EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 2159986-1
Manufacturer:	Koolcare Technology Co., Ltd. No.6-10, A5, Shandong International Tech Park, South Waihuan Road, Linyi 276017 Shandong P.R. China
EUDAMED Single Registration No.:	CN-MF-000017687
Products:	Product of Class IIa: Z120602 - PHYSIOTHERAPY EQUIPMENT
Authorized representative(s):	Prolinx GmbH Brehmstr. 56, 40239, Duesseldorf, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-03-28

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	190142710-120
Effective date:	2024-03-28
Expiry date:	2029-03-27
Issue date:	2024-03-28

Wenxiang Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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Precisely Right.

Product List and Application MDR
QM part

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Name of Legal Manufacturer (shall be identical as given in General Agreement with TRLP):	Koolcare Technology Co., Ltd
Additional registered trade name or registered trade mark of the manufacturer (used on the label; MDR Annex I clause 23.2.c):	N/A
Address of Legal Manufacturer:	No.6-10, A5, Shandong International Tech Park, South Waihuan Road, Linyi, 276017 Shandong, P.R. China
EUDAMED Single Registration No:	CN-MF-000017687
MDR (EU) 2017/745:	Annex IX Chapter I, Section 2 and 3
Reason for submission:	Other changes in existing product list

☑ **This Product List and Application replaces all previous applications.** In case of changes to a previous version of the Product List and Application, please mark all changes in red font color and in bold. In case of deleting products from the portfolio, please cross out the relevant products.

☐ **This Product List and Application is an addendum to the initial application** dated YYYY-MM-DD. (Please only list the added products)

Please provide a legally binding signed version of this document by fax, 2-fold by post (note: not all data will be printed) or electronically signed (advanced or qualified signature according to eIDAS Regulation (EU) No 910/2014). In addition please provide this Product List and Application as as Excel file.

Declaration of the applicant
I hereby apply for the assessment of my quality management/assurance system with respect to the product(s) listed hereafter.

I hereby declare
- that no application has been lodged with any other notified body for the same device-related quality system.

In relation to the quality assurance system I assure
- to fulfil the obligations imposed by the Medical Device Regulation 2017/745 on establishing, documenting, implementing and maintaining a quality management system;
- to keep the approved quality system adequate and efficacious;
- to institute and keep up to date a system to review experience gained from post-market surveillance, including the provisions referred to in Annex III, and to inform the notified body about initiated corrective and / or preventive actions;
- to notify the competent authorities and TÜV Rheinland LGA Products GmbH of the following as described in accordance with Article 87:
  a) any serious incident involving devices made available on the Union market, except expected side-effects which are clearly documented in the product information and quantified in the technical documentation and are subject to trend reporting pursuant to Article 88;
  b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country. The reports referred to in the first subparagraph shall be submitted through the electronic system referred to in Article 92.
- to notify the competent authorities and TÜV Rheinland LGA Products GmbH of the following as described in accordance with Article 88:
  Any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side-effects that could have a significant impact on the benefit-risk analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.

For applications according to Annex XI Part A:
- I ensure and declare that the class IIa devices in question are manufactured in conformity with the technical documentation referred to in Annexes II and III

Additionally I declare:
- **that I have not withdrawn an application with another notified body prior to the decision of that notified body, OR**
- **that I provide all information about any previous application with another notified body prior to the decision of that notified body for the same conformity assessment that has been withdrawn, including information about the refusal by that other notified body, as applicable**

- to submit to the notified body the relevant documentation as defined in Annex IX, Chapter, I Section 2.1;
- to keep the relevant documentation including documents provided by TÜV Rheinland LGA Products GmbH for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market in order to fulfil Chapter II Article 10 Par. 8
- that all listed devices meet the general safety and performance requirements set out in Annex I;
- that used registered trade name(s) and/or registered trade mark(s) of the manufacturer used in accordance with MDR 2017/745, Annex I, 23.2 (c) are not separate legal persons.
- to inform TÜV Rheinland LGA Products GmbH without delay in case of inquiries by any competent authority regarding the products covered by this application;
- to inform TÜV Rheinland LGA Products GmbH about any planned substantial changes to the approved quality management system (e. g. procedural changes regarding design and development, production, or end control), or the products/product range covered by it, and not to implement such substantial changes prior to a notification from TÜV Rheinland LGA Products GmbH to do so.
  Note: For guidance on substantial change notification refer to NBOG best practice guide 2014-3;
- to submit an informal application for certificate re-assessment to the notified body, at least 6 months before expiry of the certificate. A different date may be agreed by means of a contract:

TÜV Rheinland LGA Products GmbH
Certification Office Medical
Am Grauen Stein 29
51105 Cologne
Germany
E-Mail: medical-products@de.tuv.com
E-mail for vigilance cases: medical-vigilance@tuv.com

In case of an application for a conformity assessment procedure according to Annex XI Part A (Production quality assurance) the manufacturer shall attach a copy of the EU type-examination certificate referred to in Section 4 of Annex X and relevant notified body examination reports, as applicable.

