EC DECLARATION OF CONFORMITY

We FOSHAN KAIYANG MEDICAL EQUIPMENT CO., LTD., declare that the following products which we manufactured: ELECTRIC WHEELCHAIR

BRAND: KAIYANG

ELECTRIC WHEELCHAIR :

KY101LA, KY110A-46, KY110A-41, KY110LA-46, KY110LA-41,KY111A-46KY111A-41,KY111A-51,KY112-41,KY112-46,KY112A-46, KY112A-41.KY115,KY116LA,KY117A, KY117LA, KY118,KY118A,KY118LAC,KY118LAC-BKY118LAC-20",KY119,KY119Y, KY119Z,KY119Z-A,KY119L,KY120,KY121CKY122,KY122L,KY123-41,KY123-46, KY123-49,KY123-51,KY124-46KY124-51,KY124-56,KY125-41,KY125-46,KY125-51, KY131L,KY133LKY133LP,KY133LPF,KY1333L,KY1332L,KY134L,KY139,KY140LA, KY140LA-A,KY152-46,KY152-51,KY153L,KY154,KY154-B,KY154CKY155,KY158L, KY159,KY159L, KY160-A,KY160,KY160(B),KY160(C)KY160(D),KY170,KY170-A, KY171,KY171-A,KY172,KY173,KY173-A,KY173-BKY174,,KY184,KY186,KY187,KY188, KY189,KY190, KY191, KY192KY193, KY194, KY195,KY196, KY197, KY198, KY1991, KY1992, KY1993KY1994,KY1995,KY1996,KY1997,KY1998,KY1999,KY2001,KY2002, KY2003,KY2004，KY2005,KY2006，KY2007，KY2008，KY2009，KY2010KY2012， KY2013,KY2014,KY2015，KY2016,KY2017,KY2018

Basic UDI-DI：69753714901YB

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.

Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The 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 14971: 2019,
EN ISO 20417: 2021,
EN ISO 15223-1: 2021,
EN ISO 10993-1:2020,
EN ISO 10993-5:2009,
EN ISO 10993-10:2013

FOSHAN KAIYANG MEDICAL EQUIPMENT CO., LTD.
3 of No.21. The 3rd Hongling Road, Shishan Town, Nanhai District, Foshan City, Guangdong Province, China Tel: 0086-757-85502506 Fax: 0086-757-85502630

Sales Manager：Tim

Signature date: 2025-1-1

佛山凯洋医疗器械有限公司
FOSHAN KAIYANG MEDICAL EQUIPMENT CO., LTD.