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EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Shenzhen Kentro Medical Electronics Co., Ltd

Main Site: No. 11, Shanzhuang Road, Xikeng Village, Yuanshan Street, Longgang District, Shenzhen City, Guangdon Province, China

Product Category:

- Transcutaneous electrical nerve and muscle stimulators

For further identification of the products covered, see the MDD product list/product schedule.

*Previously certified by Intertek AMTAC (NB0473) to date 26 January 2018

Certificate Number:
41371473-03

Initial Certification Date:
26 January 2018*

Certificate Valid from:
3 November 2020

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Peter Nermander
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

2 November 2020
Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.

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MDD – Product List

Products included in the certificate no: 41371473-03
Issued to: **SHENZHEN KENTRO MEDICAL ELECTRONICS CO., LTD.**
2nd Floor, No. 11, Shanzhuang Road, Xikeng Village, Yuanshan Street, Longgang District, Shenzhen City, Guangdon Province, China

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Transcutaneous electrical nerve and muscle stimulators					
	Neck Electronic Muscle Stimulator KTR-101	IIa	No	32554	Jan 26, 2018
	Neck Electronic Muscle Stimulator KTR-102	IIa	No	32554	Jan 26, 2018
	Neck Electronic Muscle Stimulator KTR-103	IIa	No	32554	Jan 26, 2018
	Neck Electronic Muscle Stimulator KTR-105	IIa	No	32554	Jan 26, 2018
	Neck Electronic Muscle Stimulator KTR-106	IIa	No	32554	Jan 26, 2018
	Neck Electronic Muscle Stimulator KTR-107	IIa	No	32554	Jan 26, 2018
	Transcutaneous Electrical Nerve and Muscle Stimulators KTR-2230	IIa	No		Jun 04, 2019
	Transcutaneous Electrical Nerve and Muscle Stimulators KTR-2220	IIa	No		Jun 04, 2019
	Transcutaneous Electrical Nerve and Muscle Stimulators KTR-2210	IIa	No		Jun 04, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-301	IIa	No		Mar 19, 2018
	Transcutaneous Electrical Nerve Stimulators KTR-302	IIa	No		Mar 19, 2018
	Transcutaneous Electrical Nerve Stimulators KTR-303	IIa	No		Mar 19, 2018
	Transcutaneous Electrical Nerve Stimulators KTR-401	IIa	No		Mar 19, 2018
	Transcutaneous Electrical Nerve Stimulators KTR-402	IIa	No		Mar 19, 2018

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Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Product List

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	Transcutaneous Electrical Nerve Stimulators KTR-403	IIa	No		Mar 19, 2018
	Transcutaneous Electrical Nerve Stimulators KTR-208	IIa	No		Mar 19, 2018
	Transcutaneous Electrical Nerve Stimulators KTR-209	IIa	No		Mar 19, 2018
	Transcutaneous Electrical Nerve Stimulators KTR-233	IIa	No		Mar 19, 2018
	Transcutaneous Electrical Nerve Stimulators KTR-234	IIa	No		Mar 19, 2018
	Transcutaneous Electrical Nerve Stimulators KTR-2231	IIa	No		Jun 04, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2232	IIa	No		Jun 04, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2211	IIa	No		Jun 04, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2212	IIa	No		Jun 04, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2221	IIa	No		Jun 04, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2222	IIa	No		Jun 04, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2240	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2241	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2242	IIa	No		Dec 10, 2019

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Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	Transcutaneous Electrical Nerve Stimulators KTR-2250	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2251	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2252	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2610	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2611	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2612	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2640	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2641	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2642	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2650	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2651	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2652	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2301	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2302	IIa	No		Dec 10, 2019

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MDD – Product List

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	Transcutaneous Electrical Nerve Stimulators KTR-2341	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2342	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2401	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2402	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2411	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2412	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2491	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2492	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2493	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulators KTR-2494	IIa	No		Dec 10, 2019
	Transcutaneous Electrical Nerve Stimulator KTR-201	IIa	No		Nov 22, 2020
	Transcutaneous Electrical Nerve Stimulator KTR-202	IIa	No		Nov 22, 2020
	Transcutaneous Electrical Nerve Stimulator KTR-203	IIa	No		Nov 22, 2020
	Transcutaneous Electrical Nerve Stimulator KTR-206	IIa	No		Nov 22, 2020

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MDD – Product List

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	Transcutaneous Electrical Nerve Stimulator KTR-210	IIa	No		Nov 22, 2020
	Transcutaneous Electrical Nerve Stimulator KTR-211	IIa	No		Nov 22, 2020
	Transcutaneous Electrical Nerve Stimulator KTR-230	IIa	No		Nov 22, 2020

Valid from: 22 November 2020
Signed date: 20 November 2020

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

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MDD – Decision Report

Certificate No: 41371473-03
Date: 2 November 2020
Handled by: Nina Fazil
E-mail: medtechsweden@intertek.com

SHENZHEN KENTRO MEDICAL ELECTRONICS CO.,LTD.
Attn: Mr. Zhang
No. 11, Shanzhuang Road, Xikeng Village
Yuanshan Street, Longgang District
Shenzhen City, Guangdon Province
China

Purpose	Assessment to issue a new certificate due to five year extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Activity	Certification audit was performed 14 September 2020 in Shenzhen City by Cicy Xiong Qian.The technical file was reviewed by Brian Mather at Intertek's office and completed on 21 October 2020.
Scope of assessment	Transcutaneous electrical nerve and muscle simulators, Class IIa
Result	1 minor non conformity was noted during the audit. From the TD assessment 1 minor non-conformity is pending follow-up of implemented corrective action, thus this does not prevent renewal.
Certificate Valid from	3 November 2020
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko 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 Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD