



# EU DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

Lotus NL B.V.  
Koningin Julianaplein 10, 1e Verd,  
2595AA, The Hague, Netherlands  
SRN: NL-AR-000000121

## Conformity Assessment

Conformity Assessment Procedure  
Annex II+III of Regulation (EU) 2017/745

### Applicable Standards

EN ISO 14971:2019  
EN ISO 15223-1:2016  
EN 1041:2008+A1:2013  
ISO 10993-1:2018  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013

### Remark

*The declaration of conformity is valid in connection with the release technical document CEMDR-LW10.*

*All the supporting documentation is retained at the premises of the manufacturer.*

*The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer*

## Manufacturer

Name: Mingguang Longway Medical Technology Co., LTD.

Address: No. 59 Lingji Rd, Industrial Park,  
Mingguang City, Anhui, China

SRN:CN-MF-000001292

## Product Information

Name: BEDRAIL AND POLE

Model : LW10204, LW10205, LW10206, LW10207,  
LW10208, LW10209, LW10210, LW10211, LW10212,  
LW10215

Basic UDI-DI: 6974283905001C7

Classification: Class I, according to Rule 13, Annex VIII, Regulation (EU) 2017/745

## Declaration

We herewith declare that the above-mentioned products are marketed in compliance with REGULATION(EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 April 2017 on Medical Devices

Signature:  Date: 2020.12.30

Position: General Manager Place: Anhui, China