



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
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: 2023
EN ISO 10993-23: 2021

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.

Manufacturer

Name: Hunan Greatmade Medical Tech Limited
Address: NO.101, 1st floor, A2 building, 1st Phase, Changsha E center, No.18 Xiangtai road, Liuyang Economic Development zone, Changsha, Hunan Province, China
SRN: CN-MF-000042754

Product Information

Name: Blood Pressure Cuff with Connector
Model: See annex
EMDN: Z12030285
Basic UDI-DI: 697754356BC001F9
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: *Zhanghanzhi* Date: 2025.1.12

Position: GM Place: Hunan /China



Appendix

Name	Model
Blood Pressure Cuff with Connector	<p>CF001A, CF002A, CF003A, CF004A, CF004LA, CF004TA, CF001B, CF002B, CF003B, CF004B, CF004LB, CF004TB, CF001A-V, CF002A-V, CF003A-V, CF004A-V, CF004LA-V, CF004TA-V, CF001B-V, CF002B-V, CF003B-V, CF004B-V, CF004LB-V, CF004TB-V, CF001C, CF002C, CF003C, CF004C, CF004LC, CF004TC, CF001D, CF002D, CF003D, CF004D, CF004LD, CF004TD, CF1501A, CF1502A, CF1503A, CF1504A, CF1505A, CF1506A, CF1507A, CF1508A, CF1509A, CF1510A, CF1512A, CF1513A, CF1501B, CF1502B, CF1503B, CF1504B, CF1505B, CF1506B, CF1507B, CF1508B, CF1509B, CF1510B, CF1512B, CF1513B, CF1101A, CF1102A, CF1103A, CF1104A, CF1105A, CF1107A, CF1108A, CF1109A, CF1110A, CF1111A, CF1112A, CF1113A, CF1101B, CF1102B, CF1103B, CF1104B, CF1105B, CF1107B, CF1108B, CF1109B, CF1110B, CF1111B, CF1112B, CF1113B, CF1201A, CF1202A, CF1203A, CF1204A, CF1205A, CF1207A, CF1208A, CF1209A, CF1210A, CF1211A, CF1212A, CF1213A, CF1201B, CF1202B, CF1203B, CF1204B, CF1205B, CF1207B, CF1208B, CF1209B, CF1210B, CF1211B, CF1212B, CF1213B, CF1201C, CF1202C, CF1203C, CF1204C, CF1205C, CF1201D, CF1202D, CF1203D, CF1204D, CF1205D, CF1301C, CF1301C-T, CF1302C, CF1302C-T, CF1303C, CF1303C-T, CF1304C, CF1304C-T, CF1305C, CF1305C-T, CF1301D, CF1301D-T, CF1302D, CF1302D-T, CF1303D, CF1303D-T, CF1304D, CF1304D-T, CF1305D, CF1305D-T, CF1401C, CF1402C, CF1403C, CF1404C, CF004XL-A, CF004XL-B, CF004LG, CF004DG, CF004BK, CF004LP, CF004O, CF004BS, CF004SN, CF004GR, CF004LG-D, CF004DG-D, CF004BK-D, CF004LP-D, CF001C-B, CF002C-B, CF003C-B, CF004C-B, CF004LC-B, CF004TC-B, CF001F-B, CF002F-B, CF003F-B, CF004F-B, CF004LF-B, CF004TF-B, CF004C-BP, CF004D-BP, CF001E-BR, CF002E-BR, CF003E-BR, CF004E-BR, CF004LE-BR, CF004TE-BR, CF001F-BR, CF002F-BR, CF003F-BR, CF004F-BR, CF004LF-BR, CF004TF-BR, CF1301C-UK, CF1302C-UK, CF1303C-UK, CF1304C-UK, CF1305C-UK, CF001E-LB, CF002E-LB, CF003E-LB, CF004E-LB, CF004LE-LB, CF004TE-LB, CF001F-LB, CF002F-LB, CF003F-LB, CF004F-LB, CF004LF-LB, CF004TF-LB, CF001E-C, CF002E-C, CF003E-C, CF004E-C, CF004LE-C, CF004TE-C, CF001F-C, CF002F-C, CF003F-C, CF004F-C, CF004LF-C, CF004TF-C, CF1501A-BK, CF1502C-BK, CF1503A-BK, CF1504A-BK, CF1505A-BK, CF1506A-BK, CF1507A-BK, CF1508A-BK, CF1509A-BK, CF1510A-BK, CF1512A-BK, CF1513A-BK, CF1501B-BK, CF1502B-BK, CF1503B-BK, CF1504B-BK, CF1505B-BK, CF1506B-BK, CF1507B-BK, CF1508B-BK, CF1509B-BK, CF1510B-BK, CF1512B-BK, CF1513B-BK, CF1901N, CF1901I, CF1901C, CF1901N-B, CF1901I-B, CF1901C-B, CF1801G, CF1801BK, CF1801BL, CF1801R, CF1801Y, CF1801GN, CF1801HB, CF1801V, CF1801N, CF1801BK-B, CF1801R-B, CF1801Y-B, CF1801GN-B, CF1801HB-B, CF1801V-B, CF1801N-B, CF1801F, CF1801G-LA, CF1510A-TW, CF004A-MR, CF004B-MR, CF1512D, CF1512C, CF1512C-B, CF1510D-B, CF1510C-B, CF1508D-B, CF1508C-B, CF1801NR-A, CF1801NR-LA, CF1801NR-PA, CF1510C,</p>

