JOYTECH HEALTHCARE CO., LTD.

EU Declaration of Conformity

Manufacturer:
JOYTECH HEALTHCARE CO. LTD.
Address:No.365, Wuzhou Road, Yuhang Economic Devel opment Zone, Hangzhou city, 311100 Zhejiang,China
Single Registration Number: CN-MF-000006020

whose single Authorized Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg，Germany
Single Registration Number:DE-AR-000000001

We, the manufacturer, herewith declare that the products
Manual Breast pump
Basic UDI-DI:6970362211LD0001V6
Model: LD-101
Common Specification: Not Available
UMDNS-Code: 10485 *CND-Code:*V02800101
meet the provisions of Regulation (EU) 2017/745 on medical device and, if applicable, with any other relevant Union legislation that provides for issuing of an EU declaration of conformity.
The medical device has been assigned to **class I by rule 1** according to Annex Ⅷ of the (EU) 2017/745 MDR. It bears the mark

CE

The product concerned has been compiled technical files compliance according to Annexes II and III, and manufactured under a quality management system according to ISO 13485:2016.

Compliance of the designated product with the (EU) 2017/745 MDR has been assured via assessment of the quality management system by the Notified Body.

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: SX 60142380 0001
Issue date: 2019-10-25
Expiry date: 2022-07-10
following the procedure relating to the EU Declaration of Conformity set out in Annex IV of the (EU) 2017/745 MDR.

The above mentioned declaration of conformity is exclusively under the responsibility of
Company: JOYTECH HEALTHCARE CO., LTD.
Address: No.365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou city, 311100 Zhejiang,China

Hangzhou, June 9, 2021
Place , date

JOYTECH HEALTHCARE CO. LTD 浙江健拓医疗仪器科技有限公司

General Manager
Legally binding signature, Function