EU Declaration of Conformity

Manufacturer:
JOYTECH HEALTHCARE CO. LTD.
Address:No.365, Wuzhou Road, Yuhang Economic Development 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
Intended Purpose: The manual breast pump is used by lactating women in the home setting to express and collect milk from their breasts.It can help prevent breast duct obstruction.
Basic UDI-DI:6970362211LD0001V6
Model: LD-101
Common Specification: Not Available
UMDNS-Code: 10485 *EMDN-Code:*V020301
meet the provisions of Regulation (EU) 2017/745 on medical device.
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 has been assured via assessment of the quality management system by the Notified Body.

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, Sep 30, 2022
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
General Manager / Ren Yunhua