

# 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:**

## EXONEURAL NETWORK AB

Main Site: Svärdvägen 11D, 182 33 Danderyd, Sweden

**Product Category:**

- Transcutaneous electric nerve and muscle stimulators

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

**Certificate Number:**

41319152-02

**Initial Certification Date:**

14 December 2012

**Certificate Valid from:**

7 October 2020

**Certificate Expiry Date:**

14 December 2022



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

  
**Peter Nermander**

Certification Authority MDD  
Intertek Semko AB, Kista, Sweden

7 October 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.

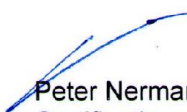


Products included in the Certificate No: 41319152-02  
Issued to: **EXONEURAL NETWORK AB**  
Svärdvägen 11D  
SE-182 33 Danderyd  
SWEDEN

Product category	Type/Model designation	Class	Sterile/ Measuring	GMDN code <small>(not mandatory)</small>	Date added
<b>Transcutaneous electric nerve and muscle stimulators</b>					
	EXOPULSE MOLLII – Control Unit	Ila	No	-	Feb 16, 2017

Date of Issue: 7 October 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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Product List for Certificate No: 41319152-02

Date: 7 October 2020

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