



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

Document Number : YK-CE-02-A

Version: A/0

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

Representative: MedNet EC-REP GmbH
 Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: Manual Wheelchairs
 Models: YK9011, YK9012, YK9022, YK9031, YK9032, YK9034, YK9041, YK9042, YK9050, YK9052, YK9053, YK9061, YK9062, YK9063, YK9064, YK9065, YK9067, YK9068, YK9069, YK9070, YK9071, YK9080, YK9081, YK9090, YK9091, YK9092, YK9093, YK9095, YK9097, YK9098, YK9130, YK9132, YK9140, YK9031kid, YK9031-1, YK9031F, YK9032-1, YK9032F, YK9041F, YK9042F, YK9061M, YK9063F, YK9063H, YK9064F, YK9064H, COMFORT

UMDNS Code: 16949

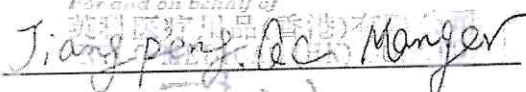
The Basic UDI-DI: 69453979-0-MWheelchairRF

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, EN 1041:2008, EN ISO 15223-1:2016, EN ISO 10993-1:2018, 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.

For and on behalf of

 Jiang peng, DC Manager

Legally binding signature, Function


 Zheng jiang, April 20th, 2021

Place, date