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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.

Organization:

RaySearch Laboratories AB (publ)

Main Site: Sveavägen 44, SE-111 34 Stockholm, Sweden

Product Category:

- Software for analysis and planning of radiation therapy and chemotherapy

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

Certificate Number:
41314834-04

Initial Certification Date:
17 November 2008

Certificate Valid from:
20 December 2019

Certificate Expiry Date:
17 September 2023

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

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

20 December 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: 41314834-04
Issued to: RaySearch Laboratories AB (publ)
Sveavägen 44
SE-111 34 Stockholm
Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Software for analysis and planning of radiation therapy and chemotherapy					
	RayStation 4.7	IIb	No	40887	*
	RayStation 4.9	IIb	No	40887	June 17, 2016
	RayStation 5.0	IIb	No	40887	Nov 27, 2015
	RayStation 6.0	IIb	No	40887	Nov 18, 2016
	RayStation 6.1	IIb	No	40887	Mar 29, 2017
	RayStation 6.2	IIb	No	40887	June 30, 2017
	RayStation 6.3	IIb	No	40887	Oct 29, 2019
	RayStation 7.0	IIb	No	40887	June 30, 2017
	RayStation 8.0	IIb	No	40887	Feb 15, 2018
	RayStation 8.1	IIb	No	40887	Nov 21, 2018
	RayStation 9.0	IIb	No	40887	May 09, 2019
	RayStation 9.1	IIb	No	40887	Dec 20, 2019
	RayStation 9.2	IIb	No	40887	Dec 20, 2019
	RayStation 10.0	IIb	No	40887	Dec 20, 2019
	RayCare 2.3	IIb	No	44087	Feb12, 2019
	RayCare 3.0	IIb	No	44087	June 18, 2019
	RayCare 3.1	IIb	No	40887	Dec 20, 2019
	RayCare 4.0	IIb	No	40887	Dec 20, 2019
	RayCare 4.1	IIb	No	40887	Dec 20, 2019

* Product added before November 27, 2015.

Date of Issue: December 20, 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.

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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

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MDD – Decision Report

Certificate No: 41314834-04
Date: 20 December 2019
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

RaySearch Laboratories AB (publ)
Attn: David Hedfors
Box 3297
103 65 Stockholm

Purpose	Assessment to issue a new EC Certificate due to change of scope. The old scope was *Software for analysis and planning of radiation therapy*. Decision was made according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Scope of assessment	Software for analysis and planning of radiation therapy and chemotherapy, Class IIb
Result	Planning of *Chemotherapy* have been added to the products (refer to separate Product Decision), and the scope can be updated
Certificate Valid from	20 December 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 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

Peter Nermander
Certification Authority MDD