As a manufacturer who does not have a registered place of business in an EU member state (including states holding an appropriate agreement with the EC), I additionally declare

- to designate per generic device group one authorised representative established in the Community;
- that the designation is accepted in writing by the authorised representative
- to inform TÜV Rheinland LGA Products GmbH in case the authorised representative has changed;
- that the authorised representative has permanently available and keeps the relevant documentation including documents provided by TÜV Rheinland LGA Products GmbH to allow the authorised representative to fulfil the tasks mentioned in Article 11(3) for a period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.
- to sign an agreement with the authorised representative which enables the authorised representative to fulfil the delegated tasks as defined in Article 11(3).

FACILITIES:

Code of facility	Scope of facility	Legal entity name of facility	Address of facility
EAR(1)	European authorised Representative	Prolinx GmbH (SRN number DE-AR-000005129)	Brehmstr. 56, D-40239 Düsseldorf, Germany
IMF(1)	Internal Manufacturing Facility	Koolcare Technology Co., Ltd	Wenlv Healthcare Park, No. 18, Zhenbei Road, Xinyi city, 221400 Jiangsu, P.R. China
EMF(1)	External Manufacturing Facility		
IR&D(1)	Internal Research & Development	Koolcare Technology Co., Ltd	Wenlv Healthcare Park, No. 18, Zhenbei Road, Xinyi city, 221400 Jiangsu, P.R. China
ER&D(1)	External Research & Development		
S_RAD(1)	Sterilization facility Radiation - Please select method		
S_GAS(1)	Sterilization facility Gas - Please select method		
S_HEAT(1)	Sterilization facility Heat - Please select method		
S_OTH(1)	Sterilization facility Other - Please specify		

Please add lines as required!

Note: To add line, please select and copy entire corresponding row, insert copied row and adapt the numbers in brackets (e.g. S_RAD (1), S_RAD (2),...

Product List and Application MDR
QM part

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PRODUCTS:

Note: Please provide an information for all columns (also the blue columns which will not be printed).

No.	Product name or Trade Name (as listed on label)	Type of device using terminology of Basic-UDI-DI, EMDN or GMDN	Basic UDI-DI code	Medical Device Category (for all medical devices)	European Medical Device Nomenclature (EMDN): Please use EMDN code 4th level (EMDN code on level 4; Letter + 6-digits; if no level 4 exists, use next upper level)	Classification of product and classification rule resulting in highest risk class		Summary list of related facilities (use facility codes from Facilities table, i.e IMF(1), IR&D(1))	Code of EU-REP (use facility No from Facilities table)	Technical documentation identifier
						Device Class	Classification Rule including subclause according to Annex VIII			
1	Instant cold pack	PHYSIOTHERAPY EQUIPMENT	697442359ICBS3	MDA 0318 Other active non-implantable devices	Z120602	IIa	Rule 9 indent 1	IMF(1), IR&D(1)	EAR(1)	KK-CE-01
2	Heat wrap (12 hours model)	PHYSIOTHERAPY EQUIPMENT	697442359IWN45P6	MDA 0318 Other active non-implantable devices	Z120602	IIa	Rule 9 indent 1	IMF(1), IR&D(1)	EAR(1)	KK-CE-02
3	Heat wrap (8 hours model)	PHYSIOTHERAPY EQUIPMENT	697442359IWN08NY	MDA 0318 Other active non-implantable devices	Z120602	IIa	Rule 9 indent 1	IMF(1), IR&D(1)	EAR(1)	KK-CE-02

Please add or delete lines as required!

Product List and Application MDR QM part	TÜVRheinland®

Xinyi	2024.03.18	GAO WENXIN
Location	Date	Legally binding signature

The Notified Body TÜV Rheinland LGA Products GmbH confirms that the infomation provided on the Product List and Application is covered by the EU conformity assessment procedure as certified by MDR (EU) certificate No: HZ 2159986-1

	Wenxiang Zhang 2024.03.28 13:38:49 +08'00'
Date	Signature (certifier of the Notified Body)

Hardcopy Original
TÜVR Beijing
Linda Yan 2024.03.22