CF1510D, CF004C-L, CF004D-L, CF1510A-RU, CF028, CF004E-C-TW, CF1801NR-XL-A, CF004A-V-BK, CF004B-V-BK, CF004O-D, CF004A-RU, CF004A-L, CF1801BL-C, CF028BL-S, CF028BL-D, CF028C-S, CF028C-D, CF028B, CF1801BK-D, CF004O-A, CF032-M, CF004A-PW, CF004B-PW, CF004LB-PW, CF004LA-PW, CF1111A-70CM, CF004A-70CM, CF003A-PW, CF003B-PW, CF1301C-PW, CF1302C-PW, CF1303C-PW, CF1304C-PW, CF1305C-PW, CF1111C-XL, CF1112C-XL, CF1801N-PA, CF1801G-U, CF032-XS, CF032-S, CF032-L, CF032-XL, CF032-XXL, CF1801G-XL-A, CF1801G-PA, CF1501A-VET, CF1502A-VET, CF1503A-VET, CF1504A-VET, CF1505A-VET, CF1115A, CF028C-D, CF2001-BK, CF6002, JH1801NR-PA, JH1801NR-A, JH1801NR-XL-A, JH1801NR-XL-B, JH1801BL-C, JH1801BL-D, JH1801BL-D1, JH1801HB-B, JH1801HB-B1, JH1801HB-C, JH1801HB-D, JH1801HB-D1, JH1801Y-A, JH1801Y-B, JH1801Y-B1, JH1801Y-C, JH1801Y-D, JH1801Y-D1, JH1801R-A, JH1801R-B, JH1801R-B1, JH1801R-C, JH1801R-D, JH1801R-D1, JH1801GN-A, JH1801GN-B, JH1801GN-B1, JH1801GN-C, JH1801GN-D, JH1801GN-D1, JH1801BL-A, JH1801BL-B, JH1801BL-B1, JH1801V-D1, JH1801NR-PA, JH1801G-LA, JH1801NR-A, JH1801BK-C, JH1801NR-LA, JH1801BK-D, JH1801NR-XL-A, JH1801BK-A, JH1801BK-B1, JH1801N-A, JH1801N-B, JH1801N-C, JH1801N-D, JH1801BK-B, JH1801N-B1, JH1801BK-D1, JH1801N-D1, JH1801V-D, JH1801V-A, JH1801V-B, JH1801V-B1, JH1801V-C, JH1801HB-A, CF023-BL, CF023-BK, CF024-BK, CF023-BL-P, CF023-BK-L, CF023-BK-P, CF023-WH-P, CF023-BK-XL, CF023-BL-L, CF023-BL-XL, CF023-BL-L-P, CF023-BL-XL-P, CF023-BK-L-P, CF023-BK-XL-P, CF024-BK-P, CF023-WH, CF023-BK-A, CF023-BK-PB, CF026, CF029, CF030, CF031, CF033, CF026-40CM, CF026B, CF033B, CF034A, CF034B, CF035A, CF035B, CF036A, CF036B, BP01, BP03-1/8, BP03-3/16, BP03-3/32, BP03-4.0MM, BP03-Y, BP04, BP05, BP06-1/4, BP06-1/8, BP06-3/16, BP06-3/32, 2.4mm, BP06-4.0MM, BP07, BP08, BP09-MF, BP09-MM, BP09-P, BP12, BP12-S, BP12-P, BP12-4.0, BP15, BP15-S, BP15-4.5MM, BP15-4.6MM, BP16, BP16B, BP17, BP17-S, BP18-IT, BP18, BP18-S, BP19, BP20, BP21, BP21G-3/16, BP22, BP24, BP24-3, BP25, BP26, BP27, BP28, BP2T, BP2T-1, BP2T-P, BP2T-PO, BP31, BP32, BP33, BP34, BP35, BP36, BP37, JHT03-Z3, BP38, BP39F, BP39M, BP39-2T, BP3T-P-1.6, BP3T-P-2.4, BP3T-P-3.2, BP3T-P-4.0, BP3T-P-4.8, BP3T-P-6.4, BP3-Y-1/16, BP3-Y-1/4, BP3-Y-1/8, BP3-Y-3/32, BP3-Y-3/36, BP3-Y-5/32, BP40, BP41, BP41-6MM, BP41-AL, BP41-BL, BP41-CL, BP42, BP43, BP44, BP45, BP46, BP47, BP48, BP49, BP50, BP51, BP52, BP53, BP54, BP55, BP56, BP57, BP58, BS21, BS21-S, BS21-S-3/16, BS21-BMD1603, BS21-BMD1602PH, BS21-BMD1604, BS21-ILD1604, BS21-BLD1604, BS21-BMD1604PH, BS22, BP21-IM1602, BP21-IM1603, BP21-IM1604, BP21-IMD1604PH, BP21-IMD1603PH, BP21-IMD1602PH, DM-P, ML, ML-S, NIBP-D, NIBP-H, NIBP-S, NIBP-Y, NIBP-Y-BP212T, Redel-F, Redel-M, XY, JHT03-Z1S



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Conformity Assessment Procedure

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2021; EN ISO 20417:2021; EN ISO
10993-1: 2020; EN ISO 10993-5: 2009
EN ISO 10993-10: 2023; EN ISO
10993-23: 2021; EN
60601-1:2006/A2:2021; EN
60601-1-2:2015/A1:2021

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: Hunan Greatmade Medical Tech Limited
Address: NO.101, 1st floor, A2 building, 1st Phase,
Changsha E center, No.18 Xiangtai road, Liuyang
Economic Development zone, Changsha, Hunan
Province, China
SRN: CN-MF-000042754

Product Information

Name: Patient Adapter Cable
Model: See annex
EMDN: Z12030680
Basic UDI-DI: 697754356PC001L3
Classification: Class I, According to Rule 13, 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: *Zhanghanchi* Date: 2025.1.12

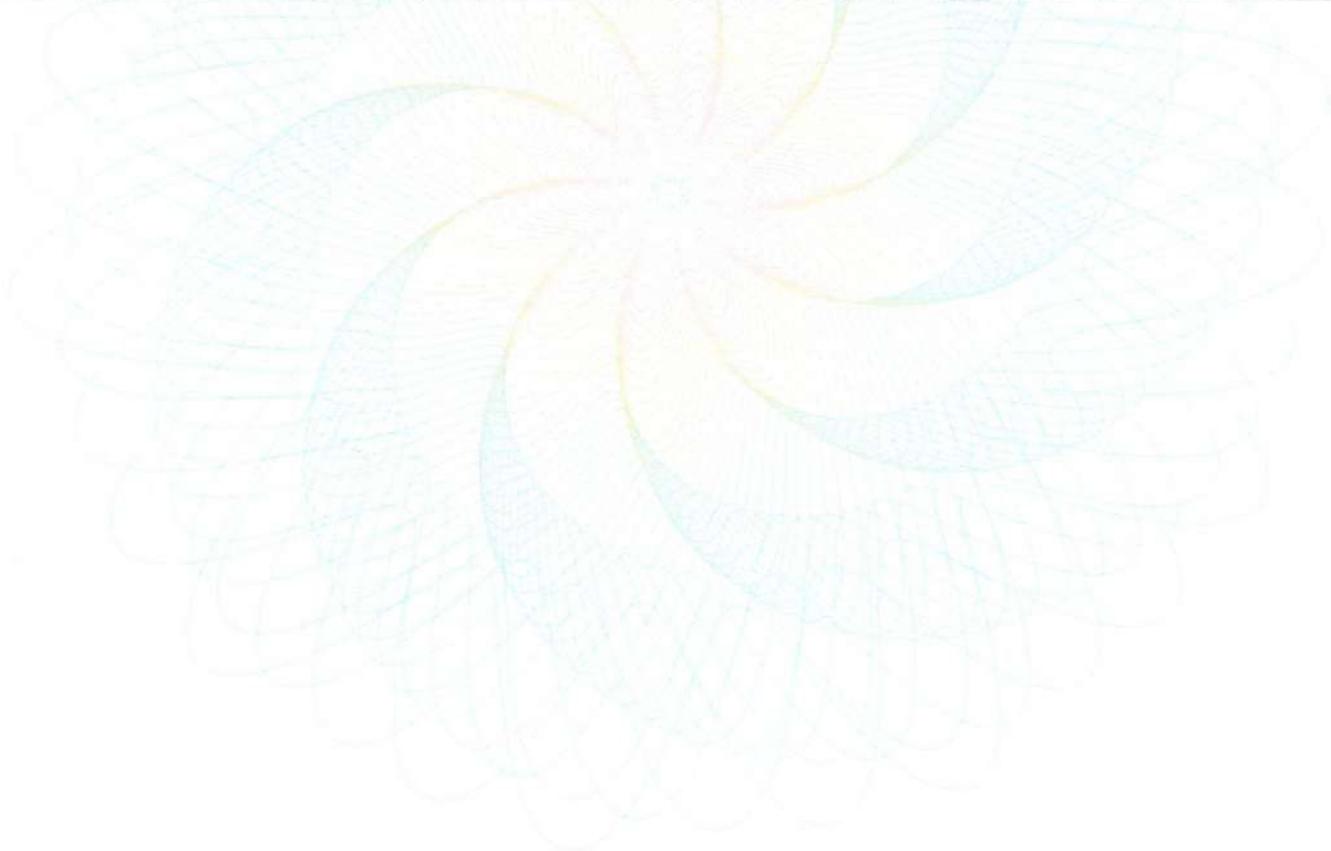
Position: GM Place: Hunan /China



Appendix

Name	Model
Patient Adapter Cable	<p>EX001, EX001-D, EX002, EX003, EX004, EX005-1, EX005, EX005-3, EX006, EX007, EX008, EX008L, EX008-M, EX009, EX010, EX011, EX012, EX013, EX014, EX015, EX016, EX017, EX016-M, EX018, EX019, EX019-M, EX020B, EX020G, EX020G-1.5, EX020L, EX021-1.2, EX021-1.5, EX021, EX021G, EX022, EX023, EX024, EX024 (3M), EX024L, EX025, EX025-(3M), EX025-OXI, EX025-L, EX025-M, EX025-M6, EX026, EX026-TW, EX027, EX028, EX029, EX030, EX031, EX031-OXI, EX031-1, EX031-1.2, EX031-1.5, EX031-M, EX031-DB9, EX032, EX033, EX033-M, EX033-X, EX035, EX036, EX037, EX037B, EX038, EX039, EX040, EX041-OXI, EX041, EX041B, EX042, EX043, EX044, EX044-3, EX045, EX046, EX047, EX048, EX048 (3M), EX048-3, EX049, EX050, EX051, EX052, EX052-M, EX052-S, EX052-OXI, EX053, EX054, EX055, EX056, EX057-M, EX058, EX059A, EX060, EX060B, EX061, EX062, EX062B, EX063, EX063-M/B, EX064, EX065, EX066, EX067-M, EX069, EX070, EX070-N, EX070-N(3M), EX071, EX072, EX073, EX074-M, EX074-OXI, EX075, EX076, EX077, EX078, EX078-BR, EX079, EX080-5S, EX081, EX082, EX083, EX084, EX085, EX086, EX087, EX088, EX090, EX091, EX093, EX094, EX095, EX097, EX098, EX099, EX100, EX101, EX102, EX103, EX105, EX106, EX107, EX108, EX109, EX121, EX122, EX123, EX124, EX125, EX126, EX127.</p> <p>TP013, TP013-3, TP013-5, TP014, TP014-5, TP014-4, TP014-3, TP014-3.5, TP015, TP015-1, TP015-3, TP015-3.5, TP015-4, TP015-5, TP015B, TP020-3, TP020, TP020-5, TP021, TP022, TP023, TP024, TP025, TP025-3, TP025-5, TP026, TP031, TP031-Y, TP034, TP034-3, TP034-5, TP052, TP052-5</p> <p>CF005, CF005-6, CF005N, CF005C, CF005M, CF005-6, CF006, CF006N, CF006-H, CF006-A, CF006-1, CF007, CF007B, CF007C, CF007K, CF007D, CF007D-L, CF007E, CF007F, CF007M, CF007H, CF007G, CF007N, CF007L, CF008, CF009, CF009B, CF009C, CF009-Y, CF010, CF011, CF012, CF013, CF016, CF016B, CF017, CF017B, CF017C, CF017H, CF018A, CF018B, CF018C, CF020, CF021, CF021B, CF022</p>

