EC Declaration of Conformity

Manufacturer:

Name: Rmist(Tianjin) Medical Device Co.,Ltd.
SRN of Eudamed: CN-MF-000010408
ADD:No.15, KaituoRoad, Balitai Town, Jinnan District, Tianjin, China
Zip Code: 3003500
Tel: +86-22-88822756
Web: www.rmist.cn

whose single Authorized EU-Representative:

Name: Caretechion GmbH
SRN of Eudamed: DE-AR-000005946
Add: Niederrheinstr. 71, 40474 Duesseldorf, Germany
Dimdi Code DE/0000048026

We, the manufacturer, herewith declare that the products

Intracuff Pressure Monitor
Model: IPM1, IPM2, IMP3
Basic UDI-DI:697307763IPMU7

meet the provisions of Regulations 2017/745(EU) which apply to them.

The medical device has been assigned to **CLASS I** according to **Annex VIII** of the **Medical Device Regulations 2017/745(EU)**. It bears the mark

CE

Following the procedure relating to the EC Declaration of conformity set in Annex IV of Regulations 2017/745(EU) and Conformity assessment procedure: ANNEX II+ III in conformity to the following standards or other normative documents

EN ISO13485:2016, EN ISO 15223-1:2021, EN ISO 20417:2021, ISO 14971:2019, EN ISO 10933-1:2018, IEC 62366-1:2015, ASTM D 4169-16, MEDDEV 2.7.1 Rev.4, MDR 2017/745(EU)

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The above mentioned declaration of conformity is exclusively under the responsibility of

Rmist(Tianjin) Medical Device Co.,Ltd.
No.15,KaituoRoad,Balitai Town,Jinnan District,Tianjin,China

RMIST(TIANJIN)MEDICAL DEVICE CO.,LTD 亚美斯特(天津)医疗器械有限公司 91120116683

May 30, 2024 at Tianjin, China

Lu zhi dong

Legally binding signature,