

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:

SyntheticMR AB

Main Site: Storgatan 11, SE-582 23 Linköping, Sweden

Product Category:

- Magnet resonance imaging post processing software

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

Certificate Number:

41317029-03

Initial Certification Date:

18 June 2009

Certificate Valid from:

19 June 2019

Certificate Expiry Date:

27 May 2024




Peter Nermander

Certification Authority MDD
Intertek Semko AB, Kista, Sweden

10 June 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: 41317029-03
Issued to: **SyntheticMR AB**
Storgatan 11
SE-582 23 Linköping
Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Magnet resonance imaging post processing software	SyMRI™ 7.2 Plug-In	Ila	No		Dec 19, 2014
	SyMRI™ 7.2 StandAlone	Ila	No		Dec 15, 2014
	SyMRI 7.3 StandAlone	Ila	No		Nov 6, 2015
	SyMRI 7.3 Plug-In	Ila	No		Nov 6, 2015
	SyMRI 8	Ila	No		Aug 12, 2016
	SyMRI 11	Ila	No		May 21, 2018

Issue date: 10 June 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.

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: 41317029-03

Date: 10 June 2019

Page 1 of 1