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

EU Declaration of Conformity

Name of manufacturer:	JIANGSU INTCO MEDICAL PRODUCTS CO., LTD.
Address:	No. 298 Yandunshan Road, Zhenjiang New District 212132 Jiangsu P.R. China
Tel:	0086-511-83174088
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

Digitally signed by Alexa Gheorghe
Date: 2026.05.29 13:06:27 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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 Max 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	2025.11.1	A/1

Appendix1-Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

No.	Standards	Version	Description of Standards
1.	EN ISO 14971	2019+A1:2021	Medical devices - Application of risk management to medical devices
2.	ISO/TR 24971	2020	Medical devices-Guidance on the application of ISO 14971
3.	EN ISO 20417	2021	Medical devices - Information to be supplied by the manufacturer
4.	EN ISO 10993-1	2020	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
5.	EN ISO 10993-5	2009	Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
6.	EN ISO 10993-10	2023	Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization
7.	EN ISO 10993-23	2021	Biological evaluation of medical devices-Part 23: Tests for irritation
8.	EN ISO 15223-1	2021	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
9.	ASTM F1980-21	2021	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Device
10.	ASTM D4169-23e1	2024	Standard Practice for Performance Testing of Shipping Containers and Systems
11.	EN ISO 13485	2016+A1:2021	Medical device-Quality management systems – Requirements for regulatory purpose
12.	MEDDEV 2.7/1	Rve4	Guidelines for clinical evaluation of medical devices
13.	EN 62366-1	2015/A1:2020	Medical device-Part 1: Application of usability engineering to medical devices
14.	IEC TR 62366-2	2016	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices
15.	EN ISO 11607-1	2020/A1:2023	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
16.	EN ISO 11607-2	2020/A1:2023	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
17.	ISO/TR 20416	2020	Medical devices — Post-market surveillance for manufacturers
18.	MDCG 2020-5	2020	Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies
19.	MDCG 2020-6	2020	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC A guide for manufacturers and notified bodies
20.	MDCG 2020-7	2020	Guidance on PMCF Plan Template
21.	MDCG 2020-8	2020	Post-market clinical follow-up (PMCF) Evaluation Report Template - A

No.	Standards	Version	Description of Standards
			guide for manufacturers and notified bodies
22.	MDCG 2022-21	2022	GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR) ACCORDING TO REGULATION (EU) 2017/745 (MDR)
23.	MDCG 2023-7	2023	Guidance on exemptions from the requirement to perform clinical investigations pursuant to Article 61(4)-(6) MDR and on sufficient levels of access' to data needed to justify claims of equivalence
24.	ISO/TR 20416	2020	Medical devices — Post-market surveillance for manufacturers
25.	Regulation (EU) 2017/745	2017	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
26.	MEDDEV 2.12/1 Rev 8	2013	Guidelines on a medical devices vigilance system
27.	MEDDEV 2.12/2 Rev 2	2012	Guidelines on post market clinical follow-up
28.	EN ISO 13732-3	2008	Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 3: Cold surfaces (ISO 13732-3:2005)
29.	Regulation (EC) No 1907/2006	2019	REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
30.	Language requirements for manufacturers	Rev. 2 (August 2024)	MDR - Language requirements for manufacturers
31.	REGULATION (EU) 2021/2226	2021	Laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices
32.	REGULATION (EU) 2025/1234	2025	Amending Implementing Regulation (EU) 2021/2226 as regards the medical devices for which the instructions for use may be provided in electronic form