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

Manufacturer

Name: Wellmed Dental Medical Supply Co., Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

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
ISO 13485: 2016

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-WM-09.

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.

Product Information

Name: Air/Water Syringe Tips
GMDN: 45131
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865AWST-001-250FV ,697460865AWST-002-250G8, 697460865AWST-003-250GK, 697460865AWST-RC-250F9

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:Renxian Tang Date:7/24/2023

Position: GM Place: Shenzhen/China

Wellmed Dental Medical Supply Co., Ltd
深圳伟迈联合口腔医疗材料发展有限公司

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
ISO 13485: 2016

Manufacturer

Name: Wellmed Dental Medical Supply Co., Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

Product Information

Name: Apparels
GMDN: 58388
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865IG-001CU, 697460865IG-002CW,697460865IG-003CY, 697460865PG-001FP,697460865PG-002FR, 697460865PG-003FT,697460865PG-001YKL, 697460865PG-002YKP,697460865PG-003YKS, 697460865PG-001GJG,697460865PG-002GJK, 697460865PG-003GJN,697460865PG-001WKG, 697460865PG-002WKK,697460865PG-003WKN, 697460865SCT-001VF,697460865SCT-002VH, 697460865SCT-003VK,697460865SCT-004VM, 697460865SCT-005VP,697460865SCT-006VR, 697460865SCT-007VT,697460865SCT-008VV, 697460865SCT-009VX,697460865SCT-010VG, 697460865SCT-011VJ,697460865SCT-012VL, 697460865BC-21D7,697460865BC-24DD, 697460865BC-001CBCY,697460865BC-6413A6, 697460865BEFT-001YB,697460865BEFT-003YF, 697460865BEFT-008YR,697460865SCDM-0026A, 697460865SCDM-0036C,697460865SCDM-0046E, 697460865SCDM-0056G,697460865SCDM-0066J, 697460865SCDM-ASSDY,697460865SCDM-00168, 697460865SCDM-001AGB,697460865SCDM-001BGD,

697460865SCDM-001CGF,697460865SCDM-001DGH,
697460865SCDM-001ASSKU,697460865ISC-001QS,
697460865ISC-002QU,697460865ISC-003QW,
697460865ISC-004QY,697460865ISC-ASSYJ,
697460865SC-3818KG,697460865SCPE-4115KS,
697460865AS-1000-XC3W,697460865TA-1000-XC87

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:Renxian Tang Date:7/24/2023

Position: GM Place: Shenzhen,China

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-WM-05.

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.

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
ISO 13485: 2016

Manufacturer

Name: Wellmed Dental Medical Supply Co., Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

Product Information

Name: Barrier Sleeves
GMDN: 12535
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865BFR-001LX,
697460865BFR-002LZ,697460865BFR-003M3,
697460865BFR-004M5,697460865BFR-005M7,
697460865BFR-006M9,697460865BFR-007MB,
697460865BFR-008MD,697460865BFR-009MF,
697460865HL-6562HK,697460865HL-6563HM,
697460865HL-6564HP,697460865HL-6565HR,
697460865HL-6607HG,697460865HL-6566HT,
697460865HL-6567HV,697460865HL-6583HT,
697460865HL-6568HX,697460865HL-6569HZ
697460865HL-6571HL,697460865HL-6572HN,
697460865HL-6573HQ,697460865HL-6573RQZ,
697460865HL-6574HS,697460865HL-6575HU,
697460865HL-6576HW,697460865HL-6575RR7,
697460865HL-6578J2,697460865HL-6579J4,
697460865HL-6579SRM,697460865HL-6580-2287,
697460865HL-6580-2389,697460865HL-6580-248B,
697460865HL-6580-258D,697460865HL-6581HP,
697460865HL-6582-1UJ,697460865HL-6582-2UL,
697460865HL-6585HX,697460865HL-6586HZ,
697460865HL-6586CQH,697460865HL-6586BQF,
697460865HL-6587J3,697460865HL-6591HS,
697460865HL-6594HY,697460865HL-6601H4,

