



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.

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2909VA Capelle aan den IJssel, The
Netherlands

SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019

EN ISO 15223-1: 2016

EN ISO 20417: 2021

ISO 10993-1: 2018

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013

Remark

*The declaration of conformity is valid in connection
with the release technical document
CE/MDR-PT-01.*

*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.*

Manufacturer

Name: Kanghui Medical Technology (Suzhou)
Co.,Ltd.

Address: Guizhuang Industry Park, Shaxi,
Taicang, Jiangsu Province, China

Product Information

Name: PATIENT TRANSFER TROLLEY

Model: JY-YWS01, JY-YWS02, JY-YWS03, JY-YWS04

GMDN: 64169

Basic UDI-DI: 69524907KHPTTX7

Classification: Class I, According to Rule 1, Annex
VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned
products meet the requirements of Medical Device
Regulation (EU) 2017/745 and the applicable
standards above.

Signature:

Position: GM.

Date:

Jan 25th, 2024

Place: Suzhou/China