IBP001A, IBP001B, IBP001C, IBP001D, IBP001E, IBP001F, IBP001G, IBP002A,
IBP002B, IBP002C, IBP002C-2-ED/ IBP002C-2, IBP002D, IBP002E, IBP002F,
IBP002G, IBP002H, IBP003A, IBP003B, IBP003C, IBP003D, IBP003E, IBP003F,
IBP004A, IBP004B, IBP004C, IBP004D, IBP004E, IBP004F, IBP005A, IBP005B,
IBP005C, IBP005D, IBP005E, IBP005F, IBP006A, IBP006B, IBP006C, IBP006D,
IBP006E, IBP006F, IBP007A, IBP007B, IBP007C, IBP007D, IBP007E, IBP007F,
IBP008A, IBP008B, IBP008C, IBP008D, IBP008E, IBP009, IBP010A, IBP010B,
IBP010C, IBP010D, IBP010E, IBP010F, IBP011A, IBP011B, IBP011C, IBP011D,
IBP011E, IBP012A, IBP012B, IBP012C, IBP012D, IBP012E, IBP013A, IBP013B,
IBP013C, IBP013D, IBP013E, IBP014A, IBP014B, IBP014C, IBP014D, IBP014E,
IBP015A, IBP015B, IBP015C, IBP015D, IBP015E, IBP016A, IBP016B, IBP016C,
IBP016D, IBP016E, IBP018A, IBP018B, IBP018C, IBP018D, IBP018E, IBP019A,
IBP020B, IBP020C, IBP021A, IBP021B, IBP021C, IBP021D, IBP021E, IBP022A,
IBP022B, IBP022C, IBP022D, IBP022E, IBP023A, IBP023B, IBP023C, IBP023D,
IBP023E, IBP024A, IBP024B, IBP024C, IBP024D, IBP024E, IBP025A, IBP025B,
IBP025C, IBP025D, IBP025E, IBP026, IBP027A, IBP027B, IBP027C, IBP027D,
IBP027E, IBP028A, IBP028B, IBP028C, IBP028D, IBP028E, IBP029A, IBP030A,
IBP030C, IBP031A, IBP033, IBP034A, IBP034B, IBP035B, IBP036H, IBP037A, IBP038





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10993-1: 2020; EN ISO 10993-5: 2009
EN ISO 10993-10: 2023; EN ISO
10993-23: 2021; EN
60601-1:2006/A2:2021; EN
60601-1-2:2015/A1:2021

Remark

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with the release technical document CE/MDR-
Z12030680-01.*

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premises of the manufacturer.*

*The Declaration of Conformity is exclusively under
the sole responsibility of the manufacturer.*

Manufacturer

Name: Hunan Greatmade Medical Tech Limited
Address: NO.101, 1st floor, A2 building, 1st Phase,
Changsha E center, No.18 Xiangtai road, Liuyang
Economic Development zone, Changsha, Hunan
Province, China
SRN: CN-MF-000042754

Product Information

Name: ECG EKG Cable with Lead Wires
Model: See annex
EMDN: Z12030680
Basic UDI-DI: 697754356EW001LN
Classification: Class I, According to Rule 13, 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: 2025.1.12