697460865HL-BC01MD,697460865HL-BC02MF,
697460865HL-BC03MH,697460865HL-3DRENR,
697460865HL-6615HF,697460865HL-20831LP,
697460865HL-20963M9,697460865HL-20855M5,
697460865HL-21013KL,697460865HC-1010BF
697460865HC-1013BM,697460865DSP-001SL,
697460865DSP-002SN,697460865DCS-001M5,
697460865DCS-002M7,697460865DCS-003M9,
697460865DCS-003-300PZ,697460865DCS-004MB,
697460865DCS-005MD,697460865DCS-001VTN,
697460865DCS-002VTR,697460865DCS-003VTU,
697460865DCS-003V-300KM,697460865DCS-004VTX,
697460865DCS-005VU2,697460865PPBE00HZC,
697460865PPBE01HZF,697460865PPBE02HZJ,
697460865PPBE00V2B,697460865PPBE01V2E,
697460865PPBE02V2H,697460865PPBE02V-300VF,
697460865DCS-003V-BIORX,697460865HL-BC02-Bio96,
697460865HL-BC01-BIO4L,697460865HL-BC02-BIO4X,
697460865HL-BC03-BIO5A,697460865HL-BC04-BIO5M,
697460865HL-3DRE-BIOGR,697460865HL-6577-BIOTY,
697460865HL-6573-BIOSL,697460865HL-6575-BIOTA,
697460865HL-6576-BIOTM,697460865HL-6568-BIOTW,
697460865HL-6569-BIOU9,697460865HL-6569S-BIOKS,
697460865HL-6571-BIORW,697460865HL-6572-BIOS9,
697460865HL-6563-BIOS7,697460865HL-6565-BIOSV,
697460865HL-6566-BIOT8,697460865HL-6564-BIOSJ,
697460865HL-6567-BIOTK,697460865HL-6583-BIOSZ,
697460865HL-6592-BIOT3,697460865HL-6593-BIOTE,
697460865HL-6595-BIOU4,697460865HL-6596-BIOUF,
697460865HL-6594-BIOTR,697460865HL-6581-BIOSB,
697460865HL-6582-1-BION5,697460865HL-6582-2-BIONG,
697460865HL-6588S-BIOLF,697460865HL-6588L-BIOJ2,
697460865HL-6579-BIOUN,697460865HL-6601-BIOPL,
697460865KPD-001-BIO5H,697460865KPD-002-BIO5U,
697460865HL-6585-BIOTP,697460865HL-6586-BIOU2,
697460865HL-6587-BIOUD,697460865HL-6607-BIORN,
697460865HL-6591-BIOSQ,697460865FSP-001-BIOBZ,
697460865FSP-002-BIOCC,697460865HL-GRAB-BIOTJ,
697460865DCS-001-BIOVM,697460865DCS-002-BIOVY,
697460865DCS-003-BIOWB,697460865DCS-003-300BIOF4,
697460865DCS-004-BIOWN,697460865DCS-005-BIOWZ,

697460865DCS-001V-BIOR5,697460865DCS-002V-BIORJ,
697460865DCS-003V-BIORX,697460865DCS-003V300BIO4F,
697460865DCS-004V-BIOSC,697460865DCS-005V-BIOSR

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-WM-08.

