people from the bed to the wheelchair and vice versa or help to stand up (for LW06202 and LW06203); could not be used to transport the person from room to room.		
Basic UDI-DI	6974283906100CH		
Classification and rule	I, rule 1	Conformity Assessment Route	Article 19, Annex II and Annex III





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Applicable Standards and CS:

EN ISO 13485:2016/A11:2021	ISO 10993-1:2025
EN ISO 10993-5:2009/A11:2025	EN ISO 10993-10:2023
EN ISO 10993-23:2021/A1:2025	EN ISO 14971:2019/A11:2021
EN ISO 20417:2021	EN 62366-1:2015+A1:2020
EN ISO 10535:2021	EN ISO 15223-1:2021

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meets the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process

Signed:  Alan Xie

Date: February 11, 2026

Place: Anhui, China

Name of authorized signatory: Xiaosheng Xie

Position held in the company: General Manager

Anhui Longway Medical Technology Co., Ltd.

