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Document Number : YK-CE-02-A

Version: A/0

Declaration of Conformity

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

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Representative: MedNet EC-REP GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: Manual Wheelchairs

Models: YK9011, YK9012, YK9022, YK9031, YK9032, YK9034, YK9041, YK9045, YK9065, 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, YK9064F, YK9064H, COMFORT

UMDNS Code: 16949

The Basic UDI-DI: 69453979-0-MWheelchairRF

Classification: Class I, based on Rule 1 of Chapter III of 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, 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