EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

EU Regulation 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation has been carried out following the requirements of EU Regulation 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Certificate Number:
28620117938-01

Initial Certification Date:
28 September 2021

Certificate Issue Date:
24 November 2021

Certificate Expiry Date:
27 September 2026

RaySearch Laboratories AB (publ)

Eugeniavägen 18 SE-113 68 Stockholm Sweden

Manufacturer SRN: SE-MF-000001908

Scope:

- Software for analysis and planning for radiation therapy and chemotherapy

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached Product List

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**None**
Audit Report Reference	**Special Visit On-Site - ACTY-2021-507909**

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

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CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620117938	2021-09-28	Change of Address

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MDR – Decision Report

Certificate No: 28620117938-01
Date: 24 November 2021
Handled by: Carmina Luz Pecson
E-mail: IMNB@intertek.com

RaySearch Laboratories AB (publ)
Attn: David Hedfors
Eugeniavägen 18 ,
Stockholm, SE-113 68 ,
Sweden (Sverige)

Purpose

Assessment to issue a new certificate due to address change from Sveavägen 44, 111 34 Stockholm.
Decision made according to the Medical Device Regulation 2017/745, Annex IX.

Activity

Audit Type	Location	Auditor Name	Audit Date
Special Visit	Stockholm	Gabriel Johansson	10 Nov 2021

Scope of assessment

Software for analysis and planning for radiation therapy and chemotherapy
Class IIb

Result

The address change has been accepted. Revised MDR Certificate and Product List will be issued to reflect the address change.

Certificate Valid from

24 November 2021

Conclusions/Decision

Referring to the above a Certificate of Conformance with the Device Regulation 2017/745, Annex IX will be issued. The Certificate is valid for products specified in the “MDR – Product List”.

Follow-up

Follow-up assessments are going to be performed once per year.

Appeals

Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Medical Notified Body AB, PO-Box 1103, SE-164 22 Kista, Sweden (imnb@intertek.com).

Others

Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Medical Notified Body has the right to review this documentation.

Intertek Medical Notified Body AB
Notified Body MDR

Brian Mather
Certification Authority

PRODUCT LIST FOR CERTIFICATE

Issued to: RaySearch Laboratories AB

Certificate number: 28620117938-01

Certificate valid from: 2021-11-24

Product List Issue Date:
24 November 2021

Product	Classification and EMDN	Intended use[1]	Date Added
Software for analysis and planning of radiation therapy and chemotherapy			
Basic UDI-DI: 73500020101H8			
RayStation 12.0 - RayStation 11B	Class IIb Z11019082	RayStation is a software system for radiation therapy and medical oncology. Based on user input, RayStation proposes treatment plans. After a proposed treatment plan is reviewed and approved by authorized intended users, RayStation may also be used to administer treatments. The system functionality can be configured based on user needs.	2021-11-09
RayStation 10.1 - RayStation 10B	Class IIb Z11019082	RayStation is a software system for radiation therapy and medical oncology. Based on user input, RayStation proposes treatment plans. After a proposed treatment plan is reviewed and approved by authorized intended users, RayStation may also be used to administer treatments. The system functionality can be configured based on user needs.	2021-09-28
Basic UDI-DI: 73500020102HA			
RayCare 5.1 - RayCare 5B	Class IIb Z11019082	RayCare is an oncology information system used to support workflows and scheduling, as well as clinical information, planning and treatment management for oncology care. RayCare may be used in the transfer, storage, conversion and display of patient data in all areas of cancer care including radiation therapy, medical oncology and surgical oncology. RayCare is not intended for use in diagnostic activities.	2021-11-09
RayCare 4.0 - RayCare 4A	Class IIb Z11019082	RayCare is an oncology information system used to support workflows and scheduling, as well as clinical information, planning and treatment management for oncology care. RayCare may be used in the transfer, storage, conversion and display of patient data in all areas of cancer care including radiation therapy, medical oncology and surgical oncology. RayCare is not intended for use in diagnostic activities.	2021-09-28
RayCare 4.1 - RayCare 4B	Class IIb Z11019082	RayCare is an oncology information system used to support workflows and scheduling, as well as clinical information, planning and treatment management for oncology care. RayCare may be used in the transfer, storage, conversion and display of patient data in all areas of cancer care including radiation therapy, medical oncology and surgical oncology. RayCare is not intended for use in diagnostic activities.	2021-09-28

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added

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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620117938-01
Product list issue date: 24 November 2021