ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## **EU Representative**

CE

Name: SUNGO Europe B.V. Address: 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 10993-5: 2029

 EN ISO 10993-23: 2021

 EN 12184:2022

 EN 60601-1:2006/A2:2021

 EN 60601-1:2015/A1:2021

 EN 62366-1:2015

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122127-01. 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: Guangdong Dayang Medical Technology Co., Ltd. Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, 528234, Foshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA. SRN: CN-MF-000003324 Product Information

Name: Electric Wheelchair Model: Refer to Annex EMDN: Y122127 Basic UDI-DI: '697000639DYEW01GF 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.



Position: GM

Annex	
Electric	DY01110LA, DY01101, DY01102, DY01105, DY01106, DY01107, DY01108, DY01109,
Wheelchair	DY01126, DY01120, DY01168, DY01123LA, DY01122LA, DY01112, DY01117, DY0112A,
	DY01103, DY01111, DY01114, DY01121, DY01122, DY01123, DY01125, DY01152,
	DY01113, DY01140, DY01124, DY01110

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## **EU Representative**

CE

Name: SUNGO Europe B.V. Address: 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 ISO 10993-23: 2021

## Manufacturer

Name: Guangdong Dayang Medical Technology Co., Ltd.

Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, 528234, Foshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA. SRN: CN-MF-000003324

## **Product Information**

Name: Rollator Model: Refer to Annex EMDN: Y120612 Basic UDI-DI: 697000639DYROLLATOR01SC Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

#### Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y120612-01. 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.

## Declaration

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



Position: GM

Rollator	DY049142, DY049143, DY049145L, DY049146L(2), DY049144L, DY049146
	DY049151L, DY049147L, DY049148L, DY049149L, DY049150L, DY049144(4
	DY049144L(4), DY04202L, DY04203L, DY04204L, DY04104L, DY049146L(4
	DY049146L(7), DY049146L(8), DY05946L, DY049147L

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## **EU Representative**

CE

Name: SUNGO Europe B.V. Address: 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

## Manufacturer

Name: Guangdong Dayang Medical Technology Co., Ltd. Address: Xingxian Development Zone,

Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, 528234, Foshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA. SRN: CN-MF-000003324

## **Product Information**

Name: Stick Model: Refer to Annex **EMDN: Y1203** Basic UDI-DI: 697000639DYSTICK01W5 Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

#### Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y1203-02. 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

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



Annex Stick

DY059201L-M1, DY059201L-M2, DY059201L-M3, DY059201L-M4, DY059201L-M5, DY059201L-M6, DY059201L-M7, DY059201L-M10, DY05927L-M2, DY05927L-M1, DY05927L-M9, DY05910L, DY05920L, DY059201LB, DY05927L-M3, DY059203LB, DY05927LB, DY05927L(5)B, DY5927LB-2, DY5927LB-1, DY05927L(5)H, DY05939L, DY05929L, DY05930L, DY05928L, DY059281L, DY05938L, DY05938LB, DY059282L, DY05936L, DY05936L(S), DY05927L-M4, DY05927L-M5, DY05927L-M6, DY05927L-M7, DY05927L-M8, DY05927L-M10, DY05927L(6)H DY05911L, DY05911LB. DY05922, DY05924, DY05926, DY05932, DY05934, DY05921, DY05931, DY05941, DY05942L-Y, DY05942L-GN, DY05942LH-BK, DY05943L, DY05944, DY05946LB, DY05947, DY05940L, DY05950L, DY05951L, DY05952L, DY05953L, DY05954L, DY05955L, DY05956L, DY05953-01, DY05953-02, DY05920LH, DY05934V, DY05911L(4), DY05911L(5)

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## **EU Representative**

CE

Name: SUNGO Europe B.V. Address: 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 11334-4:1999 ISO 11334-1:2007

#### Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y1203-01. 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: Guangdong Dayang Medical Technology Co., Ltd. Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, 528234, Foshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA. SRN: CN-MF-000003324

## **Product Information**

Name: Crutch Model: Refer to Annex **EMDN: Y1203** Basic UDI-DI: 697000639DYCRUTCH01LU 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.



Annex	
Crutch	DY05925L(L), DY05925L(M), DY05925L(S), DY05935L, DY05935M, DY05935S, DY05933L(S), DY05933L, DY059331L, DY05923L, DY05937L, DY05937L-RD, DY05937L-BK, DY05937L-BL, DY05925L(6), DY059331(9)S, DY059331L(2), DY05933L-M, DY05933L(4), DY05933L(5), DY059331L(7), DY059331L(8)

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## **EU Representative**

CE

Name: SUNGO Europe B.V. Address: 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

## Manufacturer

Name: Guangdong Dayang Medical Technology Co., Ltd. Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, 528234, Foshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA. SRN: CN-MF-000003324 Product Information

# Name: Commode Chair

Model: Refer to Annex EMDN: Y091212 Basic UDI-DI: 697000639DYCC01CV Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

#### Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y091212-01. 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.

