



INTCO MEDICAL(HK) CO., LTD.

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Declaration of Conformity

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

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SRN: CN-MF-000011338

Name of EU Representative: MedNet EC-REP GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

Tel: +49-251-32266-61

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SRN: DE-AR-000000002

Product Name: HOT/COLD PACKS

Trade Name: HOT&COLD gel paking, COMPRESS COLD/HOT REUSABLE, HOT AND COLD GEL PACK, cold/hot pack, Hot/cold compress, Cold/Hot compress, Reusable Hot& Cold Pack, Reusable Hot & cold Gel Pack, REUSABLE COLD-HOT PACK, Reusable hot/cold pack, HOT&COLD GEL PACK, HOT COLD GEL PACK, Hot Cold Pack, Hot-Cold soft gel, HOT OR COLD GEL PACK, warm/cold compress , gel compress , Kalt Warm Mehrfach Komprese, HOT/COLD REUSABLE PACK, HypaGel Re-Usable Hot/Cold Gel Pack, YPSIMED cold/warm pack, BTS HOT/COLD COMPRESS, Compression cap, Compression elbow, Compression wrist, Compression hamstring, Compression knee, Compression calf
DP Active Hot/Cold Pack

UMDNS Code: 16207

The Basic UDI-DI: 489712866-0-HotColdPack3E

489712866-1-HotColdPack4P

489712866-2-HotColdPack5Y

Classification: Class I, based on rule 1 of ANNEX VIII Chapter III of 2017/745 MDR

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

REF: Q2988; Q2987; DL08156; 2350013; 2350040; 2350026; 2350037,2350038; 2350016; 0355201; 0355202; 0355203; 02083663000000; HY-301; 165-360; GEL0511; GEL3057; GEL3510-F; GEL3710-P; GEL0510-F; GEL0511-F; GEL1015-F; GEL0710-P; N10554-RIE; N11406-RIE; N11741-RIE; 99225; 99239; 99226; 99240; 99227; 99241; 122865; 132935; 25.00201; 2350015; 188513.5; CDM100; FOR.010.049; HOTCP; 007916; 7533106; 47895; 4786; 47897; 418518; 0618547; 1130105; 159318.4; CHP201; CHP202; CHP203; CHP204; 69710072; 69710073; 69710074; 69710075; BRA-CLAY; EYE0310; HC0506; HC0508; HC0710; QU/SP9612; Q2998; k2999; 38053; 38055; 007817; 7642; 76421; 76422; 858841; 02010012; 02010022; 02010072; 5108411; 69710071; G133272PS310;

CC1-A (S,M,L) ; CC1-B (S,M,L) ; CC1-C (S,M,L) ; CE1-A (S,M,L) ; CE1-B (S,M,L) ; CW1-A (S,M,L) ; CH1-A (S,M,L) ; CK1-A (S,M,L) ; CCa1-A (S,M,L)



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CC2-A (S,M,L) ; CC2-B (S,M,L) ; CC2-C (S,M,L) ; CE2-A (S,M,L) ; CE2-B (S,M,L);
CW2-A (S,M,L) ; CH2-A (S,M,L) ; CK2-A (S,M,L) ; CCa2-A (S,M,L)
4013 0114;4013 0113;522053/0;522054/0;522153/0;522154/0;522253/0;522254/0;522353/0

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.

Zhenjiang 2023.07.11

Place , date

Sun guihua Manager

Legally binding signature, Function