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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.

RaySearch Laboratories AB (publ)

Eugeniavägen 18 C, SE-113 68 Stockholm, Sweden

Manufacturer SRN: SE-MF-000001908

Scope:

- Software for analysis and planning for radiation therapy and chemotherapy

Certificate Number:
28620117938-02

Initial Certification Date:
28 September 2021

Date of Certification Decision:
5 September 2022

Certificate Issue Date:
5 September 2022

Certificate Expiry Date:
27 September 2026

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	None

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None.

Certificate Number:

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accordance with the requirements set out in EU Regulation
2017/745 on medical devices, with the identification number
2862.

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620117938	2021-09-28	Change of Address
28620117938-01	2021-11-24	Administrative changes on address

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PRODUCT LIST FOR CERTIFICATE

Issued to:	RaySearch Laboratories AB	
Certificate number:	28620117938-02	**Product List Issue Date:** 31 May 2023
Certificate valid from:	2022-09-05	

Product	Classification and EMDN	Intended use[1]	Date Added
Software for analysis and planning of radiation therapy and chemotherapy			
Basic UDI-DI: 73500020101H8			
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
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 12.1 - RayStation 11B SP1	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.	2023-03-06
RayStation 12.3 - RayStation 11B SPT1	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.	2023-03-06
RayStation 13.0 - RayStation 12A	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.	2022-05-24
RayStation 13.1 - RayStation 12A SP1	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.	2022-09-27
RayStation 14.0 - RayStation 2023B	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.	2023-05-31
Basic UDI-DI: 73500020102HA			

[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
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
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 6.0 - RayCare 6A	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	2022-05-24

Mikael Hagelin

Certification Authority, MDR

Intertek Medical Notified Body AB, Torshamnsgatan 43,

Box 1103, SE-164 22 Kista, Sweden

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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: 28620117938-02

Product list issue date: 31 May 2023