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:Renxian Tang Date:7/24/2023

Position: GM Place: Shenzhen,China

Dental Medical Supply Co.,Ltd
深圳佳迈联合口腔医疗材料发展有限公司

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

ISO 13485: 2016

Manufacturer

Name: Wellmed Dental Medical Supply Co., Ltd

Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China

SRN: CN-MF-000003243

Product Information

Name: Cotton Roll

GMDN: 31815

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

Basic UDI-DI:697460865CTP-105SV, 697460865CTP-106SX,697460865CTP-107SZ, 697460865CTP-108T3,697460865CTP-109T5, 697460865CTP-110SN,697460865CTP-105B2B, 697460865CTP-106B2E,697460865CTP-107B2H, 697460865CTP-108B2L,697460865CTP-109B2P, 697460865CTP-110BZW,697460865CRG-001NK, 697460865CRG-002NM,697460865CRG-003NP, 697460865CRG-001-500TM,697460865CRG-002-500TY, 697460865CRG-003-500UB,697460865CRG-001-600TS, 697460865CRG-002-600U5,697460865CRG-003-600UG, 697460865CRG-001-840UG,697460865CRG-002-600U5, 697460865CRG-003-450UM,697460865CRX-001UE, 697460865CRX-002UG,697460865CRX-003UJ, 697460865CRX-001-8258W,697460865CRX-002-6008F, 697460865CRX-003-4508X,697460865CA-0038G, 697460865CA-0068N

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-WM-06.

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:Renxian Tang Date:7/24/2023

Position: GM Place:Shenzhen,China

Dental Medical Supply Co., Ltd
深圳伟迈联合口腔医疗材料发展有限公司
Wellmed

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
ISO 13485: 2016

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-WM-11.

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: Wellmed Dental Medical Supply Co., Ltd

Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China

SRN: CN-MF-000003243

Product Information

Name: Dental Bib Holder

GMDN: 44603

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

Basic UDI-DI:697460865NWB-001UQ, 697460865DSBH-0063L,697460865DSBH-0073N, 697460865DSBH-0083Q,697460865DSBH-0093S, 697460865DSBH-0103B,697460865ZS-8603W3, 697460865BCA-001DV,697460865BCA-002DX, 697460865BCA-003DZ,697460865BCA-004E3, 697460865BCA-005E5,697460865BCA-006E7, 697460865BC-0018M

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:Renxian Tang Date:7/24/2023

Position: GM Place: Shenzhen/China

Wellmed Dental Medical Supply Co.,Ltd 深圳佳迈联合口腔医疗材料发展有限公司

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

Manufacturer

Name: Wellmed Dental Medical Supply Co., Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

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
ISO 13485: 2016

Product Information

Name: Disposable Bite Trays
GMDN: 16350
Classification: Class I, According to Rule 5, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865ITRL-001AS9, 697460865ITRL-002ASC,697460865ITRL-003ASF, 697460865ITRL-004ASJ,697460865ITRL-005ASM, 697460865ITRL-006ASQ,697460865ITRL-007AST, 697460865ITRL-008ASW,697460865ITRL-009ASZ, 697460865ITRL-010ASB,697460865ITRL-000AS6, 697460865ITRL-001EN,697460865ITRL-002EQ, 697460865ITRL-003ES,697460865ITRL-004EU, 697460865ITRL-005EW,697460865ITRL-006EY, 697460865ITRL-007F2,697460865ITRL-008F4, 697460865ITRL-009F6,697460865ITRL-010EP, 697460865ITRL-000EL,697460865ITB-101AXN, 697460865ITB-102AXR,697460865ITB-103AXU, 697460865ITB-104AXX,697460865ITB-105AY2, 697460865ITB-106AY5,697460865ITB-107AY8, 697460865ITB-108AYB,697460865ITB-109AYE, 697460865ITB-110AXQ,697460865ITB-000AXC, 697460865ITB-101QZ,697460865ITB-102R3, 697460865ITB-103R5,697460865ITB-104R7, 697460865ITB-105R9,697460865ITB-106RB, 697460865ITB-107RD,697460865ITB-108RF, 697460865ITB-109RH,697460865ITB-110R2,

697460865ITB-000QS,697460865FT-001G4,
697460865FT-002G6,697460865FT-003G8,
697460865FT-001NJV,697460865FT-002NJY,
697460865FT-003NK3

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:Renxian Tang Date:7/24/2023

Position: GM Shenzhen/China

Remark

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

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

Manufacturer

Name: Wellmed Dental Medical Supply Co.,Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

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
ISO 13485: 2016

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR- Q010504-01.

