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

Manufacturer

Name: SHENZHEN YKD TECHNOLOGY CO.,LTD.
Address: 6F, Building 6. Huaxinruiming Industrial Area, Langrong RD,Xinwei Village, Dalang Community, Dalang Street, Longhua, Shenzhen, China.

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 ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Product Information

Name : Blood Pressure Cuff With Hose

Model : CC001AY, CC001BY, CC001CY, CC001DY, CC001EY, CC001FY, CC002AY, CC002BY, CC002CY, CC002DY, CC002EY, CC002FY, CC001A, CC001B, CC001C, CC001D, CC001E, CC001F, CC002A, CC002B, CC002C, CC002D, CC002E, CC002F, CC005A, CC005B, CC005C, CC005D, CC005E, CC005F, CC006A, CC006B, CC006C, CC006D, CC006E, CC006F, CC007A, CC007B, CC007C, CC007D, CC007E, CC007, CC007AF, CC007BY, CC007CY, CC007DY, CC007EY, CC007FY, CC008A, CC009A, CC010A, CC010B
CT001,CT002,CT003,CT004,CT005,CT006,CT007,CT008, CT009,CT009A,CT009B,CT015,CT016,CT018,CT018B, CT018C,CT018D,CT015C,CT015B,CT015,,CT019F,CT019E, CT019D,CT019C,CT019BCT021A,CT021,CT021B,CT021C, CT025-A,CT024,CT023,CT022C,CT022B-1,CT022B,CT022 CT029,CT028,CT027,CT026,CT037,CT036,CT035,CT034, CT033,CT032,CT030,CT040,CT040A,CT040B,CT040C, CT039,CT038,CT038B,CT045,CT045A,CT045B,CT044,CT043, CT042,CT041C,CT041B,CT041,CT050A,CT050,CT049,CT048, CT047,CT046B,CT046A,CT059,CT058,CT057,CT056,CT055, CT054,CT053,CT052,CT051,CT068,CT067,CT066,CT065, CT064,CT062,CT061,CT060,CT079,CT078,CT077,CT076, CT075,CT073,CT072,CT071,CT070,CT069,CT088,CT087, CT086,CT085,CT084,CT082,CT081,CT080,CT096,CT095, CT094,CT093,CT090,CT089,CT101,CT100,CT098,CT097 CT107,CT105,CT104,CT102,CT108,CT111

EMDN : Z12030285

Basic UDI-DI : 697145973YKD002QY

Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z12030285-01.

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.

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: 2024-11-02

Position: GM Place: Shenzhen/China