

# EC Certificate

## FULL QUALITY ASSURANCE SYSTEM

### Directive 93/42/EEC on Medical Devices, Annex II

**Certificate Number**  
41314834-02

**Initial Certification Date**  
November 17, 2008

**Certificate Valid from**  
July 17, 2017

**Certificate Expiry Date**  
September 17, 2018

*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.*

*Intertek Semko AB  
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Sweden  
Telephone +46 8 750 00 00  
medtechsweden@intertek.com*

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)

Sveavägen 44, SE-111 34 Stockholm, Sweden

#### Product Category:

- Software for analysis and planning of radiation therapy

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

July 17, 2017

Signed date



Bob Andersson, Certification Authority MDD  
Intertek Semko AB, Kista, Sweden

Products included in the Certificate No: 41314834-02  
 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
<b>Software for analysis and planning of radiation therapy</b>					
	RayStation 4.0	IIb	No	40996	*
	RayStation 4.3	IIb	No	40996	*
	RayStation 4.5	IIb	No	40996	*
	RayStation 4.7	IIb	No	40996	*
	RayStation 4.9	IIb	No	40996	June 17, 2016
	RayStation 5.0	IIb	No	40996	Nov 27, 2015
	RayStation 6.0	IIb	No	40996	Nov 18, 2016
	RayStation 6.1	IIb	No	40996	Mar 29, 2017
	RayStation 6.2	IIb	No	40996	June 30, 2017
	RayStation 7.0	IIb	No	40996	June 30, 2017

\* Product added before November 27, 2015.

Valid from: July 17, 2017

Sign Date: July 17, 2017

**Intertek Semko AB**  
 Notified Body MDD



Bob Andersson  
 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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