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.

Product Information

Name: Disposable Mouth Mirrors
GMDN: 64029
Classification: Class I, According to Rule 5, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865DM-001CV, 697460865DM-002CX,697460865DM-001CEA, 697460865DM-002CED,697460865DM-003CEG, 697460865DM-004CEK,697460865DM-005CEN, 697460865DM-006CER,697460865DM-007CEU, 697460865DM-008CEX,697460865DM-009CF2, 697460865DM-010CEC,697460865DM-011CEF, 697460865DM-012CEJ,697460865DM-ASSLM

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:Renxian Tang Date:7/24/2023

RENXIAN TANG

Position: GM Place: Shenzhen/China

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

Manufacturer

Name: Wellmed Dental Medical Supply Co., Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

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
ISO 13485: 2016

Product Information

Name: Disposable Dental Bib
GMDN: 61050
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865PT-001EPM, 697460865PT-002EPQ,697460865PT-003EPT, 697460865PT-004EPW,697460865PT-005EPZ, 697460865PT-006EQ4,697460865PT-007EQ7, 697460865PT-008EQA,697460865PT-009EQD, 697460865PT-010EPP,697460865PT-011EPS, 697460865PT-012EPV,697460865PT-013EPY

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:Renxian Tang Date:7/24/2023

Position: GM Place: Shenzhen/China

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-WM-13.

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.

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
ISO 13485: 2016

Manufacturer

Name: Wellmed Dental Medical Supply Co.,Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

Product Information

Name: Disposable Dental Boxes
GMDN: 35893
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865RB-001ES, 697460865RB-002EU,697460865RB-003EW, 697460865RB-004EY,697460865RB-005F2, 697460865RB-006F4,697460865RB-007F6, 697460865RB-008F8,697460865RB-009FA, 697460865RB-010ET,697460865RB-ASSNJ, 697460865DB-00194,697460865DB-00296, 697460865DB-00398,697460865DB-0049A, 697460865DB-0059C,697460865DB-0069E, 697460865DB-0079G,697460865DB-0089J, 697460865DB-0099L,697460865DB-01095, 697460865DB-ASSGU

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-V9099-02.

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.

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

Signature:Renxian Tang Date:7/24/2023

Position: GM Place: Shenzhen/China

Dental Medical Supply Co.,Ltd 深圳伟迈联合口腔医疗材料发展有限公司

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
ISO 13485: 2016

Manufacturer

Name: Wellmed Dental Medical Supply Co.,Ltd

Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China

SRN: CN-MF-000003243

Product Information

Name: Disposable Dental Needles

GMDN: 58894

Classification: Class I, According to Rule 5, Annex VIII, Regulation (EU) 2017/745

Basic UDI-DI:697460865DAN-2312PA, 697460865DAN-2316PJ,697460865DAN-2321PB, 697460865DAN-2325PK,697460865DAN-2332PG, 697460865DAN-2335PN,697460865DAN-2338PU, 697460865DAN-2712PW,697460865DAN-2716Q6, 697460865DAN-2721PX,697460865DAN-2725Q7, 697460865DAN-2732Q4,697460865DAN-2735QA, 697460865DAN-2738QG,697460865DAN-3012P2, 697460865DAN-3016PA,697460865DAN-3021P3, 697460865DAN-3025PB,697460865DAN-3032P8, 697460865DAN-3035PE,697460865DAN-3038PL, 697460865EIN2325SYA,697460865EIN2725SZ6, 697460865EIN3025SXY,697460865EIN2325DXC, 697460865EIN2725DY8,697460865EIN3025DX2, 697460865EIN2325NXY,697460865EIN2725NYU, 697460865EIN3025NXN, 697460865WM-PINK-18GFH, 697460865WM-BLACK-19GUY, 697460865WM-YELLOW-20G23, 697460865WM-GREY-22GFP, 697460865WM-BLUE-25G9F,697460865D466J2, 697460865D2566CB,697460865G455JJ,

