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 1041:2008+A1:2013, EN ISO 15223-1: 2016, ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN 12183-2014

Remark

The declaration of conformity is valid in connection with the release technical document CE-MDR-TCF001.

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: FOSHAN SHUNKANGDA MEDICAL TECH CO.,LTD
Address: Pingnan Industrial Area , Guicheng Nanhai District , 528251 Foshan City,Guangdong P.R. China

Product Information

Name: Wheelchair
Model: See Annex
GMDN: See Annex
Basic UDI-DI: -
Classification: Class I, according to Rule 1, Annex VIII, Regulation (EU) 2017/745

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

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: Apr 7th 2021

Name: Yu Jinwei Place: Foshan / China
Position: GM

Digitally signed by Jighili Tatiana
Date: 2021.06.04 16:53:46 EEST
Reason: MoldSign Signature
Location: Moldova

Annex

Product Name	Model	GMDN	Basic UDI-DI
Wheelchair	CA608, CA608GC, CA609, CA609GC, CA902, CA903, CA903-35, CA9041-43, CA904-51, CA905, CA907E, CA912BE, CA913, CA9221, CA922B, CA9232, CA926-51, CA928B, CA931B, CA932B, CA951E, CA952, CA955, CA9612LHB, CA9622L, CA9631L, CA963LF, CA963LFH, CA9654LH, CA965LH, CA966LEH, CA9671FH-A, CA9671FH-B, CA9671LFH, CA967LHB, CA9671LHB-A, CA9671LHB-B, CA9682LFH, CA9712LFH, CA9731LFH, CA973LFH, CA9781LF, CA9784LFH, CA978LFH, CA9791LFQ, CA979LFH-B, CA9801LQ, CA980LQ, CA9810, CA981LH, CA9821LG, CA982LGC, CA9831LGC, CA983LGC, CA9841LGC, CA984LGC, CA9861LFQ, CA9862LQ, CA9863LQ, CA9865LQ, CA9866LFH, CA9868, CA991LB, CA992LB, CA993LF, CA994LB, CA995LBQ, CA901, CA902B, CA907, CA912BC , CA913B, CA914E, CA922BC, CA923, CA926, CA932BC, CA933B, CA933BC, CA941, CA951, CA951F, CA956L, CA962L, CA965LEH, CA966LFH, CA971LF, CA9752LH, CA975LH, CA9781LFH, CA977LH, CA991L, CA9791LFHQ, CA979LFH, CA9862LFQ, CA9865LFHQ-24, CA9866LFH, CA9869LQ, CA9873LFQ, CA9874LFQ, CA909, CA909L, CA910F, CA9792LF, CA9793LF, CA9861LFQ, CA9863LQ, CA9880LQ, CA9881LQ,CA9882LQ	46137 41631 41632 37687 45052 45353	-

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

Signature: Xu Ruizhuo Date: Apr 7th 2021

Position: GM Place: Foshan / China

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 1041:2008+A1:2013, EN ISO 15223-1: 2016, ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 24415-1:2009, EN ISO 11334-1:2007, ISO 24415-2:2011

Remark

The declaration of conformity is valid in connection with the release technical document CE-MDR-TCF005.

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: FOSHAN SHUNKANGDA MEDICAL TECH CO.,LTD
Address: Pingnan Industrial Area , Guicheng Nanhai District , 528251 Foshan City,Guangdong P.R. China

Product Information

Name: Cane&Crutch
Model: See Annex
GMDN: See Annex
Basic UDI-DI: -
Classification: Class I, according to Rule 1, Annex VIII, Regulation (EU) 2017/745

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

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: XuRuizhuo Date: Apr 7th 2021

