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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.

Certificate Number:
41312909-03

Initial Certification Date:
11 February 1999

Certificate Valid from:
12 February 2019

Certificate Expiry Date:
11 February 2024

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

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.

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

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

05 February 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.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request

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MDD – Product List

Products included in the Certificate No: 41312909-03
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		*
Incontinence Equipment	U-Control (SA8800)	I	Yes		*

* Product added before October 5, 2011.

Signed Date: 05 February 2019
Valid Date: 12 February 2019

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

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MDD – Decision Report

Certificate No: 41312909-03
Date: 05 February 2019
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 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 V.
Activity	Certification audit was performed 10 July 2018 in Montreal West by Walid Akoury and Michel Houde.
Scope of assessment	Equipment for biofeedback and for therapy of urinary and faecal incontinence, Class I with measuring function
Result	3 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.
Certificate Valid from	12 February 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 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

Peter Nermander
Certification Authority MDD