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EC CERTIFICATION

PRODUCTION QUALITY ASSURANCE

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

We hereby declare that an examination of the under mentioned product 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 VI of the Directive 93/42/EEC on medical devices. We certify that the product 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:

Vista Medical LtD.

Main Site: Unit 3-55 Henlow Bay, Winnipeg, Manitoba, R3Y 1G4, CanadA

Product Category:

- Class I measuring devices

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

Certificate Number:
41314784-02

Initial Certification Date:
21 September 2004

Certificate Valid from:
22 September 2019

Certificate Expiry Date:
27 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

27 August 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: 41314784-02
Issued to: **Vista Medical Ltd.**
Unit 3 – 55 Henlow Bay
Winnipeg, Manitoba, R3Y 1G4
Canada

Product category	Type/Model designation	Class	Measuring	GMDN code (not mandatory)	Date added
Class I measuring devices					
Pressure Sensing Mat	FT 1005	I	Yes		*
	FT 1015	I	Yes		*
	FT 1020	I	Yes		*
	FT 1030	I	Yes		*
	FT 1035	I	Yes		*
	UT 3010	I	Yes		*
	BT1510	I	Yes		Oct 2, 2012
	BT1526	I	Yes		Oct 2, 2012
	BT3510	I	Yes		Oct 2, 2012
	BT4510	I	Yes		Oct 2, 2012
	BT5010	I	Yes		Oct 2, 2012
	BT5510	I	Yes		Oct 2, 2012
	BT5526	I	Yes		Oct 2, 2012
	BT6510	I	Yes		Oct 2, 2012
	BT6511	I	Yes		Apr 25, 2014
	BT2-xxyy-zzz Where "xx" and "yy" represent the dimensions of the array with numerals ranging from 04 to 64, and "zzz" represents style with numerals ranging from 000 to 999	I	Yes		April 03, 2019
Software	Version 4	I	Yes		*

* Product added before February 12, 2010.

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Telephone +46 8 750 00 00, Fax +46 8 750 60 30, www.intertek.se
Registered in Sweden: No SE556024059901, Registered office: As address

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MDD – Product List

Sign Date: 27 August 2019
Valid Date: 22 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.

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MDD – Decision Report

Certificate No: 41314784-02
Date: 27 August 2019
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

Vista Medical Ltd.
Attn: Ted Duthoit
Unit 3-55 Henlow Bay
Winnipeg, Manitoba, R3Y 1G4
Canada

Purpose	Assessment to issue a new certificate due to change of scope from FSA Pressure Mapping Systems and five year extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II. Scope has been changed due to Client has clarified that they no longer call the system FSA Pressure Mapping System but BodiTrak, however since all devices are Class I measuring they have agreed that the scope can be changed to Class I measuring devices.
Activity	Certification audit was performed 30 April 2019 in Winnipeg by Karen Delaney and Paul Murgatroyd.
Scope of assessment	Product category, Class
Result	10 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.
Certificate Valid from	22 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 VI 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

MDD – Product Decision

Certificate No: 41314784-02
Date: August 27, 2019
Handled by: Carolina Escobar
E-mail: medtechsweden@intertek.com

Vista Medical Ltd.
Att: Ted Duthoit
Unit 3 – 55 Henlow Bay
Winnipeg, Manitoba, R3Y 1G4
Canada

Purpose

Assessment of the notification dated August 20, 2019 to remove products from your certified quality system according to LVFS 2003:11, Annex VI (Swedish implementation of MDD 93/42/EEC).

Products concerned

See following page

Conclusions/Decisions

The products are removed because they are old and obsolete.

The notification has been accepted and the products can be removed

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

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MDD – Product Decision

Certificate No: 41314784-02
Date: August 27, 2019
Handled by: Carolina Escobar
E-mail: medtechsweden@intertek.com

Product category	Type/Model designation	Class	Measuring	GMDN code (not mandatory)
Pressure Sensing Mat	UT 1009	I	Yes	
	UT 1010	I	Yes	
	UT 1021	I	Yes	
	UT 1025	I	Yes	
	UT 1026	I	Yes	
	UT 1027	I	Yes	
	UT 3010	I	Yes	
	UT 3020	I	Yes	
	UT 4010	I	Yes	
	UT 5010	I	Yes	
	UT 5010S	I	Yes	
	UT 6010	I	Yes	
	CP 1000	I	Yes	
	ST1500	I	Yes	
	ST1526	I	Yes	
	ST3510	I	Yes	
FSA Interface Module	Type 4	I	Yes	
	Type 5 Interface Module	I	Yes	
	Type 5E Interface Module	I	Yes	