Name: Yu Jinwei Place: Foshan / China

Position: GM

Annex

Product Name	Model	GMDN	Basic UDI-DI
Cane&Crutch	CA831L3, CA832L1, CA832L2, CA832L3, CA832L4, CA832L5, CA832L6, CA832L7, CA832L8, CA833L1, CA833L2, CA833L3, CA833L4, CA833L5, CA833L6, CA834L1, CA834L2, CA834L3, CA834L4, CA834L5, CA834L6, CA834L7, CA835L, CA835L1, CA835L2, CA836, CA838L, CA8391, CA8392, CA8411, CA8412, CA8413, CA8415, CA842, CA8421, CA8422, CA8423, CA8423L, CA8423M, CA8423S, CA8424, CA8426, CA8427, CA843, CA8430L, CA8431, CA8432, CA8433, CA8434L, CA8435, CA8436, CA8437L, CA845L, CA8451, CA8452L, CA8453, CA8454L, CA8455, CA8456, CA853, CA853-N, CA801LL, CA801LM, CA801LS, CA801LXS, CA8011LL, CA8011LM, CA8012LL, CA8012LM, CA8012LS, CA8012LXS, CA8013LL, CA8013LM, CA8013LS, CA8014LL, CA8014LM, CA8014LS, CA8014LXS, CA802LL, CA802LM, CA802LS, CA802LXS, CA803L, CA803M, CA803S, CA805LL, CA805LM, CA805LS, CA806L, CA8061L, CA8062L, CA807LL, CA807LM, CA807LS, CA808LL, CA808LM, CA808LS, CA8425, CA851L1, CA851L2, CA851L3, CA851L4, CA851L5, CA852L1-L, CA852L1-M, CA852L1-S, CA852L1-N, CA852L2, CA854L, CA8541LL, CA8541LM, CA8541LS, CA856LL, CA856LM, CA856LS, CA856LXS, CA8561LL, CA8561LM, CA8561LS, CA8561LXS, CA8563LL, CA8563LM, CA8563LS, CA857L	31115 31113 31112 31116 45847	-

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

Signature: Xu Ruizhuo Date: Apr 7th 2021

Position: GM Place: Foshan / China

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 1041:2008+A1:2013, EN ISO 15223-1: 2016, ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013,

Remark

The declaration of conformity is valid in connection with the release technical document CE-MDR-TCF003.

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: FOSHAN SHUNKANGDA MEDICAL TECH CO.,LTD
Address: Pingnan Industrial Area , Guicheng Nanhai District , 528251 Foshan City,Guangdong P.R. China

Product Information

Name: Commode Chair
Model: See Annex
GMDN: See Annex
Basic UDI-DI: -
Classification: Class I, according to Rule 1, Annex VIII, Regulation (EU) 2017/745

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

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: Yu RuiZhuo Date: Apr 7th 2021

Name: Yu Jinwei Place: Foshan / China
Position: GM

Annex

Product Name	Model	GMDN	Basic UDI-DI
Commode Chair	CA601, CA602, CA603, CA611, CA611U, CA612, CA613, CA613L, CA6131, CA6132, CA614L, CA614LW, CA6143L, CA6144L, CA615, CA615L, CA616, CA616E, CA616L, CA616S, CA618, CA618A, CA618L, CA6181, CA619, CA6201L, CA6203L, CA6204L, CA6205L, CA6208L, CA6206L, CA6209L, CA6210L, CA620L, CA622U, CA623L, CA651L, CA6511L, CA652, CA6521, CA653, CA6531, CA662, CA6621, CA663, CA6642, CA6642L, CA667, CA6671, CA667S, CA668, CA669, CA670, CA670L, CA671, CA6712, CA672, CA673L, CA6731L, CA674-2", CA674-4", CA674-6", CA6741-2", CA6741-4", CA6741-6", CA6742-2", CA6742-4", CA6742-6", CA676, CA677, CA691L, CA6911L, CA693, CA697, CA697A, CA697U, CA698, CA698A, CA6981, CA6982, CA699, CA699W, CA6992L, CA6993L, CA6995, CA6995W, CA6996L, CA6997, CA613U, CA697S	40539	-

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

Signature: Xu Ruzhuo Date: Apr 7th 2021

Position: GM Place: Foshan / China

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 1041:2008+A1:2013, EN ISO 15223-1: 2016, ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013, ISO11199-2:2005

Remark

The declaration of conformity is valid in connection with the release technical document CE-MDR-TCF002.

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: FOSHAN SHUNKANGDA MEDICAL TECH CO.,LTD
Address: Pingnan Industrial Area , Guicheng Nanhai District , 528251 Foshan City,Guangdong P.R. China

Product Information

Name: Rollator
Model: See Annex
GMDN: See Annex
Basic UDI-DI: -
Classification: Class I, according to Rule 1, Annex VIII, Regulation (EU) 2017/745

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

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: Xu Ruizhuo Date: Apr 7th 2021

Name: Yu Jinwei Place: Foshan / China
Position: GM

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Annex

Product Name	Model	GMDN	Basic UDI-DI
Rollator	C8860L, CA8611L, CA861L, CA862L, CA871L, CA873L, CA874, CA8741L, CA8761L, CA880, CA8801, CA8821W, CA882L, CA882LW, CA882W, CA8851L, CA8861L, CA8862L, CA8863L, CA8865L, CA8882L, CA888L, CA891L, CA892, CA894, CA8761L, CA881L, CA883L, CA884L, CA885L, CA8871L, CA887L, CA889L, CA891, CA893, CA8616L-KD, CA8617-KD, CA8870L, CA8864L, CA8880L, CA8854L	37951	-

Signature: Xu Ruizhuo Date: Apr 7th 2021

Position: GM Place: Foshan / China

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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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 1041:2008+A1:2013, EN ISO 15223-1: 2016, ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013, ISO 17966:2016

Remark

The declaration of conformity is valid in connection with the release technical document CE-MDR-TCF004.

