广东凯洋医疗科技集团有限公司
Guangdong Kaiyang Medical Technology Group Co.,Ltd.

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

CE

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: KY691, KY696, KY875-A-46,KY809F-46
Basic UDI-DI: 69404248003SB

CLASS: I
PRODUCT NAME: COMMODE CHAIR
MODELS: KY893, KY894
Basic UDI-DI: 69404248004SD

CLASS: I
PRODUCT NAME: BACKREST
MODELS: KY-F10
Basic UDI-DI: 69404248014SG

CLASS: I
PRODUCT NAME: HOSPITAL BED
MODELS: KY213S-32
Basic UDI-DI: 69404248008SM

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Liao Youfeng

CLASS: I
PRODUCT NAME: MATTRESS
MODELS: KY-H3
Basic UDI-DI: 69404248013SE

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

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: SEP 16TH, 2021

广东凯洋医疗科技集团有限公司
GUANGDONG KAIYANG MEDICAL TECHNOLOGY GROUP CO., LTD.

Liao Youfeng