# Jiangsu Intco Medical Products Co., Ltd.

Document Number ： ZJ-CE-002-A Version: A/1

CE

## Declaration of Conformity

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|---|---|
| Name of manufacturer: | Jiangsu Intco Medical Products Co., Ltd. |
| Address: | No. 298 Yandunshan Road, Zhenjiang New District 212132 Jiangsu P.R. China |
| SRN: | CN-MF-000016338 |
| Name of EU Representative: | MedNet EC-REP C IIb GmbH |
| Address: | Borkstrasse 10, 48163 Muenster, Germany |
| SRN: | DE-AR-000011194 |
| 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 Kompresse， 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, Mini First Aid Teddy Reusable Hot & Cold Pack, PIC SOLUTION THERMOGEL TOP CONF, PIC SOLUTION THERMOGEL GINOCCHIO TOP CONF, PIC SOLUTION THERMOGEL LOW COST CONF, PIC SOLUTION THERMOGEL MAXI LOW COST CONF, DR MARCUS CUSCINO PER LA TERAPIA CALDO/FREDDO CONF, HOT & COLD THERAPY GEL PACK, HOT & COLD THERAPY GEL CAP, HOT & COLD GEL SLEEVE, Wochenbettkompresse, Brustgelkissen, GEL PAD, Cooler / Warmer Pack, Gel - Kompresse, Kompres zelowy, Kühl- und Wärmepad mit Tiermotiv, Kühl- und Wärmepad 4 Tiere, Compresse chaud/froid, Cuscinetto gel CALDO FREDDO SPALLE, COMPRESA REUTILIZABLE, COMPRESAFRIO/CALORREUTILIZABLE, KOUD-WARM KOMPRES LARGE, KALT/WARM MEHRFACH KOMPRESSE, KALT-WARM KOMPRESSE, HOT COLD COMPRESS, HOT COLD EYE MASK, COLD HOT COMPRESS, Re-Usable Hot/Cold Pack, POCHE THERMIQUE CHAUD/FROID, ColdHot Pack, HOT AND COLD PACK, Hot & Cold Clay Pack, Reusable Cold Pack, Hot & Cold Pack, Cold/hot pack, Busta caldo freddo con fascia porta busta, COLD/HOT GEL PACK FOR SHOULDER, KOMPRES ŻELOWY, Kälte-UND WärmeKompresse, GEL CALDO-FREDDO, GEL BEAD HOT AND COLD PACK 5; PACK GEL FRÍO & CALOR MAXI; PACK GEL FRÍO & CALOR MIDI; PACK GEL FRÍO & CALOR MINI, ACTIPOCHE GEL CERV TRAPEZES U, ACTIPOCHE GEL GENOU U, ACTIPOCHE GEL MASQUE YEUX U, ACTIPOCHE BILLES CERVICALES U, ACTIPOCHE BILLES DOS&VENTRE U, ACTIPOCHE BILLES GENOU U, ACTIPOCHE BILLES MASQUE U, ACTIPOCHE BILLES MULTI ZONES U, ACTIPOCHE BILLES ZONE CIBLEE U |
| UMDNS Code: | 16207 |
| GMDN: | 37240 |
| EMDN Code | Z120602，PHYSIOTHERAPY EQUIPMENT |
| The Basic UDI-DI: | 69453979-0-HotColdPackVQ<br>69453979-1-HotColdPackWZ<br>69453979-2-HotColdPackYA |
| #: | XXXX - XX - N,<br>XXXX - XX - N - R<br>Note:XXXX:Gel type,XX:Bag material,N:Net weight,R:Color |

# Jiangsu Intco Medical Products Co., Ltd.

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| 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 |
| Intended Purpose: | Hot/cold pack is used for providing heat/cold therapy.<br>For cold therapy:<br>for providing cold therapy for temporarily relief of pain, reduces swelling, and aids in cooling.<br>For hot therapy:<br>for temporary relief of muscle stiffness and soreness, promotes local blood circulation, and helps relax soft tissues， and to regulate blood and disperse stasis.<br>Suitable for local cold therapy in medical institutions or at home. Refer to the warning instructions for restrictions. |

