Jiangsu Intco Medical Products Co., Ltd.

Document Number: ZJ-CE-001-A Version: A/1

EU Declaration of Conformity

Name of manufacturer:	JIANGSU INTCO MEDICAL PRODUCTS CO., LTD.
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Fax:	0086-511-83174188
SRN:	CN-MF-000016338
Name of EU Representative:	MedNet EC-REP C IIb GmbH
Address:	Borkstrasse 10, 48163 Muenster, Germany
Tel:	+49-251-32266-61
Fax:	+49-251-32266-22
SRN:	DE-AR-000011194
the STATE medical device:	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 ; Instant Freeze ; Instant cold pack ; Instant Cold Compress ; cold pad ; Instant Perineal Cold Pack ;Cool Power Compress ;Cool Pack Mini ;Cool Pack Midi ; Cool Pack Maxi ; Cold Compress ; Quick-Cold Compress ; Instant Cooling Pack ; Quick Cold Compress ; KALTE-SOFORT-KOMPRESSE ; SUCHY LOD 100g Ice pack ; insta gelo ; engangs ispose ; Kälte Sofort kompresse
UMDNS Code:	10932
GMDN Code:	60790
EMDN Code:	Z120602, PHYSIOTHERAPY EQUIPMENT
Basic UDI-DI:	69453979-0-ColdPackRU
Models:	C125150NB；C128150NA；C135285ND；C150170NC；C140150NC；C153229NE；C133275NC；C127153NB；C153229ND；C150170ND；C150250ND；C140220NE；C110150NB；C130150NB；C127127NA；C150200ND；C128158NB；C140178NE；C153210ND；C127152NC；C160170NC；C170190NC；C108330NB；C140200NE；C070300ND；C100130NA；C140180NC；C140240ND；C135150ND；C110145NB；C125145NA；C110235ND；C145175ND；C130235ND；C135190NE；C110250NC；C095130NA；C150230ND；C080130NB；C140155ND；C150230NE；C150180ND；C140180ND；C140250NE；C110355NC;C1350300NE；C145335NB；C120150ND；C127152NB；C150210ND；C150270NE

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Intended Purpose:	Cold pack is used for providing cold therapy for temporarily relief of pain, reduces swelling, and aids in cooling. Suitable for local cold therapy in medical institutions or at home.Refer to the warning instructions for restrictions.
Of class:	Class IIa, based on Rule 9 (sub-clause 1, no indent) of according to Annex VIII of Regulation (EU) 2017/745 (MDR)

CE 0197

Conformity assessment route:	Annex XI Part A (Technical Documentation Assessment & Production Quality Assurance)

We herewith declare under our sole responsibility that the above-mentioned products meet the applicable provisions of the Regulation (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

C/S References:	None
Registration No.	DZ 2028764-1
Issue Date：	2025-10-17
Expiry Date：	2030-10-16
Notified Body：	Name: TÜV Rheinland LGA Products GmbH Address: Tillystraße 2, 90431, Nürnberg, Germany CE identifier: CE 0197

Zhenjiang, 2025-11-01
Ort, Datum / Place, date /
Lieu, date / Luogo, data

QA Manager Mayo Li
Name und Funktion / Name and function /
Nometfonction / Nome e funzione

Change History

No.	Change History	Prepared by	Date	Version
1	Initial release	Li yijun	2023.5.6	A/0
2	Revise Conformity assessment route	Andy liu	2025.9.1	A/1