Jiangsu Intco Medical Products Co., Ltd.

Document Number: ZJ-CE-001-A Version: A/2

EU Declaration of Conformity

Name of manufacturer:	JIANGSU INTCO MEDICAL PRODUCTS CO., LTD.
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Name of EU Representative:	MedNet EC-REP C IIb GmbH
Address:	Borkstrasse 10, 48163 Muenster, Germany
Tel:	+49-251-32266-61
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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

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, 2026-01-29
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
3	Delete ISO11607 standards	Andy liu	2026.01.29	A/2

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.	ISO/TR 20416	2020	Medical devices — Post-market surveillance for manufacturers
16.	MDCG 2020-5	2020	Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies
17.	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
18.	MDCG 2020-7	2020	Guidance on PMCF Plan Template
19.	MDCG 2020-8	2020	Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies
20.	MDCG 2022-21	2022	GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR) ACCORDING TO REGULATION (EU) 2017/745 (MDR)
21.	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
22.	ISO/TR 20416	2020	Medical devices — Post-market surveillance for manufacturers
23.	Regulation (EU)	2017	Regulation (EU) 2017/745 of the European Parliament and of the

No.	Standards	Version	Description of Standards
	2017/745		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
24.	MEDDEV 2.12/1 Rev 8	2013	Guidelines on a medical devices vigilance system
25.	MEDDEV 2.12/2 Rev 2	2012	Guidelines on post market clinical follow-up
26.	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)
27.	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
28.	Language requirements for manufacturers	Rev. 2 (August 2024)	MDR - Language requirements for manufacturers
29.	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
30.	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

Product Specification
Cold Packs

1. Quality requirement

A)Appearance

The surface is clean, the seal is not slanting, no damage, leakage or foreign matter is allowed, the seal cannot be sealed to the inner material, no break or hole on the surface, the printing is clear and not blurry, the color difference is not obvious, the surface cannot have white powder, and the water bag cannot have chronic seepage and water bag activation.

B)Size and seal width

Bag size：x±2mm;

Seal width：9±2mm.

C)Weight

weight：x±5g.

D)Force test

196N，1min，the inner bag is not damaged；

Activate the product at horizontal Force >196N and ≤588N;

735N，1min，No leakage or rupture in outer bag.

E)Temperature test

Room temperature: Under the condition of 20-24 °C.

The specifications 15* 23cm and above, the minimum cooling temperature shall not be higher than 4℃, and the temperature rise shall not be higher than 10℃ after 15 minutes.

The specifications 15* 23cm and below, the minimum cooling temperature shall not be higher than 4℃ and 12℃ after 15 minutes.

2.Model/Specification description

No.	Model type			
	Product code	Size Code	Material category Code	Weight/g
1	C	XXXXXX	Y	N

Note：

C:Represents cold pack

Y:Represents material type，N:urea,X:calcium ammonium nitrate,H：Urea and ammonium chloride are mixed

XXXXXX: Represents cold pack size code

N:Represents cold pack weight range code

N Code	A	B	C	D	E
Weight range/g	≤100	100~150	150~200	200~250	＞250

Example:

Model: C127153NA

Indicates: The size of the urea cold pack is 12.7*15.3cm, and the weight is less than or equal to 100g.

Model: C127153XA

Indicates: The size of the calcium ammonium nitrate cold pack is 12.7*15.3cm, and the weight is less than or equal to 100g.

Models and specification:

No.	Model	Specification	
		Size	Material
1	C125150NB	12.5*15cm±3cm	N
2	C128150NA	12.8*15cm±3cm	N
3	C135285ND	13.5*28.5cm±3cm	N
4	C150170NC	15*17cm±3cm	N
5	C140150NC	14*15cm±3cm	N
6	C153229NE	15.3*22.9cm±3cm	N
7	C133275NC	13.3*27.5cm±3cm	N
8	C127153NB	12.7*15.3cm±3cm	N
9	C153229ND	15.3*22.9cm±3cm	N
10	C150170ND	15*17cm±3cm	N
11	C150250ND	15*25cm±3cm	N
12	C140220NE	14*22cm±3cm	N
13	C110150NB	11*15 cm±3cm	N
14	C130150NB	13*15cm±3cm	N
15	C127127NA	12.7*12.7cm±3cm	N
16	C150200ND	15*20cm±3cm	N
17	C128158NB	12.8*15.8cm±3cm	N
18	C127152NC	12.7*15.2cm±3cm	N
19	C170190NC	17*19cm±3cm	N
20	C108330NB	10.8*33cm±3cm	N
21	C100130NA	10*13cm±3cm	N
22	C140180NC	14*18cm±3cm	N
23	C140240ND	14*24cm±3cm	N
24	C110145NB	11*14.5cm±3cm	N
25	C125145NA	12.5*14.5cm±3cm	N
26	C110235ND	11*23.5cm±3cm	N
27	C145175ND	14.5*17.5cm±3cm	N
28	C130235ND	13*23.5cm±3cm	N
29	C135190NE	13.5*19cm±3cm	N
30	C110250NC	11*25cm±3cm	X
31	C150230ND	15*23cm±3cm	N
32	C080130NB	8*13cm±3cm	N
33	C140155ND	14*15.5cm±3cm	N
34	C150230NE	15*23cm±3cm	N
35	C150180ND	15*18cm±3cm	N
36	C140180ND	14*18cm±3cm	X
37	C140250NE	14*25cm±3cm	N
38	C110355NC	11*35.5cm±3cm	N
39	C140178NE	14.*17.8cm±3cm	N

40	C153210ND	15.3*21cm±3cm	N
41	C095130NA	9.5*13cm±3cm	N
42	C135150ND	13.5*15cm±3cm	N
43	C140200NE	14*20cm±3cm	N
44	C070300ND	7*30cm±3cm	N
45	C160170NC	16*17cm±3cm	N
46	C135300NE	13.5*30cm±3cm	N
47	C145335NB	14.5*33.5cm±3cm	N
48	C120150ND	12*15cm±3cm	N
49	C127152NB	12.7*15.2cm±3cm	N
50	C150210ND	21*15 cm±3cm	N
51	C150270NE	27*15 cm±3cm	N

3.Change History

No.	Change History	Prepared by	Date	Version
1	Initial release	Andy liu	2025.04.20	A/0
	Add model	Andy liu	2025.05.07	A/1