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 ISO 10535:2006

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-LW09.

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: Manual Lifter
Model: LW06101
Basic UDI-DI: 6974283906000CC
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