



2010亚洲残疾人运动会轮椅和病床独家供应商
2010 Asian Para Games Wheelchair and Hospital Bed Exclusive Supplier



中华人民共和国第八届残疾人运动会指定轮椅赞助商
8th National Games Of Disabled Persons Specified Wheelchair Sponsor



EC DECLARATION OF CONFORMITY

We Guangdong Kaiyang Medical Technology Group Co., Ltd. declare that the following products which we manufactured:

CLASS: I

PRODUCT NAME: WHEELCHAIR/COMMODE WHEELCHAIR

MODELS: KY875-A-46, KY691, KY980AC-35, KY903AJ-46, KY909B-46, KY809F-46, KY875-A-46, KY681C-51, KY696

Basic UDI-DI: 69404248003SB

CLASS: I

PRODUCT NAME: COMMODE CHAIR

MODELS: KY810-C-72, KY893, KY894, KY894L, KY691, KY696

Basic UDI-DI: 69404248004SD

CLASS: I

PRODUCT NAME: RAISED TOILET SEATS

MODELS: KY880, KY882

Basic UDI-DI: 69404248005SF

CLASS: I

PRODUCT NAME: WALKER

MODELS: KY917L, KY919L, KY912L-3", KY912L-5", KY913L,

Basic UDI-DI: 69404248006SH

CLASS: I

PRODUCT NAME: ROLLATOR

MODELS: KY9144L

Basic UDI-DI: 69404248006SH

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CLASS: I

PRODUCT NAME: SHOWER CHAIR

MODELS: KY797L, KY794L, KY795L, KY798LQ

Basic UDI-DI: 69404248005SF

CLASS: I

PRODUCT NAME: CANE

MODELS: KY926, KY922, KY934

Basic UDI-DI: 69404248007SK

CLASS: I

PRODUCT NAME: CRUTCH

MODELS: KY9331L, KY925L(M), KY925L(L), KY937L

Basic UDI-DI: 69404248007SK

CLASS: I

PRODUCT NAME: STICK

MODELS: KY920L, KY939L, KY927L, KY930L

Basic UDI-DI: 69404248007SK

CLASS: I

PRODUCT NAME: HOSPITAL BED

MODELS: KY213S-32

Basic UDI-DI: 69404248008SM

CLASS: I

PRODUCT NAME: MATTRESS

MODELS: KY-H3

Basic UDI-DI: 69404248013SE

CLASS: I

PRODUCT NAME: TREATMENT TROLLEY

MODELS: KY-D12

Basic UDI-DI: 69404248016SL

CLASS: I

PRODUCT NAME: ALTERNATING PRESSURE BUBBLE MATTRESS

MODELS: KY-H5, KY-QJ-01

Basic UDI-DI: 69404248013SE

CLASS: I

PRODUCT NAME: PEDAL EXERCISER

MODELS: KY-F8B

Basic UDI-DI: 69404248012SC

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CLASS: I

PRODUCT NAME: BACKREST

MODELS: KY-F10

Basic UDI-DI: 69404248014SG

CLASS: I

PRODUCT NAME: I.V STAND WITH

MODELS: KY-G7

Basic UDI-DI: 69404248017SN

CLASS: I

PRODUCT NAME: AIR PRESSURE OPERATION STOOL

MODELS: KY-F20

Basic UDI-DI: 69404248015SJ

CLASS: I

PRODUCT NAME: FOOT STOOL

MODELS: KY-F2,KY-F3

Classification of the above products as the medical device: [Class I, according to Rule 1, Annex VIII, Regulation \(EU\) 2017/745](#)

Are safe under the conditions of common use in compliance with the instruction and that measures have been take to ensure the conformity of all the products brought to market with technical documentation and basic requirements of directives related thereto.

European representative: [SUNGO Europe B.V.](#)

[Olympisch Stadion 24, 1076DE Amsterdam, Netherlands](#)

Fulfilled technical requirements:

This product's characteristics comply with the technical parameters related to it and stated in statutory all orders which stipulate the technical parameters for healthcare products.

Means of assessing conformity:

Conformity was assessed by the procedure stated [\(EU\) 2017/745 MEDICAL DEVICE REGULATION.](#)

Used norms:

The said products fulfill the requirements of these harmonized technical norms which were used for assessing of conformity:

[EN ISO 9001:2015](#)

[EN ISO 13485:2016](#)

[ISO14001: 2015](#)

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GUANGDONG KAIYANG MEDICAL
TECHNOLOGY GROUP CO., LTD.

Liao You feng

GUANGDONG KAIYANG MEDICAL TECHNOLOGY GROUP CO., LTD.

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

General manager: LIAO YOUFENG

Signature date: MARCH 10TH, 2022



Liao Youfeng