



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
EN 62366-1:2015
EN 60601-1-2:2015+A1:2021
EN 60601-2-52:2010+A1:2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-LW06.

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: Homecare Bed

Model:LW05202, LW05202B, LW05203, LW05203B,
LW05207, LW05207B, LW05208, LW05208B,
LW05202S, LW05202SL, LW05206, LW05211,
LW05212, LW05204

Basic UDI-DI: 6974283905000C5

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