JIANGSU INTCO MEDICAL PRODUCTS CO., LTD.

Document Number ： ZJ-CE-007-A Version: A/2

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
SRN:	CN-MF-000016338
Name of EU Representative:	MedNet EC-REP C IIb GmbH
Address:	Borkstrasse 10, 48163 Muenster, Germany
SRN:	DE-AR-000011194
The STATE medical device:	Heat Patches
Trade Name:	Heat Patch；Warmer；Heltes Heat Patch；Heat Therapy Patches；Warming Eye Mask；Heat pads；Warm Relief Patch；Warm Flaster；HEAT THERMAL PATCH；Warmer Pad；Heating Patch；Extra-large Heating Patch；Heating Mask；Heating pad；Heating Pad Neck and Shoulder；Direct to Skin Heat Patch；Arôma patch；Warm Hands；Riscaldante；ThermoHelp Heat Patch；Warmeplaster；Eye warmer；Face warmer；WÄRMESOHLEN；HANDWÄRMER；KÖRPERWÄRMER；SELF-HEATING PATCHES；Steam Eye Mask
UMDN Code:	15610
GMDN Code:	37697
EMDN Code:	Z120602, PHYSIOTHERAPY EQUIPMENT
The Basic UDI-DI:	69453979-0-HeatPatchSF 69453979-1-HeatPatchTE 69453979-2-HeatPatchUD 69453979-3-HeatPatchVC 69453979-4-HeatPatchWB 69453979-5-HeatPatchXA
Models:	69453979-0-HeatPatchSF: H095130A8 69453979-1-HeatPatchTE: H080185B0.5,H070095B6,H095130B8,H070193B0.5,H245404B0.5,H076230B8,H085250B8,H086260B8,H095285B8,H055095B8 69453979-2-HeatPatchUD: H095130C6,H095130C8,H1401100C4,H095130C12 69453979-3-HeatPatchVC: L055950A8,L130192A12,L095300A12,L140390A12,L090295A12,L130190A12,L095130A12,L070095A8,L100150A8,L090295A8,L095130A8,L095220A8,L130192A8,L095300A8,L095130A16,L130190A16,L100200A12 69453979-4-HeatPatchWB: L055950B8,L140390B8 69453979-5-HeatPatchXA: L055950C8
Intended Purpose:	Heat patch is used for providing heat therapy for temporary relief of Back pain,Knee pain,Neck pain,Joint pain,Muscle Tension and Soreness and Menstrual pain.Suitable for those suffering from acute, chronic and occasional pain.

Steam eye mask:Provide gentle warming to the periocular area for the purpose of supporting user comfort and helping to relieve sensations of eye fatigue and discomfort associated with dryness or extended visual tasks.
Support the maintenance of normal meibomian gland function through localized warming.
Suitable for local heat 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
Place , date

QA Manager Max Li
Legally binding signature, Function

Change History

No.	Change History	Prepared by	Date	Version
1	Initial release	Li yijun	2023.5.6	A/0
2	Revise Conformity assessment route	Li yijun	2025.11.01	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	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 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

	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 13732-1	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.	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	Llaying 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
Heat Patches

1.Quality requirement

A)Appearance

Surface clean, firm sealing, no damage, no leakage, no foreign body, pressure side not to material breathable film have no dirty, black dot are not more than 3pcs which size are not more than 2mm;
Gummy heat patch: Strong glutinosity, can be repeatedly paste, glue is not transferred, can not fall off, tear position conform to the technological sheet;
The material is powder and can not fall and accumulate, no overflow, distribution and delicate,pinch should not feel coarse particles by hand;
The appearance of packing is neat, tidy and printing, fine color, smooth, firm handfeel, toughness and strength, after opening the packaging can't have odor and the printing on bag can't be fail off.

B) Weight

Weight less than 100g product±5g, or in accordance with the requirements of the operating instructions

C)Size Length and width

Dimension deviation: ±5mm, edge seal size ≥5mm, and the error on both sides cannot exceed 2mm

D)Temperature performance

Maximum temperature	Low temperature heat patch: The maximum temperature measured from the beginning to the end of heating.	≤ 43℃
	High temperature heat patch: The maximum temperature measured from the beginning to the end of heating.	≤ 68℃
Temperature rise time	The time required from product activated to temperature rise to therapeutic time.	≤ 30min
Temperature guarantee time	The total amount of time that the heating temperature is maintained above37℃ (≤ 43℃) or 40℃ (≤ 68℃).	0.5,4,8,12,16h

We can also customize the temperature guarantee time for customers.