697460865T4058HH,697460865500727XS,
697460865500728XU

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:Renxian Tang Date:7/24/2023

Position: GM Place: Shenzhen/China

Dental Medical Supply Co.,Ltd
深圳伟迈联合口腔医疗材料发展有限公司

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR- Q010599-06.

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.

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

Manufacturer

Name: Wellmed Dental Medical Supply Co., Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

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
ISO 13485: 2016

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-WM-14.

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.

Product Information

Name: Disposable Non Woven Sponge
GMDN: 48131
Classification: Class I, According to Rule 4, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865NWS-0012N, 697460865NWS-0022Q,697460865NWS-0032S, 697460865NW-0900PU,697460865DA-0018R, 697460865DA-0028T,697460865DA1-0018Y, 697460865DA1-00292

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:Renxian Tang Date:7/24/2023

Position: GM Place: Shenzhen,China

Wellmed Dental Medical Supply Co., Ltd
深圳伟迈联合口腔医疗材料发展有限公司

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
ISO 13485: 2016

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR- Q01010403-03.

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: Wellmed Dental Medical Supply Co.,Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

Product Information

Name: Disposable Prophy Brushes
GMDN: 64015
Classification: Class I, According to Rule 5, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865PB370K5, 697460865PB380-WLV,697460865PB380-CKM, 697460865PB380-BLRU,697460865PB380-PPTE, 697460865PB380-BKK,697460865PB380-GKV, 697460865PB380-FGRW,697460865PB380-PLF, 697460865PB380-PKT4,697460865PB380-OLD, 697460865PB380-FKT,697460865PB380-BGRJ, 697460865PB380-ASS42

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:Renxian Tang Date:7/24/2023

Position: GM Place: Shenzhen, China

Wellmed Dental Medical Supply Co.,Ltd 深圳伟迈联合口腔医疗材料发展有限公司

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
ISO 13485: 2016

Manufacturer

Name: Wellmed Dental Medical Supply Co.,Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

Product Information

Name: Disposable Prophy Cups
GMDN: 46938
Classification: Class I, According to Rule 5, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865PA-001DM, 697460865PA-001BPLZ,697460865PA-005DV, 697460865PA-007DZ,697460865PA-001-105XS, 697460865PA-001BP-1054C,697460865PA-005-105Z6, 697460865PA-007-105ZU,697460865PC-001EB, 697460865PC-002ED,697460865PC-003EF, 697460865PC-004EH,697460865PC-005EK, 697460865PC-006EM,697460865PC-007EP, 697460865PC-008ER,697460865PC-009ET, 697460865PC-010EC,697460865PC-011EE, 697460865PC-012EG,697460865PC-ASSN3, 697460865PC4-001H7,697460865PC4-002H9, 697460865PC4-003HB,697460865PC4-004HD, 697460865PC4-005HF,697460865PC4-006HH, 697460865PC4-007HK,697460865PC4-008HM, 697460865PC4-009HP,697460865PC4-010H8, 697460865PC4-011HA,697460865PC4-012HC, 697460865PC4-ASSQX

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR- Q010502-04.

