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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.

Certificate Number:
41319383-02

Initial Certification Date:
7 March 2014

Certificate Valid from:
7 March 2019

Certificate Expiry Date:
6 March 2024

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

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.

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
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: 41319383-01
Issued to: **Medviso AB**
Griffelvägen 3
224 67 Lund
Sweden

Product category	Type/Model designation	Class	Sterile/ Measuring	GMDN code (not mandatory)	Date added
Software for Medical image analysis	Segment CMR (Cardiovascular image analysis software)	IIa	-	-	2014-03-07
	Segment CT (Cardiovascular image analysis software)	IIa	-	-	2015-03-20
	Segment 3DPrint	IIa	-	-	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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Intertek Semko AB
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Registered in Sweden: No SE556024059901, Registered office: As address

MDD – Decision Report

Certificate No: 41319383-02
Date: 7 March 2019
Handled by: Nina Fazil
E-mail: medtechsweden@intertek.com

Medviso AB
Attn: Helen Fransson
Griffelvägen 3, SE-224 67 Lund
Sweden

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 II.
Activity	Certification/Five year assessment audit was performed 17 December 2018 in Lund by Gabriel Johansson. The technical file was reviewed by Göran Pilenkvik and Lian Zhan at Intertek's office.
Scope of assessment	Software for medical image analysis, class IIa
Result	1 minor non conformitiy was noted during the audit. Presented corrective action plans have been examined and approved by us. 13 minor non-conformities were identified by the review of technical file, all non-conformities have been closed.
Certificate Valid from	7 March 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 II will be extended. 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
Certificate Authority