



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: Jiangsu Saikang Medical Equipment Co., Ltd.
Address: No. 35 Lehong Road, Modern Agriculture Demonstration Park, Zhangjiagang City, Jiangsu Province, China
SRN: CN-MF-000002228
EC Representative: SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247
Product Name: Medical Trolley
Model/Size: See Annex
Intended Use: Intended to be used for help to provide immediate support in the event of health emergencies (resuscitation, defibrillation) or to contain and transport medical equipment and devices in critical contexts or contribute indirectly to the diagnosis, prevention, monitoring, treatment or mitigation of a disease or injury

Basic UDI-DI: 697453996MedicalTrolleyAC

Classification: Class I
Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment Procedure: Annex II+III of Regulation (EU) 2017/745

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, we, the manufacturer herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following standards.

EN ISO 14971: 2019/A11: 2021	ISO 15223-1: 2021/Amd 1: 2025
EN ISO 20417: 2021	EN ISO 10993-1: 2020
EN ISO 10993-5: 2009/A11:2025	EN ISO 10993-10: 2023
EN ISO 10993-23: 2021/A1:2025	IEC 62366-1: 2015/Amd1: 2020

Signature: Bessie Wang

Position: General Manager

Date: November 28, 2025

Place: Jiangsu / China

江苏赛康医疗设备股份有限公司
Jiangsu Saikang Medical Equipment Co., Ltd.

江苏赛康医疗设备股份有限公司
Jiangsu Saikang Medical Equipment Co., Ltd.

Annex

SK-AT75077A2

SK-ET75077A

SKR054-ET

Bessie Wang
江苏赛康医疗设备股份有限公司
Jiangsu Saikang Medical Equipment Co., Ltd.

November 28, 2025

公司
Co., Ltd.