## Declaration

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



Position: GM

Commode Chair	DY02691, DY02692E, DY02692, DY02695, DY02692(2), DY02692(4), DY02819
	DY02819L, DY02699L, DY02696(5), DY02696(2), DY02697(2), DY02894(2),
	DY02894(5), DY02896(2), DY02896(2)F, DY02894L(2), DY02895L, DY02893
	DY02815, DY02817, DY02817U(2), DY02817U(2)V, DY02800, DY02800(2), DY02810
	DY02899(3), DY02899(2), DY02899U, DY02898, DY02890, DY02897, DY02897(3)V
	DY0289(11), DY02897(2), DY02811, DY02816L, DY02818L, DY02897L, DY02899L,
	DY074006, DY074007, DY077600-46, DY077600-51, DY077600(2), DY077600(3),
	DY077600(4), DY077600(5), DY077600(6), DY077600(7), DY077600(8), DY077600(8),
	DY077600(9), DY077600(10), DY077600(11), DY077600(12), DY077600(13),
	DY077600(14), DY077600(15), DY077600(16), DY077600(17), DY077600(18),
	DY077600(19), DY077600(20), DY077600(21), DY077600(22), DY077600(23),
	DY077600(24), DY077600(25), DY01118, DY01118(2), DY01118(3), DY01118(4),
	DY01118(5), DY01118(6), DY01118(6), DY01118(7), DY01118(8), DY01118(9),
	DY02695-51, DY02695C-51, DY02817U, DY02805, DY02820L, DY02894,
	DY02894(5)E, DY02696(5)E, DY02804, DY02821L, DY02688L, DY02806, DY02824,
	DY02896(4)F, DY02823(2), DY02890(2), DY06992L, DY02604LJ, DY02810(2)

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## **EU Representative**

CE

Name: SUNGO Europe B.V. Address: 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

## Manufacturer

Name: Guangdong Dayang Medical Technology Co., Ltd.

Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, 528234, Foshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA. SRN: CN-MF-000003324

## **Product Information**

Name: Walker Model: Refer to Annex EMDN: Y120603 Basic UDI-DI: 697000639DYWALKER01JX Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

#### Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y120603-01. 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.

## Declaration

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



Position: GM

Annex Walker	DY04912L-5, DY04912L-4, DY04912L-2.5, DY04919L, DY04913L, DY04915L
- / 41114/1	DY04962L, DY04962L(2), DY04916L,DY04917L, DY04918L, DY04963L
	DY04963L(M) DY04914L, DY04961L, DY04961L(2), DY04964L, DY04965L-5
	DY04965L, DY04912L(S)-5, DY04913L(S), DY04966L(S)-2.5, DY04966L(S), DY04977L
	DY049148, DY049155, DY049156, DY04967, DY04972, DY04912L(4)-3, DY04970L-5
	DY04979L, DY04912L(5), DY04912L(6)-5, DY04912L(7)-5, DY04912L(8)-5
	DY04913L(5), DY04974, DY04976, DY04973, DY04971(2), DY04915L-5
	THE PERMINENT

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## **EU Representative**

CE

Name: SUNGO Europe B.V. Address: 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

### Manufacturer

Name: Guangdong Dayang Medical Technology Co., Ltd.

Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, 528234, Foshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA. SRN: CN-MF-000003324

## **Product Information**

Name: Shower Chair Model: Refer to Annex EMDN: Y093303 Basic UDI-DI: 697000639DYSC01GD Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

#### Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y093303-01. 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.

## Declaration

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



Position: GM

Shower Chair	DY03790, DY03791, DY03792, DY03791S, DY03794L, DY03793S, DY037971 DY03798L, DY03799L, DY03798LQ, DY03795L, DY03796L, DY03780L, DY03782L DY03782LU, DY03781L, DY03783L, DY03784L, DY03785L, DY03782L(2 DY03797L-01, DY03780L-01, DY03798L-01, DY03783L-01, DY03781L-07 DY03782L-01, DY03782L(2)-01, DY03790-01, DY03794L-01, DY03795L-07 DY03796L-01, DY03799L-01, DY03784LQ, DY076010

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## **EU Representative**

CE

Name: SUNGO Europe B.V. Address: 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 12183:2022

# Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122103-01. 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: Guangdong Dayang Medical Technology Co., Ltd. Address: Xingxian Development Zone, Changhongling Industrial Park (2nd Phase), Shishan, Nanhai District, 528234, Foshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA. SRN: CN-MF-000003324 Product Information

Name: Manual Wheelchair Model: Refer to Annex EMDN: Y122103 Basic UDI-DI: 697000639DYMW01J7 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.



