

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:

Medviso AB

Main Site: Griffelvägen 3, SE-224 67 Lund, Sweden

Product Category:

- Software for medical image analysis, class IIa

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

Certificate Number:

41319383-02

Initial Certification Date:

7 March 2014

Certificate Valid from:

7 March 2019

Certificate Expiry Date:

6 March 2024



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

07 March 2019

Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
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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: 41319383-01
 Issued to: **Medviso AB**
 Griffelvägen 3
 224 67 Lund
 Sweden

Product category	Type/Model designation	Class	Sterile/ Measuring	GMDN code <small>(not mandatory)</small>	Date added
Software for Medical image analysis	Segment CMR (Cardiovascular image analysis software)	Ila	-	-	2014-03-07
	Segment CT (Cardiovascular image analysis software)	Ila	-	-	2015-03-20
	Segment 3DPrint	Ila	-	-	2018-10-09

Date of Issue: October 16, 2018

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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