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:Renxian Tang Date:7/24/2023

Position: GM Place: Shenzhen/China

Wellmed Dental Medical Supply Co.,Ltd 深圳市维德联合口腔医疗材料发展有限公司

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

ISO 13485: 2016

Manufacturer

Name: Wellmed Dental Medical Supply Co., Ltd

Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China

SRN: CN-MF-000003243

Product Information

Name: Disposable Suction Tips

GMDN: 37434

Classification: Class I, According to Rule 5, Annex VIII, Regulation (EU) 2017/745

Basic UDI-DI:697460865SE-001G8

697460865SE-002GA,697460865SE-003GC,
697460865SE-004GE,697460865SE-005GG,
697460865SE-006GJ,697460865SE-007GL,
697460865SE-008GN,697460865SE-009GQ,
697460865SE-010G9,697460865HVST-001AJJ8,
697460865HVST-002AJJD,697460865HVST-003AJJJ,
697460865HVST-004AJJP,697460865HVST-005AJJU,
697460865HVST-006AJJZ,697460865HVST-007AJK6,
697460865HVST-008AJKB,697460865HVST-009AJKG,
697460865HVST-010AJJA,697460865HVST-011AJJF,
697460865HVST-012AJJL,697460865HVST-022AJJT,
697460865HVST-023AJJY,697460865HVST-ASSAJ4E,
697460865VE-001HF,697460865VE-002HH,
697460865VET-001XU,697460865VET-003XY,
697460865VET-004Y2,697460865VET-005Y4,
697460865VET-006Y6,697460865VET-007Y8,
697460865VET-008YA,697460865VET-009YC,
697460865VET-010XV,697460865VET-012XZ,
697460865STA-001VT,697460865STA-002VV,
697460865STA-003VX,697460865STA-004VZ

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:Renxian Tang Date:7/24/2023

Position: GM Made in Shenzhen, China

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-WM-07.

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.

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
ISO 13485: 2016

Manufacturer

Name: Wellmed Dental Medical Supply Co.,Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

Product Information

Name: Disposable Syringes
GMDN: 60366
Classification: Class I, According to Rule 5, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865DES-001MX, 697460865DES-002MZ,697460865DES-003N3, 697460865DES-005N7,697460865DES-010MY, 697460865DES-020N3,697460865CTS-001TH, 697460865CTS-002TK,697460865SC-001FJ, 697460865DS-001EX,697460865D062-002-03L6, 697460865D089-003-01RU,697460865D090-001-02LU, 697460865D091-001-01MD,697460865D083-001-03MY, 697460865D082-001-02MB,697460865DSN-2332NBH, 697460865DSN-2732NCD,697460865500727XS, 697460865500728XU

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR- Q010599-07.

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:Renxian Tang Date:7/24/2023

Position: GM Place: Shenzhen, China

Dental Medical Supply Co., Ltd
深圳市迈联合口腔医疗材料发展有限公司

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

Manufacturer

Name: Wellmed Dental Medical Supply Co., Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

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 14683: 2019
EN 62366-1:2015
ISO 13485: 2016

Product Information

Name: Face masks
GMDN: 35177
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865CP-001DH,
697460865CP-002DK,697460865CP-003DM,
697460865CP-004DP,697460865CP-005DR,
697460865CP-006DT,697460865CP-007DV,
697460865CP-008DX,697460865CP-009DZ,
697460865CP-010DJ,697460865CP-011DL,
697460865CP-012DN,697460865CP-013DQ,
697460865CP-014DS,697460865CP-015DU,
697460865CP-016DW,697460865CP-017DY,
697460865CP-018E2,697460865CP-019E4,
697460865CP-020DM,697460865CP-021DP,
697460865CP4-001FK,697460865CP4-002FM,
697460865CP4-003FP,697460865CP4-004FR,
697460865CP4-005FT,697460865CP4-006FV,
697460865CP4-007FX,697460865CP4-008FZ,
697460865CP4-009G3,697460865CP4-010FL,
697460865CP4-011FN,697460865CP4-012FQ,
697460865CP4-013FS,697460865CP4-014FU,
697460865CP4-015FW,697460865CP4-016FY,
697460865CP4-017G2,697460865CP4-018G4,
697460865CP4-019G6,697460865CP4-020FP,

