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EC Declaration of Conformity

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

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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 (E U) 2017/745MDR

Conformity assessment route: Annex II and III of (E U) 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 (EU) 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.

Jiang peng. QC Manager

Legally binding signature, Function

zhengjiang. April 20th, 2021

Place, date