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: FOSHAN SHUNKANGDA MEDICAL TECH CO.,LTD

Address: Pingnan Industrial Area , Guicheng Nanhai District , 528251 Foshan City,Guangdong P.R. China

Product Information

Name: Shower Chair

Model: See Annex

GMDN: See Annex

Basic UDI-DI: -

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

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

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: Yu Rui Zhuo Date: Apr 7th 2021

Name: Yu Jinwei Place: Foshan / China

Position: GM

Annex

Product Name	Model	GMDN	Basic UDI-DI
Shower Chair	CA311, CA314, CA330, CA333L, CA336L, CA3361L, CA3362L, CA3362U, CA337L, CA3372L, CA3373L, CA3374L, CA338L, CA339L, CA340L, CA3402L, CA341, CA342L, CA342L-KD, CA342LW-KD, CA343L, CA343LW, CA3432L, CA344L, CA3442L, CA345L, CA3451, CA346L, CA347L, CA3472L, CA3473L, CA348L, CA3481L, CA350L, CA3501L, CA351L, CA351LS, CA351LW-KD, CA3511L-KD, CA3512L, CA3521L-KD, CA3522L, CA354L, CA3542L, CA355L, CA3552L, CA3553L, CA3555L, CA3561L, CA3562L, CA3563L, CA3563LQ, CA357U, CA3571, CA3573U, CA3581L, CA359L, CA360L, CA3601L, CA3602L, CA362L, CA363L, CA3631L, CA364L, CA3525L, CA371LW, CA374, CA3741, CA3742, CA3742L, CA358L, CA333L2, CA343L2, CA3522L2	34936	-

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

Signature: Xu Rui Zhuo Date: Apr 7th 2021

Position: GM Place: Foshan / China

佛山市康达医疗科技有限公司 4406050019065

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 1041:2008+A1:2013, EN ISO 15223-1: 2016, ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO11199-1:1999

Remark

The declaration of conformity is valid in connection with the release technical document CE-MDR-TCF006.

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: FOSHAN SHUNKANGDA MEDICAL TECH CO.,LTD
Address: Pingnan Industrial Area , Guicheng Nanhai District , 528251 Foshan City,Guangdong P.R. China

Product Information

Name: Walker
Model: See Annex
GMDN: See Annex
Basic UDI-DI: -
Classification: Class I, according to Rule 1, Annex VIII, Regulation (EU) 2017/745

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)

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: Yukui Zhuo Date: Apr 7th 2021

Name: Yu Jinwei Place: Foshan / China
Position: GM

Annex

Product Name	Model	GMDN	Basic UDI-DI
Walker	CA811L, CA811LG, CA811L-Y, CA8115L, CA812L, CA812L-C, CA812LW, CA812LG, CA812LMG, CA812LSG, CA8124LG, CA8125L, CA8126LG, CA8127LG, CA8128L, CA8128LS, CA814LG, CA815LG, CA816L, CA816LG, CA8163L, CA817LG, CA819LL, CA819LM, CA819LS, CA821L, CA821L(variant), CA821LS, CA821LW, CA8211L, CA8212L, CA8213L, CA823L, CA824L, CA8241L, CA8242L, CA8246L, CA826L, CA828L, CA829L, CA818L, CA827CX, CA8272TX, CA8273, CA8273W, CA8274CX, CA8275, CA8276, CA8773,CA8773F,CA8776,CA810L,CA810L-4,CA810LD-5,CA8112L, CA8114LG-44,CA811L-5,CA811LG-5,CA8122LG-3,CA8122LG-4,CA8122LG-5, CA8123LG-3,CA812LXS,CA816LG-5,CA8211LW-55,CA821L-5,CA8243LL,CA8243LM, CA8243LS,CA8244L-3,CA824L-4,CA825,CA875,CA8117LG-44, CA8118,CA8116LG	37961	-

Signature: Xu Rui Zhao Date: Apr 7th 2021

Position: GM Place: Foshan / China

On behalf of SUNGO Europe office, I confirmed we are EC REP of the company who issue this document.

Sungo global service

Authorized Signature (S)