

RAYCARE 3B

IHE-RO Integration Statement

Declaration of conformity



Complies with 93/42/EEC Medical Device Directive as amended by M1 to M5. A copy of the corresponding Declaration of Conformity is available on request.

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INTEGRATION STATEMENT

1.1 INTRODUCTION

This IHE Integration Statement is prepared and published to describe the conformance of RayCare with the IHE-RO Technical Framework. It identifies specific IHE-RO capabilities that are supported in terms of actors and integration profiles described in the technical frameworks of each domain.

Users familiar with these concepts can use Integration Statements to determine the integration of RayCare with complementary systems and what clinical and operational benefits such integration might provide. This Integration Statements is intended to be used in conjunction with the RayCare DICOM Conformance Statements.

1.2 PRODUCT VERSION

This Integration Statement is valid for RayCare 3B.

1.3 ABOUT THE TESTING PROCESS

IHE provides a process for vendors to test their implementations of IHE actors and integration profiles. The IHE testing process, culminating in a multi-party interactive testing event called the Connect-a-thon, provides vendors with valuable feedback and provides a baseline indication of the conformance of their implementations. The process is not intended to independently evaluate, or ensure, product compliance. In publishing the results of the Connect-a-thon and facilitating access to vendors' IHE Integration Statements, IHE and its sponsoring organizations are in no way attesting to the accuracy or validity of any vendor's IHE Integration Statements or any other claims by vendors regarding their products.

RaySearch Laboratories has done further validation beyond the IHE-RO Connect-a-thon to ensure that RayCare conforms to applicable standards. This Integration Statement shall not be used a guarantee that RayCare will work in any environment or with any external system.

1.4 REFERENCES

Reference	Resource
DICOM	https://www.dicomstandard.org/
IHE	https://www.ihe.net/
IHE-RO	https://www.ihe.net/ihe_domains/radiation_oncology/

1.5 DEFINITIONS

Term	Meaning
CE	CE marking is a certification mark that indicates conformity with health, safety, and environmental protection standards for products sold within the European Economic Area (EEA)
DICOM	Digital Imaging and Communications in Medicine
EEC	European Economic Community
IHE	Integrating the Healthcare Enterprise
IHE-RO	Integrating the Healthcare Enterprise Radiation Oncology
BRT0-II	Basic RT Object Interoperability-II (IHE-RO Profile)
MMRO-III	Multi-Modality Registration in Radiation Oncology-III (IHE-RO Profile)

TPPC	Treatment Planning – Plan Content (IHE-RO Profile)
TDW-II	Treatment Delivery Workflow-II (IHE-RO Profile)

1.6 INTEGRATION STATEMENT

IHE-Integration Statement	Date	27 September 2021
Vendor	Product Name	Version
RaySearch Laboratories	RayCare	3B
This product implements all transactions required in the IHE Technical Framework to support the IHE Integration Profiles, Actors and Options listed below:		
Integration Profiles Implemented	Actors Implemented	Options Implemented
BRT0-II	Archive	-
MMRO-III	Archive	–
TDW-II	Treatment Management System	Retain Original Treatment Records
	Object Storage	Retain Original Treatment Records
Links to Standards Conformance Statements for the Implementation		
DICOM IHE	https://www.raysearchlabs.com/product-configurations/	
Links to general information on IHE		
In North America: www.ihe.net	In Europe: www.ihe-europe.org	In Japan: www.jira-net.or.jp/ihe-j



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