2.Model/Specification description

No.	Model type			
	Temperature code	Size Code	Product structure code	Heating duration code
1	H	XXXXXX	A	N
2	H	XXXXXX	B	N
3	H	XXXXXX	C	N
4	L	XXXXXX	A	N
5	L	XXXXXX	B	N
6	L	XXXXXX	C	N

Note：

L:Represents not more than 43 ℃

H: Represents not more than 68 ℃

XXXXXX: Represents heat patch size code

A: Represents gummy heat patch

B: Represents double sided nonwoven heat patch

C: Represents double sided nonwoven heat patch and protective clothing

N:Represents heating time length value， unit hour

Example:

1.Model : H950130A6

Indicates:the maximum temperature of heat patch is not more than 68℃, the size is 95*130cm,and the heating time is more than 6h, with adhesive backing heat patch.

2.Model : H950130B8

Indicates: the maximum temperature of heat patch is not more than 68℃, the size is 95*130cm, the heating time is more than 8h,double sided non-woven cloth heat patch.

3.Model :L950130C12

Indicates: the maximum temperature is no more than 43℃, the size is 95*130cm, and the heating time is more than 12h,double sided non-woven with protector heat patch.

No.	Model	Specification			
		Size	Temperature	Product structure	Heating duration/h
1	L095130A16	9.5*13cm±3cm	L	A	16
2	L130190A16	13*19cm±3cm	L	A	12
3	L095130A12	9.5*13cm±3cm	L	A	12
4	H095130B8	9.5*13cm±3cm	H	B	8
5	L090295A12	9*29.5cm±3cm	L	A	12
6	H095130C8	9.5*13cm±3cm	H	C	8
7	L095130A8	9.5*13cm±3cm	L	A	8
8	L130190A12	13*19cm±3cm	L	A	12
9	H080185B0.5	8*18.5cm±3cm	H	B	0.5
10	L070095A8	7*9.5cm±3cm	L	A	8
11	L090295A8	9*29.5cm±3cm	L	A	8
12	L130192A12	13*19.2cm±3cm	L	A	12
13	L100150A8	10*15cm±3cm	L	A	8
14	H070095B6	7*9.5cm±3cm	H	B	6
15	L055950A8	5.5*9.5cm±3cm	L	A	8
16	L095300A12	9.5*30cm±3cm	L	A	12
17	L140390A12	14*39cm±3cm	L	A	12
18	H095130C6	9.5*13cm±3cm	H	C	6
19	H095130A8	9.5*13cm±3cm	H	A	8
20	L095220A8	9.5*22cm±3cm	L	A	8
21	L130192A8	13*19.2cm±3cm	L	A	8

22	L095300A8	9.5*30cm±3cm	L	A	8
23	H070193B0.5	7*19.3cm±3cm	H	B	0.5
24	H245404B0.5	24.5*40.4cm±3cm	H	B	0.5
25	H076230B8	23*7.6cm±3cm	H	B	8
26	H085250B8	25*8.5cm±3cm	H	B	8
27	H086260B8	8.6*26.5cm±3cm	H	B	8
28	H095285B8	9.5*28.5cm±3cm	H	B	8
29	H055095B8	5.5*9.5cm±3cm	H	B	8
30	H1401100C4	14*110cm±3cm	H	C	4
31	L140390B8	14*39cm±3cm	L	B	8
32	L055950B8	5.5*9.5cm±3cm	L	B	8
33	L055950C8	5.5*9.5cm±3cm	L	C	8
34	H095130C12	9.5*13cm±3cm	H	C	12
35	L100200A12	10*20cm±3cm	L	A	12
36	H095130B12	9.5×13cm±3cm	H	B	12
37	L100150A12	10×15cm±3cm	L	A	12

3.Change History

No.	Change History	Prepared by	Date	Version
1	Initial release	Andy liu	2023.04.20	A/0
2	Revise quality standards,add model	Andy liu	2026.01.09	A/1