



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: 2016
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
IEC 62366-1:2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z12030680-02.

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

Product Information

Name: IBP Cable

Model : CI0001A,CI001B,CI001C,CI001D,CI001E,CI001F,CI001J
CI002,CI003,CI004,CI005,CI006,CI007,CI008,CI009,CI011,CI012,CI013,
CI014,CI015,CI016,CI017,CI018,CI019,CI020,CI021,CI022,CI023,CI024
CI025,CI026,CI027,CI028,CI029,CI030,CI031,CI032,CI033,CI034,CI035
CI036,CI037,CI038,CI039,CI040,CI041,CI042,CI043,CI044,CI045,CI046
CI047,CI048,CI049,CI050,CI051,CI052,CI053,CI054,CI055,CI056,CI057
CI058,CI059,CI060,CI061,CI062,CI063,CI064,CI065,CI066,CI067,CI068
CI070,CI071,CI072,CI073,CI074,CI075,CI076,CI077,CI078,CI079,CI080

EMDN : Z12030680

Basic UDI-DI : 697145973YKD001QW

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: 2021.11.02

Position: GM

Place: Shenzhen/China