



## INTCO MEDICAL(HK) CO., LTD

FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD, WAN CHAI, HONG KONG, P.R. China

Tel: +86 511 83174088 Fax: +86 511 83174188

Website: [www.intco.com.cn](http://www.intco.com.cn)

Document Number : YK-CE-02-A

Version: A/0

# EC Declaration of Conformity

Name of manufacturer: INTCO MEDICAL (HK) CO., LTD

Address: FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD, WAN CHAI, HONG KONG, P.R. China

Tel: 0086-511-83174088

Fax: 0086-511-83174188

SRN: CN-MF-000011338

Representative: MedNet EC-REP GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

SRN: DE-AR-000000002

Product Name: Manual Wheelchairs

Models: YK9011, YK9012, YK9022, YK9031, YK9032, YK9034, YK9041, YK9045, YK9050, YK9052, YK9053, YK9061, YK9062, YK9063, YK9064, YK9065, YK9067, YK9068, YK9069, YK9070, YK9071, YK9080, YK9081, YK9090, YK9091, YK9092, YK9093, YK9096, YK9097, YK9098, YK9130, YK9132, YK9140, YK9031kid, YK9031-1, YK9031F, YK9032-1, YK9032F, YK9041F, YK9042F, YK9061M, YK9063F, YK9063H, YK9064F, YK9064H, COMFORT

UMDNS Code: 16949

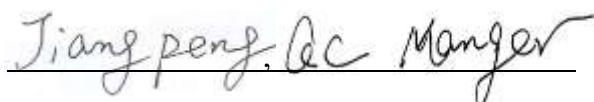
The Basic UDI-DI: 489712866-0-MWheelchairX2

Classification: Class I, based on Annex VIII of 2017/745MDR

Conformity assessment route: Annex II and III of 2017/745 Medical Device Regulation

Standards applied: EN ISO 13485:2016, EN ISO 14971:2019, ISO/TR 20417:2012, EN ISO 15223-1:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN 12183:2014, EN 12182:2012, ISTA-2A-2006, EN 62366-1:2015, Meddev 2.7.1 rev4, Meddev 2.12.1 rev8

We, Intco Medical (HK) Co., Ltd, hereby state that this EU declaration of conformity is issued under our sole responsibility. The device that is covered by this present declaration is in conformity with 2017/745 Medical Device Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.



Legally binding signature, Function



Place, date