

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Add: 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 20417: 2021,
EN 12183: 2014
ISO13485:2016

Remark

The declaration of conformity is valid in connection with the release technical document MDR-Y122103-11.

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: FOSHAN KAIYANG MEDICAL EQUIPMENT CO., LTD.

Address: 3 of No. 21. The 3rd Hongling Road,
Shishan Town, Nanhai District, Foshan Ctiy,
Guangdong Province, China
SRN: CN-MF-000008258

Product Information

Name: WHEELCHAIR/
COMMODE WHEELCHAIR

Model: See Annex

EMDN: Y122103

Basic UDI-DI: 69753714903YF

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

Declaration

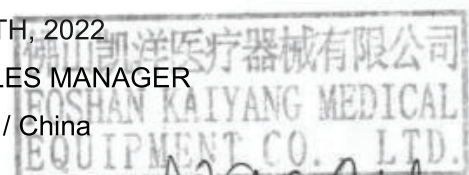
We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:

Date: NOV 15TH, 2022

Position: SALES MANAGER

Place: Foshan / China



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Annex

Product Name	Model	Basic UDI-DI
<p>WHEELCHAIR/ COMMODE WHEELCHAIR</p>	<p>KYW871AJR-12"-41,KYW871AJR-12"-43,KYW871AJR-12"-46, KYW871AJR-20"-41,KYW871AJR-20"-43,KYW871AJR-20"-46, PHW863LABJ-12"-41,PHW863LABJ-12"-43, PHW863LABJ-12"-46, PHW863LAJ JINLU, PHW863LABJ HONGLU, PHW863LAJ HUIXIANG, PHW863LABJ HUIDONG, PHW868LAJ JIEHONG, PHW809 TIEXIN, PHW809 GUANXIN, PHW9003L FEIFENG, PHW9003L QINGFENG, PHW9003L JINFENG, PHW863LAJ YINLU, PHW863LABJ OULU, PHW871LBJ LINGDONG, PHW871LBJ LINGQIAO, PHW908LAH FEIXIANG, PHW908LAH FEIDONG, PHW908LAH FEIYANG, PHW908LAH FEIYUE, PHW908LAH YUEDONG, PHW980LAC FENXIAO, PHW980LAC FENGMING, PHW980LAC FENGYING, PHW869LAJ LANYING, PHW869LAJ LVYING, PHW908LAH DAXIAO, PHW954LGCCANGYING,PHW903GCXIONGYING,PHW903GC JINYING,PHW988LAQ BAOHONG,PHW988LAQ ZUANHONG,PHW608 CHUYING, PHW608 TIANYING, PHW874Y-46 FANGXIN, PHW969LAJ JINHONG, PHW982LBGC MEIXIANG,PHW982LBGC MEILE,PHW908LAH AIXIN,PHW864LY YOUYING, KY902CB-46,KY951ACB-56,KY868B-46, KY608B-46, KY902BC-46, KY903GC-46-24", KY903GC-43-12", KY958LC-A-46, KY958LC-A-41, KY958LC-A-36, KY958LC-C-35, KY958-C-36, KY958-C-41, KY958-C-46, KY959LJ-36, KY959LJ-41, KY959LJ-46, KY959BJ-43, KY997-46, KY720L-36, KY720L-41, KY720L-46, KY721L-36, KY721L-41, KY721L-46, KY723L-41, KY723L-36, KY725L-36, KY728L-36, KY730L-A-38, KY750L-29, KY751L-40, KY756L-31, KY756L-36, KY775L-36, KY775L-41, KY775L-46, KY776L-A-36, KY776L-A-41, KY777L-36, KY778L-A-38, KY784L-36, KY802-35, KY980AC-35, KY980LA-35, KY980LA-41, KY980LA-46, KY980LQ-30, KY980LQ-35, KY863LAJ-E-20"-46, KY863LABJ-E-12"-46, KY863LABJ-12"-46, KY863LABJ-12"-41, KY863ABJ-12"-46, KY863ABJ-12"-41, KY863AJ-20"-41, KY863AJ-20"-46, KY863LABJ-A-12"-46, KY863LABJ-A-12"-41, KY863LABJ-B-12"-46, KY863LABJ-B-12"-41, KY863LABJ-C-12"-46, KY863LABJ-C-12"-41, KY863LAJ-20"-46, KY863LAJ-20"-41, KY863LAJ-B-20"-46, KY863LAJ-B-20"-41, KY863LAJ-A-20"-46, KY863LAJ-A-20"-41, KY863LAJ-C-20"-46, KY863LAJ-C-20"-41, KY862LABJ-16"-41, KY862LABJ-16"-46, KY862LAJ-20"-41, KY862LAJ-20"-46, KY864LJ-46, KY864LJ-41, KY865LABJ-12"-46, KY865LABJ-12"-41, KY867LBJ-46, KY867LBJ-41, KY868LJ-46, KY868LJ-41, KY868L-46, KY868L-41, KY868LFJ-A-46, KY868LFJ-A-43, KY868LAJ-B-46, KY868LAJ-B-43, KY868LAJ-B-41, KY868LAJ-C-46, KY868LAJ-C-43, KY868LAJ-C-41, KY868LAJ-A-46, KY868LAJ-A-43, KY869LAJ-46, KY869LAJ-41, KY870LBJ-46, KY870LBJ-41, KY870ABJ-46, KY870ABJ-41, KY871LBJ-41, KY871LBJ-46, KY872LJ-41, KY872LJ-46, KY981L-35, KY874LAH-35, KY874L-41, KY874L-46, KY9001L-36,</p>	<p>6975371 4903YF</p>

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Signature:

Date: NOV 15TH, 2022

Position: SALES MANAGER

Place: Foshan / China



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