DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z12030285-02.

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: Healingcare Medical Co., Ltd.
Address: No.1 Building, Longping West Road, Longgang District, Shenzhen, Guangdong,China
SRN: CN-MF-000031520

Product Information

Name: Reusable Non-Invasive Blood Pressure(NIBP) Cuff
Model: See Annex
EMDN: Z12030285
GMDN: 34978
Basic UDI-DI: 697391313LF11J5
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date:May 29, 2023

Position: GM Place: Shenzhen/China

Annex

Product Name	Model
Reusable Non-Invasive Blood Pressure(NIBP) Cuff	HCAD0125B12,HCLAD0125B12,HCADT0125B12,HCPE0125B12,HCCH0125B12, HCIN0125B12,HCNE0125B12,HCNED0125,HCAD02100B16,HCLAD02100B16, HCADT02100B16,HCPE02100B16,HCCH02100B16,HCIN02100B16, HCNE02100B16,HCNED02100