



DECLARATION OF CONFORMITY
Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: Wuxi Kangqiang Industrial Equipment Co.,Ltd.
Address: NO.145 Yipu Road Dapu Industrial Park Yixing City Jiangsu
Province,China
EC SUNGO Europe B.V.
Representative:
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Rollator
Model: KQ-1010,KQ-1012,KQ-1014,KQ-1015,KQ-1016,KQ-1017,KQ-1018,
KQ-1019,KQ-1128,KQ-1129,KQ-1130,KQ-1131
Classification: Class I
Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Annex II+III of Regulation (EU) 2017/745
Assessment
Procedure:
SRN: /
Basic UDI-DI: /

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

EN ISO 14971:2012	EN ISO 15223-1:2016	EN 1041:2008+A1:2013
ISO 10993-1:2018	EN ISO 10993-5:2009	EN ISO 10993-10:2013
EN ISO 13982-2:2004	EN ISO 13034:2013	EN ISO 17491-4:2008
EN 14325:2018	IEC 62366-1:2015	

Signature:

Jack Zhou

Name / Position: Jack Zhou / Vice-general Manager

Date:

26-01-2021

Place: Wuxi / China



*On behalf of SUNGO Europe office, I confirmed we are
EU REP of the company who issue this document.*

Sungo
global service

[Signature]

Authorized Signature (S)