



DECLARATION OF CONFORMITY

Regarding UK Medical Devices Regulations 2002

Manufacturer: Jiaying Xinyi Medical Equipment Co., Ltd

Address: No.100, Zhijiang Road, Economic Development Zone, Jiashan City, Zhejiang Province, China

UK Responsible Person: SUNGO Certification Company Limited

Address: 3rd floor, 70 Gracechurch Street, London. EC3V 0HR

Product Name: Steel Triwalker with Bag & Basket, Red
Steel Triwalker with Bag, Blue
Steel Triwalker with Bag, Red
Steel Triwalker with Bag, Basket & Tray, Blue
Steel Triwalker with Bag, Basket & Tray, Red
Rollator

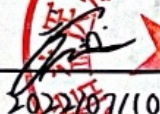
Specification: MDS86850E, XY853, XY855, XY801, XY802, XY803, XY804, XY805, XY806, XY807

Classification: Class I

Conformity Assessment Procedure: Rule 1, Annex IX, Directive 93/42, Part II of the UK MDR 2002

We herewith declare that the above-mentioned products meet the requirements of UK Medical Devices Regulations 2002 and the following standards.

BS EN ISO 20417:2021 BS EN ISO 14971:2019 BS EN ISO 15223-1:2021
BS EN ISO 10993-5:2009 BS EN ISO 10993-1: 2020 BS EN ISO 10993-10: 2013
BS EN ISO 11199-2:2021

Signature: 

Date: 2022/10/10

Position: GM

Place: Zhejiang/ China

The declaration of conformity is valid in connection with the release technical document UKCA-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.