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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:

BTE Technologies, Inc.

Main Site: 7455 L New Ridge Road, Hanover, Maryland 21076, USA

Product Category:

- Active rehabilitation device

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

Certificate Number:
41319556-01

Initial Certification Date:
1 September 2014

Certificate Valid from:
1 September 2019

Certificate Expiry Date:
24 May 2024

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

Bob Andersson
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

16 July 2019
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: 41319556-01
Issued to: **BTE Technologies, Inc.**
7455 L New Ridge Road
Hanover, Maryland 21076
USA

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Active rehabilitation device	Eccentron LE1	IIa	No		June 9, 2016

Signed Date: 16 July 2019
Valid Date: 1 September 2019

Intertek Semko AB
Notified Body MDD

Bob Andersson
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.

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

Intertek Semko AB
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Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Decision Report

Certificate No: 41319556-01
Date: 16 July 2019
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

BTE Technologies, Inc.
Attn: Eric Finegan
7455 L New Ridge Road
Hanover,
Maryland 21076
United States

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 29 November 2019 in Hanover, Maryland by Juan Zamora and Luis Lopes. The technical file was reviewed by Maria Eklycke at Intertek's office.
Scope of assessment	Active rehabilitation device, class IIa
Result	6 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.
Certificate Valid from	1 September 2019
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

Bob Andersson
Certification Authority MDD