Position: GM Place: Hunan /China



Appendix

Name	Model
ECG EKG Cable with Lead Wires	MC001-3AG, MC001-3AS, MC001-5IG, MC001-5IS, MC001-3IG, MC001-3IS, MC005-5AG, MC005-5AS, MC001A-3, MC001A-5, MC001A-SM-3, MC001B-3, MC001B-5, MC002A-3, MC002A-3-1M, MC002B-3, MC002B-3A-H, MC002C-3, MC002D-3, MC003A-5, MC003B-5, MC003B-5-GE, MC003C-5, MC003D-5, MC004A-3, MC004B-3TA, MC004A-3TI, MC004B-3, MC004C-3, MC004D-3, MC005A-5, MC005A-5TI, MC005B-5, MC005B-5TA, MC005C-5, MC005D-5, MC006-3AG, MC006-3AG-L, MC006-3AS, MC006-3IG, MC006-3IG-L, MC006-3IS, MC006-3T-GE, MC006-5AS, MC006-5AG, MC006-5IS, MC006-5IG, MC006-5IG-GE, MC006A-5, MC006A-5-L, MC006B-5, MC006DA/I-3, MC006DA/I-5, MC007A, MC007A-3R, MC007AL, MC007AM, MC007B, MC007B-3R, MC007B-3-1.3, MC007B-GE, MC007BI-1.3, MC007BI-1.3M, MC007BL, MC007BM, MC007C, MC007C-3R, MC007CL, MC007CM, MC007D, MC007D-3, MC007D-3R, MC007D-3R-1.3, MC007B-3R-1.3, MC007DL, MC007DM, MC008-3A, MC008-3AG, MC008-3AS, MC008-3I, MC008-3IG, MC008-3IS, MC008-5A/I, MC008-5AG, MC008-5AS, MC008-5IG, MC008-5IS, MC009-3IG, MC009-3IS, MC009A, MC009B-3, MC009C-5A, MC009C-5I, MC009C-5I-DX, MC009D-5A, MC009D-5I, MC009D-5I-DX, MC010-3AG, MC010-3AS, MC010-3IG, MC010-3IS, MC010-5AS, MC010-5AG, MC010-5IG, MC010-5IS, MC010A, MC010-3D, MC010A-3, MC010BA, MC010BA-3, MC010BA-3-1.02M, MC010BI, MC010BI-3, MC010CA, MC010CA-3, MC010CI, MC010CI-3, MC013-3, MC013-3AG, MC013-3AG-S5, MC013-3AS, MC013-3AS-S5, MC013-3D, MC013-3-S5, MC013-3D-S5, MC013-3IG, MC013-3IG-S5, MC013-3IS, MC013-3IS-S5, MC013-5AG, MC013-5AG-S5, MC013-5AS, MC013-5AS-S5, MC013-5D, MC013-5D-S5, MC013-5IG, MC013-5IG-S5, MC013-5IS, MC013-5IS-S5, MC015-5, MC017A-5, MC017A-5-HP, MC017B-5, MC017B-5-PW, MC018A-3, MC018B-3, MC019A-3, MC019B-3, MC019C-3, MC019D-3, MC020A-5, MC020B-5, MC020B-5-1.5, MC020B-5-2, MC020C-5, MC020D-5, MC021A-3, MC021B-3, MC022A-5, MC022B-5, MC023A-3, MC023B-3, MC023C-3, MC023D-3, MC024A-5, MC024B-5, MC024C-5, MC024D-5, MC025A-3, MC025A-3R, MC025B-3R, MC025B-3,

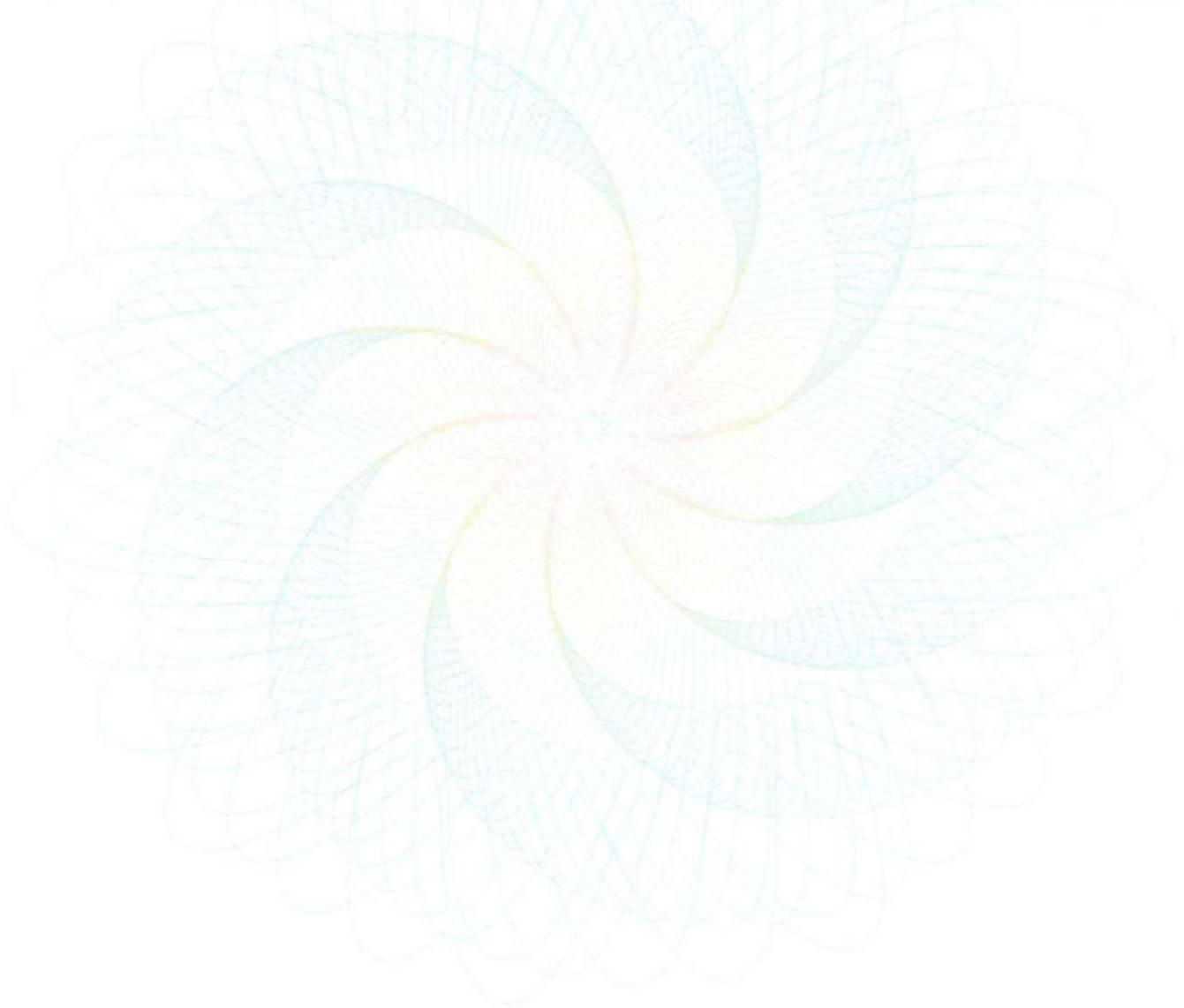
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DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
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: 2023; EN ISO
10993-23: 2021; EN
60601-1:2006/A2:2021; EN
60601-1-2:2015/A1:2021

