



INTCO MEDICAL(HK) CO., LTD

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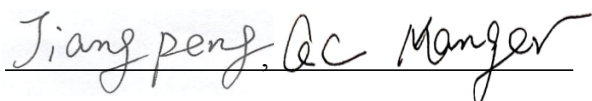
Declaration of Conformity

Name of manufacturer: INTCO MEDICAL (HK) CO., LTD
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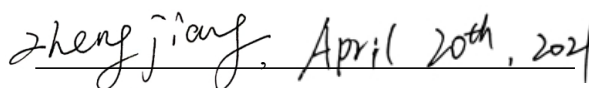
Representative : MedNet EC-REP GmbH
Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: Rollators
Models: Spirit X3, Spirit X4
UMDNS Code: 17630
The Basic UDI-DI: 69453979-0-RollatorCR
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 ISO 11199-2:2005, 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