EC CERTIFICATION

PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production 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 V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Thought Technology Ltd.

Main Site: 5250 Ferrier, Suite 812, Montreal, QC, H4P 1L3, Canada

Product Category:

- Equipment for biofeedback and for therapy of urinary and faecal incontinence, Class I with measuring function.
- Muscle stimulator with accessories, Class IIa

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

Certificate Number:
41312909-04

Initial Certification Date:
11 February 1999

Certificate Valid from:
28 August 2020

Certificate Expiry Date:
11 February 2024

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

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

28 August 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.

MDD – Product List

Products included in the Certificate No: 41312909-04
Issued to: **Thought Technology Ltd.**
5250 Ferrier, Suite 812,
Montreal, QC, H4P 1L3
Canada

Product category	Type/Model designation	Class	Measuring	GMDN code (not mandatory)	Date added
Biofeedback Equipment					
	Myotrac (SA4001P)	I	Yes		*
	Procomp Infiniti (SA7500)	I	Yes		*
	Procomp5 (SA7525)	I	Yes		*
	Procomp2/Mindmirror (SA7400)	I	Yes		*
	Flexcomp Infiniti (SA7550)	I	Yes		*
	U-Control (SA8800)	I	Yes		*
Muscle stimulator with accessories					
	MyOnyx (SA9020)	IIa	No		2020-08-26
	MyOnyx Mobile App (SA9003)	IIa	No		2020-08-26

* Product added before October 5, 2011.

Signed Date: 28 August 2020

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
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00, Fax +46 8 750 60 30, www.sweden.intertek-etlsemko.com
Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Decision Report

Certificate No: 41312909-04
Date: 28 August 2020
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

Thought Technology Ltd.
Attn:Zena Butris
5250 Ferrier, Suite 812,
Montreal, QC, H4P 1L3
Canada

Purpose	Assessment issue a new certificate due to change of scope. The old scope was - Equipment for biofeedback and for therapy of urinary and faecal incontinence, Class I with measuring function Decision was made according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V.
Scope of assessment	- Equipment for biofeedback and for therapy of urinary and faecal incontinence, Class I(m) - Muscle stimulator with accessories, Class IIa
Result	Two Class IIa products was added and scope needed to be updated.
Certificate Valid from	28 August 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 V 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

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Total Quality. Assured.

MDD – Product Decision

Certificate No: 41312909-03
Date: 26 August 2020
Handled by: Matthew Harris
E-mail: medtechsweden@intertek.com

Thought Technology Ltd. / Technologie de la Pensée Ltée
Attn: Zena Butris
5250 Ferrier, Suite 812,
Montreal, Quebec (Québec), H4P 1L3
Canada

Purpose

Assessment of the notification dated 18 October 2019 for addition of new products to your quality system certified according to LVFS 2003:11, Annex V (Swedish implementation of MDD 93/42/EEC).

Products concerned

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)
Muscle stimulator with accessories	MyOnyx (SA9020)	IIa	No	
Muscle stimulator with accessories	MyOnyx Mobile App (SA9030)	IIa	No	

Conclusions/Decisions

A review of technical documentation has been performed to expand the scope (review report dated 30 June, 2020) The products are considered to fit inside the new scope (Class IIa, MD1103 & MD1111, Muscle stimulator with accessories) and can be added to the Product List.

Application of the CE-mark is permitted when the company's own procedures for CE-marking are fulfilled.

Follow-up assessments

At the next audit your auditor will follow-up on the implementation of the new products in the Quality system.

Appeals

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

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD