



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 10,1e 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	BEDRAIL AND POLE		
Model	LW10209,LW10205,LW10211,LW10212,LW10213,LW10206,LW10210,LW10210L,LW10201,LW10217,LW10215,LW10207,LW10208,LW10216		
Intended use	Bedrail and pole intended to prevent patient falls and provide support for repositioning on a homecare bed		
Basic UDI-DI	6974283905001C7		
Classification and rule	I, rule 1	Conformity Assessment Route	Article 19, Annex II and Annex III

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 20417:2021
EN ISO 14971:2019/A11:2021	EN ISO 15223-1:2021	EN ISO 21856:2022
EN 62366-1:2015+A1:2020		

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

Signed

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.



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