697460865CP4-021FR,697460865ISM-001U8,
697460865ISM-002UA,697460865ISM-003UC,
697460865ISM-004UE,697460865ISM-ASS43,
697460865IMDM-0015L,697460865SM-001JY,
697460865HM-001EH,697460865HM-002EK,
697460865HM-003EM,697460865HM-004EP,
697460865HM-005ER,697460865HM-ASSN9,
697460865VSP-00149,697460865VSP-0024B,
697460865VSP-0034D,697460865VSP-0044F,
697460865VSP-0054H,697460865VSP-ASSBZ,
697460865MCPM-0017J,697460865MCPM-001AJD,
697460865MCPM-001BJF,697460865MCPM-001CJH,
697460865MCPM-001DJK,697460865MCPM-001ASSNN,
697460865MCPM-0027L,697460865MCPM-002AJG,
697460865MCPM-002BJJ,697460865MCPM-002CJL,
697460865MCPM-002DJN,697460865MCPM-002ASSNV,
697460865MCPM-0057S,697460865MCPM-005AJR,
697460865MCPM-005BJT,697460865MCPM-005CJV,
697460865MCPM-005DJX,697460865MCPM-005ASSPJ,
697460865SPCU-001FG,697460865SPCU-002FJ,
697460865SPCU-ASSP8,697460865BLO-001NC,
697460865BLO-002NE,697460865BLO-003NG,
697460865BLO-004NJ,697460865BLO-005NL,
697460865BLO-006NN,697460865BLO-007NQ,
697460865BLO-008NS,697460865BLO-009NU,
697460865BLO-010ND,697460865BLO-ASSW4,
697460865SSG-001XG,697460865SSG-002XJ,
697460865SSG-003XL,697460865SSG-004XN,
697460865SSG-005XQ,697460865SSG-ASS7B,
697460865DAZ-001NQ,697460865DAZ-002NS,
697460865DAZ-003NU,697460865DAZ-004NW,
697460865DAZ-005NY,697460865DAZ-ASSWG,
697460865MYC-001VC,697460865MYC-002VE,
697460865MYC-003VG,697460865MYC-004VJ,
697460865MYC-ASS57,697460865MCPM-0037N,
697460865MCPM-0047Q,697460865MCPM-0067U,
697460865MCPM-ASSFA,697460865LOC-001QR,
697460865FSLC-ASSEK

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-WM-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:Renxian Tang Date:7/24/2023

Position: GM Place: Shenzhen/China

Dental Medical Supply Co.,Ltd
深圳伟迈联合口腔医疗材料发展有限公司
WeiLmed

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

Manufacturer

Name: Wellmed Dental Medical Supply Co., Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

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
ISO 13485: 2016

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-WM-04.

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.

Product Information

Name: Face Shields
GMDN: 11961
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865FV-001GS, 697460865FV-002GU,697460865FV-003GW, 697460865FV-004GY,697460865FV-005H2, 697460865RFPFT2,697460865ES-001FC, 697460865ES-002FE,697460865ES-003FG, 697460865ES-004FJ,697460865ES-005FL, 697460865PFPHSQ,697460865FSE-001PV

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:Renxian Tang Date:7/24/2023

Position: GM Place: Shenzhen/China

Wellmed Dental Medical Supply Co.,Ltd 深圳市维德联合口腔医疗材料发展有限公司

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
ISO 13485: 2016

Manufacturer

Name: Wellmed Dental Medical Supply Co., Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