Remark

*The declaration of conformity is valid in connection
with the release technical document CE/MDR-
C020501-01.*

*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.*

Manufacturer

Name: Hunan Greatmade Medical Tech Limited
Address: NO.101, 1st floor, A2 building, 1st Phase,
Changsha E center, No.18 Xiangtai road, Liuyang
Economic Development zone, Changsha, Hunan
Province, China
SRN: CN-MF-000042754

Product Information

Name: ECG Electrode

Model: See annex

EMDN: C020501

Basic UDI-DI: 697754356EE001GQ

Classification: Class I, According to Rule 13, 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: *Zhanghanzhi* Date: 2025.1.12

Position: GM

Place: Hunan /China



Appendix

Name	Model
ECG Electrode	EC012, EC012-A, EC012A/A-HP, EC012A/B, EC012A/B-G, EC012A-HP, EC012B, EC012B/I, EC012B/A, EC012B/A-HP, EC012B-HP, EC012C, EC012C/A, EC012A-HP, EC012B-HP, EC012C-HP, EC012C-GN, EC012C-HP, EC012C-S, EC012C-SA, EC012D, EC012D-HP, EC012A/A-HP, EC012B/A-HP, EC012D-B, EC012D-HP, EC012G-HP, EC012D/A-HP, EC012E, EC012E/F, EC012F, EC013A, EC013A/B, EC013A/B-G, EC013B, EC013C, EC013C-S, EC013D, EC013E, EC013F, EC013F-S, EC013G, EC013H



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
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: 2023
EN ISO 10993-23: 2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-A03010199-01.

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.

Manufacturer

Name: Hunan Greatmade Medical Tech Limited
Address: NO.101, 1st floor, A2 building, 1st Phase, Changsha E center, No.18 Xiangtai road, Liuyang Economic Development zone, Changsha, Hunan Province, China
SRN: CN-MF-000042754

Product Information

Name: Pressure Infusion Bag
Model: See annex
EMDN: A03010199
Basic UDI-DI: 697754356PB001KU
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.

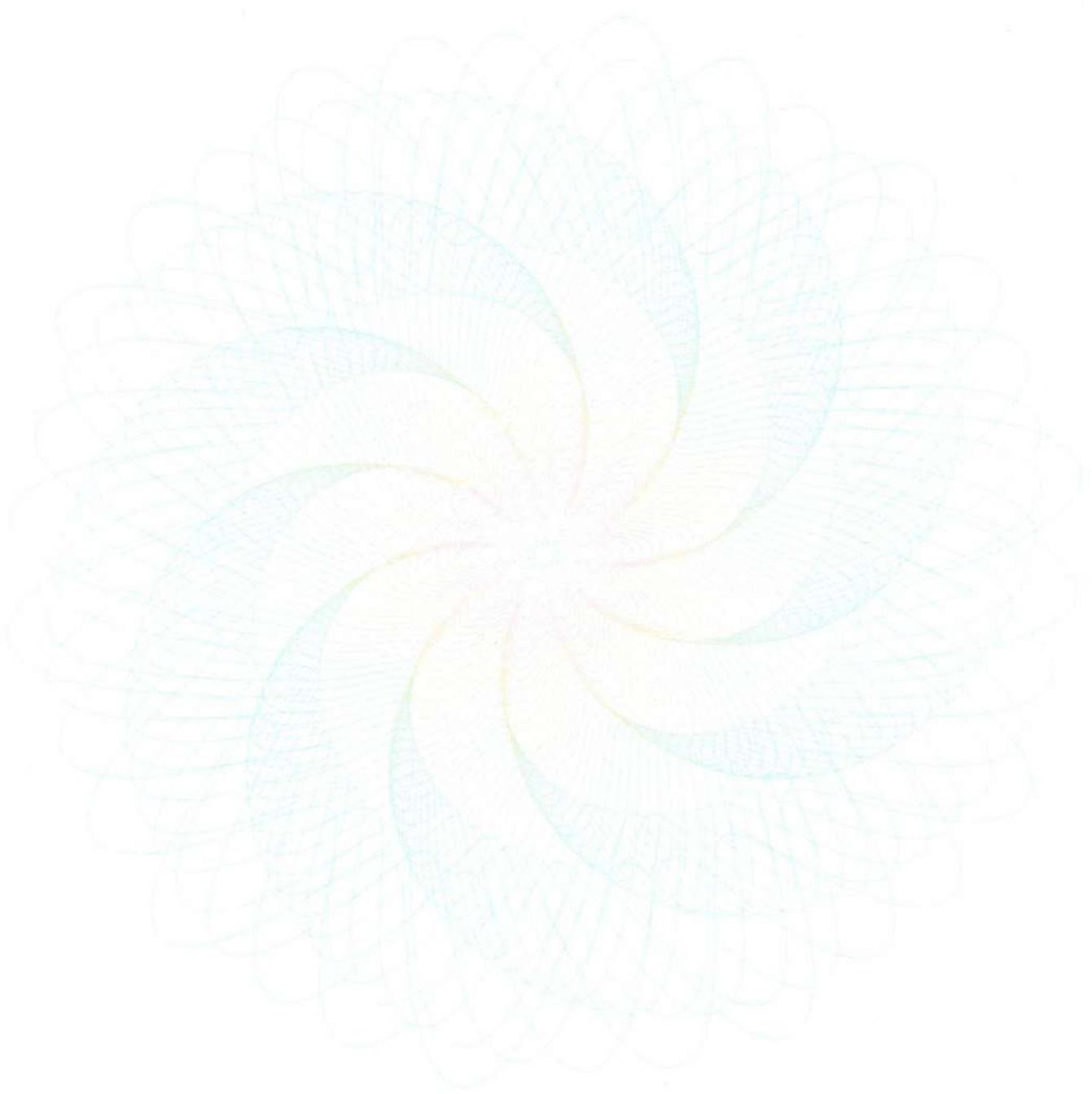
Signature: *Zhanghanzhi* Date: 2025.1.12

Position: GM Place: Hunan /China



Appendix

Name	Model
Pressure Infusion Bag	CF1701-500A, CF1701-500A1, CF1701-500A-BL, CF1701-500A1-BL, CF1701-1000A CF1701-1000A1, CF1701-1000A-BL, CF1701-1000A1-BL, CF1701-3000A CF1701-3000A1, CF1701-3000B, CF1701-500A1-TR,CF1701-500C, CF1701-500A1-DB CF1701-1000A1-DB, CF1701-1000C



Appendix

Name	Model
Tourniquet et	CF1601A, CF1602A, CF1603A, CF1601B, CF1602B, CF1603B, CF1601B-DK, CF1603B-DK, CF1604-XXS, CF1604-XS, CF1604-S, CF1604-M, CF1604-L, CF1604-XL, CF1604-XXL, CF1605A-L, CF1605A-R, CF1605B-L, CF1605B-R, CF1605C-RL, CF1605D-RL

