

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



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.



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 <small>(not mandatory)</small>	Date added
Class I measuring devices					
Pressure Sensing Mat	FT 1005	I(m)	Yes		*
	FT 1015	I(m)	Yes		*
	FT 1020	I(m)	Yes		*
	FT 1030	I(m)	Yes		*
	FT 1035	I(m)	Yes		*
	UT 3010	I(m)	Yes		*
	BT1510	I(m)	Yes		Oct 2, 2012
	BT1526	I(m)	Yes		Oct 2, 2012
	BT3510	I(m)	Yes		Oct 2, 2012
	BT4510	I(m)	Yes		Oct 2, 2012
	BT5010	I(m)	Yes		Oct 2, 2012
	BT5510	I(m)	Yes		Oct 2, 2012
	BT5526	I(m)	Yes		Oct 2, 2012
	BT6510	I(m)	Yes		Oct 2, 2012
	BT6511	I(m)	Yes		Apr 25, 2014
	BT2-xxyy-zzz	I(m)	Yes		April 03, 2019
	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				

* Product added before February 12, 2010.

Date of issue: 02 November 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.
Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on medical devices, with identification number 0413.

Product List for Certificate No: 41314784-02

Date: 02 November 2020

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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.intertek.se

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