Product Information

Name: Micro Applicators
GMDN: 33722
Classification: Class I, According to Rule 5, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865MA-001CE,
697460865MA-002CG,697460865MA-003CJ,
697460865MA-004CL,697460865MA-005CN,
697460865MA-006CQ,697460865MA-007CS,
697460865MA-008CU,697460865MA-009CW,
697460865MA-010CF,697460865MA-011CH,
697460865MA-012CK,697460865MA-013CM,
697460865MA-014CP,697460865MA-015CR,
697460865MA-016CT,697460865MA-017CV,
697460865MASW-001B5,697460865MASW-002B7,
697460865MASW-003B9,697460865MASW-004BB,
697460865MASW-005BD,697460865MASW-006BF,
697460865MASW-007BH,697460865MASW-008BK,
697460865MA-001-BIO3G,697460865MA-002-BIO3T,
697460865MA-003-BIO46,697460865MAB-001K9,
697460865MAB-002KB,697460865MAB-003KD,
697460865BTAB-003Y7,697460865BTAB-004Y9,
697460865BTAB-005YB,697460865BTAB-007YF,
697460865BTAB-010Y4,697460865BTAB-011Y6,
697460865BTAB-024YF,697460865BTAB-025YH,
697460865BTAB-003BAG89,

697460865BTAB-004BAG8G,
697460865BTAB-005BAG8P,
697460865BTAB-007BAG95,
697460865BTAB-010BAG7X,
697460865BTAB-011BAG86,
697460865BTAB-024BAG96,
697460865BTAB-025BAG9D,
697460865INBR-00172

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:Renxian Tang Date:7/24/2023

Position: GM Place:Shenzhen, China

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-WM-03.

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.

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

Manufacturer

Name: Wellmed Dental Medical Supply Co., Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

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
ASTM F1980-2021
ISO 13485: 2016

Product Information

Name: Self-Sealing Sterilization Pouches/Reels
GMDN: 13735
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865SP-001KZ, 697460865SP-002L3,697460865SP-003L5, 697460865SP-004L7,697460865SP-005L9, 697460865SP-006LB,697460865SP-007LD, 697460865SP-008LF,697460865SP-009LH, 697460865SP-010L2,697460865SP-001-MP58, 697460865SP-002-MP5F,697460865SP-003-MP5N, 697460865SP-004-MP5V,697460865SP-005-MP64, 697460865SP-006-MP6B,697460865SP-007-MP6J, 697460865SP-008-MP6R,697460865SP-009-MP6Y, 697460865SP-010-MP5C,697460865SR-001LP, 697460865SR-002LR,697460865SR-003LT, 697460865SR-004LV,697460865SR-005LX, 697460865SR-006LZ,697460865SR-007M3, 697460865SR-008M5,697460865SR-009M7, 697460865SR-010LQ,697460865SR-011LS, 697460865SR-012LU,697460865SR-013LW, 697460865MSM-001WC,697460865SW-001NE, 697460865SW-002NG,697460865SW-003NJ, 697460865SW-004NL,697460865SW-005NN, 697460865DBDTP-001HS,697460865AT-001E3,

697460865AT-002E5,697460865AT-003E7,
697460865SSI-001Y6,697460865IS-001GY,
697460865IS-002H2,697460865IS-003H4

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:Renxian Tang Date:7/24/2023

Position: GM Place: Shenzhen/China

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-WM-10.

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.

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

Manufacturer

Name: Wellmed Dental Medical Supply Co.,Ltd
Address: 301 Zhongxing Science and Technology Building, No.64, Xin'an 2nd Road, Baoan District, Shenzhen, China
SRN: CN-MF-000003243

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
ISO 13485: 2016

Product Information

Name: Disposable Probes
GMDN: 64568
Classification: Class I, According to Rule 5, Annex VIII, Regulation (EU) 2017/745
Basic UDI-DI:697460865DP-001DW, 697460865DP-002DY,697460865DP-003E2, 697460865DP-004E4,697460865DP-005E6, 697460865DP-006E8,697460865DP-007EA, 697460865DP-008EC,697460865DP-009EE, 697460865DP-010DX,697460865DP-011DZ, 697460865DP-012E3,697460865DP-ASSMN, 697460865FD-001AL,697460865FD-002AN

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:Renxian Tang Date: 7/24/2023

Position: GM Place: Shenzhen/China

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR- Q010504-05.

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.