We, Jiangsu Intco Medical Products 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 2026.01.29
*Place , date*

QA Manager Max Li
*Legally binding signature, Function*

## 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 | ASTM D4169-2016Standard Practice for Performance Testing of Shipping |
| 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<br>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<br>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) 2017/745 | 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, |

| No. | Standards | Version | Description of Standards |
|---|---|---|---|
| | | | 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 13732-1 | 2008 | Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 1: Hot surfaces (ISO 13732-1:2006) |
| 27. | 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) |
| 28. | 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 |
| 29. | Language requirements for manufacturers | Rev. 2 (August 2024) | MDR - Language requirements for manufacturers |

| No. | Change History | Prepared by | Date | Version |
|---|---|---|---|---|
| 1 | Initial release | Andy liu | 2025.11.3 | A/0 |
| 2 | Delete ISO11607 standards | Andy liu | 2026.01.29 | A/1 |

# Product Specification

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|---|---|
| PRODUCT: | COLD/HOT PACKS |
| FILE NO: | ZJ-CE-002-S |
| VERSION: | A/0 |
| PROCEDURE: | MDR(EU)2017/745 |

Compiled by: Andy liu Date: 2026-01-17

Approved by: Max li Date: 2026-01-17

## 1. Quality requirement

A)Appearance:
- The seal is not allowed to be damaged, leaked or attached with something that is not clean;
-The bag is correct, the surface is clean and tidy, and the surface cannot be composited;
-The inner material can not have large black spots (more than 1mm) or meet the sample requirements. Vacuum products should not exceed 5mm, and less than 5mm bubbles should be less than 5.

B)Size and seal width:
Size requirements：X ±2mm

C)Weight
Weight: deviation limit: weight is greater than (including) 160g product, ±3%, weight less than 160g product, ±5g.
No specification is made for the weight deviation of solid gel products.

D)Force test
196N flat pressure below 30*40cm, 2940N flat pressure of 30*40cm or above, no leakage and rupture in 1min.

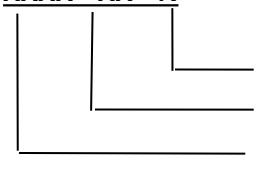
E)Temperature test
Test ambient temp: 20 ~24℃,
The cold performance: Temp ≤10 ℃ within 20min(-18℃ Freezer: ≥2h)
The thermal performance:Temp≥40 ℃ within 20min(When max temp ≥55℃).
Note:Duration depends on product size and weight.

## 2.Model/Specification description

**The model rules are as follows:**

A)

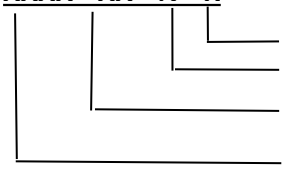
**XXXX - XX - N**



N:Net weight
XX:Bag material
XXXX:Gel type

B)

**XXXX - XX - N - R**



R:Color
N:Net weight
XX:Bag material
XXXX:Gel type

**Model type:**

| No. | Model type | | |
|---|---|---|---|
| | Material category Code | Packaging material | Weight/g |
| 1 | GELO | PN | N |
| 2 | | PV | N |
| 3 | | PF | N |
| 4 | GELS | LC | N |
| 5 | GELC | PN | N |
| 6 | | PV | N |
| 7 | | PF | N |
| 8 | | KN | N |

**Note：**
**Gel type：**
GELO: Ordinary gel
GELS: Solid gel
GELC: Clay gel
**Bag material：**
PN: stands for PE with nylon
PV: stands for PVC
PF: stands for PVC with fabric
LC: stands for Lycra fabric, spandex fiber
KN: PVC with knitted fabric
**Weight：**
N:Net weight
**Color:**
R:The initial letter of the English name of the color

## 3.Change History

| No. | Change History | Prepared by | Date | Version |
|---|---|---|---|---|
| 1 | Initial release | Andy liu | 2026.01.17 | A/0 |
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