

INTCO MEDICAL (HK) CO., LTD.

Declaration of Conformity (DOC) Corrigendum

Product name: cold packs

Trade Name:

HypaCool Instant Cold Pack, Instant Ice Pack Mini, Instant Plus Ice Pack, Instant Ice Pack, INSTANT COLD COMPRESS, HOT & COLD COMPRESS, Instant Soothe COLD pack, Cold Pack, Instant Freeze, Instant cold pack, Instant Cold Compress, cold pad, Instant Cool Pack, Instant Perineal Cold Pack, Cool Power Compress, Cool Pack Mini, Cool Pack Midi, Cool Pack Maxi, Cold Compress

Model:

T129525; Q2281; 7710; 713; 710; ICE1069; 151168; 122864; INSD; N14843; N14844; 09135; 09136; 007909; 100196.0; 99228; 99242; ICE0609; ICE0506; ICE1125; ICE0505; 751520-Q; 751315-Q; KID2; 122865; 132935; HY-303; 913-001; 30649; 193349.2; 1130109; I114-15*23; I1114-13*15; 04-018M; 25.00200

Class: IIa

Date of the DOC: 2021.6.7

This corrigendum intends to correct the following information in DoC(s) of the above listed product(s).

Add SRN of Manufacturer: CN-MF-000011338

Add Product GMDN: 60790

Renew trade Name: HypaCool Instant Cold Pack; Instant Ice Pack Mini; Instant Plus Ice Pack; Instant Ice Pack; HOT & COLD COMPRESS; INSTANT COLD COMPRESS; Instant Soothe COLD pack; Cold Pack; Cool Power Komprese; Instant Cold Pack; cold pad; Quick-Cold Compress; Instant Perineal Cold Pack; CoolPack; SUCHY LÓD 100g

Renew Models:

T129525; Q2281; 7710; 713; 710; ICE1069; 151168; 122864; INSD; N14843; N14844; 09135; 09136; 007909; 100196.0; 99228; 99242; ICE0609; ICE0506; ICE1125; ICE0505; 751520-Q; 751315-Q; KID2;
~~122865; 132935; HY-303; 913-001; 30649; 193349.2; 1130109; I114-15*23; I1114-13*15; 04-018M; 25.00200;~~

ICE0406; ICE0507; ICE0508; ICE0509; N14843-KUG; N14843-TED; N14844-KUG; N14844-TED; F014; F014-1; S454008; VDAA3844; S454009; VDAA3942; 007800; 15510; 69710076; 18872; 100695; WAL023; SAN-0024; ICE1719; PER613; ICE1420; CP201; CP202; ICE0408; 51003; 51004; 51005; 51006; 51007; 51008; 10110; 10110.100; 38050; 38051; 38053; 38055; ICE13515; 7112-1; HXF-SKK(15×17cm); WB-ICP-100; 51001-DRO; 7112; 764; S454008-VDAA3844; S454009-VDAA3942; 007701; C.N.193349.2; HY304; HY305; PC-PCK1; 3601001; INP; S01-0001-CH; 3050; QU/SP9584; ICE 1125; 2548032

According to Regulation (EU) 2017/745 (MDR), for legacy devices according to Art. 120 (3), no changes to DOCs signed prior to May 26, 2021 can be performed. In case of the above described non-significant change(s) (as defined in MDCG 2020-3), the existing DOC(s) is (are) still valid and this Corrigendum will be attached to the originally signed DOC(s). The DOC(s) will be updated upon transition to MDR.

Zhenjiang, Zhenjiang 2022.7.22
Place, date

Sun guihua Manager Sun guihua
Legally binding signature, Function