Position: GM

Annex	
Manual	DY01201LQ, DY01700LQ, DY01306LQ, DY01958LBCJ, DY01959LB, DY01960LBCJ,
Wheelch	air DY01953LQ, DY01953LCQ, DY01903LB, DY01903LQ, DY01903LABQ,
	DY01954LGC, DY01903LGC, DY01950LBQ, DY01955LB,
1	DY01955L(2)BP(R)DY01973LAH, DY01980LA-46, DY01980LA-35, DY01980L(2),
	DY01908LAJ, DY01908LA, DY01200LABJQ, DY01983L, DY01869L(2)AJ,
	DY01869LAJ, DY01869L(3)AJ, DY01864LDJ, DY01864L, DY01864L(4)J-46,
	DY01864LBJ(R), DY01864L(6), DY01872LAJ, DY01868LJ, DY01868L, DY01868LABJ,
	DY01910LAJ, DY01863L(3)AJ, DY01863(3)AJ, DY01863L(2)AJ, DY01863LAJSW(2),
	DY1863L(2)AJSW(2), DY01863(3)AJSW, DY01863LAJSW16, DY01863LAJSW(7),
	DY01906LDJ, DY01907LAJ, DY01984LJ, DY019003LABJ, DY01871LBJ,
	DY01805LABJ, DY01801LABJ, DY01863LABJ, DY019001LBJ-40, DY01905A(2)J,
	DY01904BD, DY01904A(2)BJ, DY01904BDJ, DY01976A(2)BEJ, DY01976A(2)J,
	DY01809SW, DY01990, DY01903GC, DY01903BGC-35, DY01902GC, DY01951B-56,
	DY01951B-46, DY01951B(R)-56, DY01951B(R)-60, DY01951(2)BJ(R)-51,
	DY01951(2)BJ(R)-56, DY01951(2)BJ(R)-60, DY01903(2)PQ, DY01903PQ-46,
	DY01903(2)PC, DY01903(2)CQ, DY01903(2)Q, DY01951AC-56, DY01974-51,
	DY01909B, DY01908, DY01903, DY01903B, DY01902C, DY01902CJ, DY01901,
	DY01901B, DY01980AC-35, DY01972BDE, DY01972BDEC, DY01983,
	DY01802E-35, DY01874-46, DY01874-51, DY01868, DY01809, DY01809E,
	DY01809Edouble cross bar, DY01809double cross bar, DY01809J, DY01809EJ,
	DY01809J double cross bar, DY01809Adouble cross bar, DY01809B, DY01809BDE,
	DY01809BE, DY01809BJ, DY01809D, DY01809Ddouble cross bar, DY01809(6),
	DY01809Y, DY01809(8)Y, DY01809YJ, DY01875D, DY01875, DY01871, DY01873,
	DY01906DJ, DY02609GC, DY02609GCJ , DY02608GC, DY01602GCJQ,
	DY02602GCJQ, DY02608L, DY02609, DY02608, DY02608J, DY02608C,
	DY02681, DY02683Q, DY02608LGC, DY02681C-51, DY02681BC, DY01908LABJ,
	DY01908LAJC, DY01908LAJPQ(R), DY0215L-46, DY01216LA-46, DY01213LAJ-46,
	DY01408LAJ-46, DY01409LJ, DY01303LQ-36, DY01303LQ-41, DY01303LQ-44,
	DY01303LQ-4, DY019002LAJ, DY019004LJ, DY01413(9), DY01413(10),
	DY01411LAJ, DY01407LAJ, DY02686L, DY02687LB, DY01218L, DY01218LQ,
	DY01864L(5)B, DY01950L(2)BQ(R), DY01950L(3)ABQ(R), DY01950L,
	DY01953L(5)AJQ(R), DY01951LAJSW-56, DY01606LQ, DY01951LAJSW-51,
	DY01950L(3)AJBQ(R), DY01950L(3)BQ(R), DY01809(9), DY01809(10), DY01875AD,
	DY01809H, DY01809AH, DY01809EH, DY01879LAJ(R), DY01957LAB(R)-60,
	DY01903(6)LQ, DY01907L(2)J-46, DY01961LB, DY01963LQ, DY01962BCJ,
	DY01878LAJ, DY01951(4)B(R), DY01951ABC, DY01209AE-61, DY01807LABP,
	DY01804LABJ, DY01975P, DY01976, DY01976LAJ, DY01410LAJ, DY01212LAJ,
	DY01201LAJ, DY01213LAJ, DY01217LAJ, DY01412LAJ, DY01501L(M), DY01501L(S),
	DY01907LABPH, DY01952L, DY01964L, DY01965L, DY01966L, DY01909F18