INTCO MEDICAL(HK) CO., LTD.

FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD,
WAN CHAI, HONG KONG
Tel:+86 511 83174088 Fax: +86 511 83174188
Website: www.intco.com.cn

Document Number : CE-DC-007 Version: A/5

EC Declaration of Conformity

Manufacturer:

INTCO Medical (HK) Co., Limited
FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD, WAN CHAI, HONG KONG
Tel: +86-511-83174088
Fax: +86- 511- 83174188

whose single Authorized Representative:

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Muenster, Germany
Tel: +49-251-32266-61
Fax: +49-251-32266-22

We, the manufacturer, herewith declare that the products

Warmers

（Patch, Heat Patch, KOOLPAK 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）

Modol codes

5657,6251,6245,5653,5659,5655,1704,AEC5268,6246-1,6252-1,6263-1,X1965,005301,174734.1,0350201,0350202,0350203,0350204,1706-3,1703-3,2039-3,6256-1,6258-1,6247-1,99320,99321,99322,99323,99329,99331,99334,99336,99337,99345,99346,99347,99348,99349,N18433,N18951,N19040

UMDNS Code: **15610**

meet the provisions of the Council Directive 93/42/EEC which apply to them.

Classification according to Rule 9 of ANNEX Ⅸ, MDD 93/42/EEC, warmers are in Class Ⅱa. It bears the mark

CE 0197

The product concerned has been manufactured under a quality management system according to Annex V and Annex VII of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: **DD 2068388-1**
Issue date: 11.09.2020
Expiry date: 26.05.2024

following the procedure relating to the EC Declaration of Conformity set out in Annex V and Annex VII of Directive 93/42/EEC.

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This Declaration of conformity is valid in connection with the release document for the respective batch of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: **INTCO Medical (HK) Co., Limited**
Address: FLAT/RM 19C, LOCKHART CENTRE, 301-307 LOCKHART ROAD, WAN CHAI, HONG KONG

ZHENJIANG, 2023.03.09
Place , date

Sun Guihua Manager Sun Guihua
Legally binding signature, Function

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INTCO MEDICAL(HK) CO., LTD.

FLAT/RM19C,LOCKHART CENTRE, 301-307 LOCKHART ROAD,

WAN CHAI,HONGKONG

2024/2/2

INTCO Confirmation Letter

Reference: 2024-01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

For and on be
INTCO MED
英科醫療

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

INTCO MEDICAL(HK) CO., LTD.
FLAT/RM19C,LOCKHART CENTRE, 301-307 LOCKHART ROAD,
WAN CHAI,
HONGKONG
China

SRN Number: CN-MF-000011338

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or

exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of

the MDR respectively, by March 20, 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the manufacturer,

<INTCO stamp >

For and on behalf of INTCO MEDICAL (HK) CO., LIMITED 英科醫療用品(香港)有限公司

Authorized Signature(s)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Warmers	Class IIa	Identification of the corresponding device under MDD/AIMDD	Certificate DD 2068388-1; TÜV Rheinland LGA Products GmbH
Cold packs	Class IIa	Identification of the corresponding device under MDD/AIMDD	Certificate DD 2068388-1; TÜV Rheinland LGA Products GmbH
Hot packs	Class IIa	Identification of the corresponding device under MDD/AIMDD	Certificate DD 2068388-1; TÜV Rheinland LGA Products GmbH

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
/	/	/	/

Confirmation Letter Revision History

Date	INTCO internal reference traceable to each version of the letter	Action
2024/02/02	2024-01	Initial issue

CO., LIMITED
)有限公司

d Signature(s)