EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Certificate Number:
28620156612

Revision:
00

Initial Certification Date:
13 September 2023

Certificate Decision Date:
13 September 2023

Certificate Issue Date:
13 September 2023

Certificate Expiry Date:
20 November 2027

Shenzhen Kentro Medical Electronics CO., LTD.

2nd Floor, No. 11, Shanzhuang Road, Xikeng Village, Yuanshan Street, Longgang District, Shenzhen City, Guangdong Province, China

Manufacturer SRN: CN-MF-000011247

Authorised Representative Name

Wellkang Ltd

Enterprise Hub, NW Business Complex, BT48 8SE Derry, United Kingdom (Northern Ireland only)

Scope:

Electrical nerve and muscle stimulators

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**TD00239-01 Shenzhen Kentro Medical Electronics CO., LTD. Neck Electronic Muscle Stimulator**
Audit Report Reference	**Stage 1 audit ACTY-2023-625020**
	Stage 2 audit ACTY-2023-625021

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620156612

Revision:
00

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MDR – Decision Report

Certificate No: 28620156612
Date: 13 September 2023
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

Shenzhen Kentro Medical Electronics CO., LTD.
Attn: Mr. Zhang
2nd Floor, No. 11, Shanzhuang Road, Xikeng Village, Yuanshan Street, Longgang District,
Shenzhen City, Guangdong Province,
China

Purpose

Assessment to issue a new certificate according to the Medical Device Regulation 2017/745, Annex IX.
Expiry date on MDR certificate is set to be aligned with client´s audit cycle for ISO 13485:2016 certificate.

Activity

Audit Type	Location	Auditor Name	Audit Date
Stage 1 ACTY-2023-625020	Shenzhen, China	Heidi Cai Hongbo	1 – 3 March 2023
Stage 2 ACTY-2023-625021	Shenzhen, China	Peter Mao Wenwu , Cicy Xiong Qian , Heidi Cai Hongbo	13 – 14 July 2023

Technical Documentation Report	Assessor Name	Assessment Date
draft Kentro Neck Electronic Muscle Stimulator 20230614 TDAR	Cicy Xiong / Sharmila Gardner	14 June 2023
draft Kentro Neck Electronic Muscle Stimulator 20230609 CEAR	Cicy Xiong / Sharmila Gardner	9 June 2023
Kentro Neck Electronic Muscle Stimulator RAI responsed	Cicy Xiong / Sharmila Gardner	9 June 2023

Scope of assessment

Electrical nerve and muscle stimulators, Class IIa

Result

2 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.

All non-conformities noted during the technical documentation assessment(s) have been closed.

Certificate Valid from

13 September 2023

Conclusions/Decisions

Referring to the above, a Certificate of Conformance with the Medical Device Regulation 2017/745, Annex IX will be issued. The Certificate is valid for products specified in the “MDR – Product List”.

Follow-up assessments

Follow-up assessments are going to be performed once per year.

Appeals

Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Medical Notified Body AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Others

Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Medical Notified Body has the right to review this documentation.

Intertek Medical Notified Body AB
Notified Body MDR

Brian Mather
Certification Authority (TD Assessment)

Mikael Hagline
Certification Authority (Audit)

PRODUCT LIST FOR CERTIFICATE

Issued to: Shenzhen Kentro Medical Electronics CO., LTD.

Certificate number: 28620156612

Certificate valid from: 2023-09-13

Product List Issue Date:
13 September 2023

Product	Classification and EMDN	Intended use[1]	Date Added
Electrical nerve and muscle stimulators			
Basic UDI-DI: 69246077022497B			
KTR-101 - Neck Electronic Muscle Stimulator	Class IIa Z12062801		2023-09-13
KTR-102 - Neck Electronic Muscle Stimulator	Class IIa Z12062801		2023-09-13
KTR-103 - Neck Electronic Muscle Stimulator	Class IIa Z12062801		2023-09-13
KTR-105 - Neck Electronic Muscle Stimulator	Class IIa Z12062801		2023-09-13
KTR-106 - Neck Electronic Muscle Stimulator	Class IIa Z12062801		2023-09-13
KTR-107 - Neck Electronic Muscle Stimulator	Class IIa Z12062801		2023-09-13
KTR-201 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-202 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-203 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-206 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-208 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-209 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-210 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-211 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2210 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2211 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2212 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
KTR-2220 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2221 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2222 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2230 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2231 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2232 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2240 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2241 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2242 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2250 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2251 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2252 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2301 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2302 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-230 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-233 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2341 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2342 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-234 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2401 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2402 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2411 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2412 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2491 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620156612
Product list issue date: 13 September 2023

Product	Classification and EMDN	Intended use[1]	Date Added
KTR-2492 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2493 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2494 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2610 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2611 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2612 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2640 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2641 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2642 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2650 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2651 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-2652 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-301 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-302 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-303 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-4012 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-4015 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-401 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-4021 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-4026 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-4027 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-4029 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-402 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-4031 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620156612
Product list issue date: 13 September 2023

Product	Classification and EMDN	Intended use[1]	Date Added
KTR-4032 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-4034 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-4036 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-4037 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-4039 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-403 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-405 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-4061 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-4063 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-406 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13
KTR-407 - Transcutaneous Electrical Nerve Stimulator	Class IIa Z12062801		2023-09-13

Brian Mather
Certification Authority, MDR
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Box 1103, SE-164 22 Kista, Sweden

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620156612
Product list issue date: 13 September 2023

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Name and address of the manufacturer:	Shenzhen Kentro Medical Electronics CO.,LTD. 2nd Floor, No. 11, Shanzhuang Road, Xikeng Village, Yuanshan Street, Longgang District, Shenzhen City, Guangdong Province, China
SRN:	CN-MF-000011247
Name and address European Representative:	WellKang Ltd (www.CE-marking.eu) Enterprise Hub, NW Business Complex,1 Beraghmore Road,Derry,BT48 8SE, Northern Ireland
SRN:	XI-AR-000001836
Product name:	Transcutaneous Electrical Nerve Stimulators
Product type:	KTR-2230、KTR-2220、KTR-2210、KTR-2231、KTR-2221、KTR-2211、KTR-2232、KTR-2222, KTR-2212KTR-2240, KTR-2250, KTR-2241, KTR-2251, KTR-2242, KTR-2252, KTR-2610, KTR-2640, KTR-2650, KTR-2611, KTR-2641, KTR-2651, KTR-2612, KTR-2642, KTR-2652、KTR-201、KTR-202、KTR-203、KTR-206、KTR-210、KTR-211、KTR-230、KTR-208、KTR-209
Intended use:	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, back, arm, knee and leg, due to strain from exercise or normal household and work activities, and promote local blood circulation.
Basic UDI-DI:	69246077022497B
EMDN Code:	Z12062801
Classification acc. to MDR Ax. VIII:	Class IIa, rule 9
Applied Standard:	EN ISO14971, EN1041, EN 60601-1, IEC 60601-1-6, EN 60601-1-2, IEC 62304, EN 62366-1, IEC 60601-1-11, MEDDEV 2.7.1, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, Directive 2011/65/EU,Rohs 2.0
Conformity assessment procedure:	Annex IX of the Regulation (EU) 2017/745
CE certificate no.:	/
Issue date:	/
Valid until:	/
Name, address and ID of the Notified Body:	Intertek Medical Notified Body AB Torshamnsgatan 43, Box 1103 SE -164 22 Kista Sweden CE 2862

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Shenzhen, 2024-07-17

Place, date

Zhang Jewu General Manager

Name and function