RAYCARE 3B

IHE-RO Integration Statement
Declaration of conformity

CE 0413

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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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

<table>
<thead>
<tr>
<th>Reference</th>
<th>Resource</th>
</tr>
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<tbody>
<tr>
<td>DICOM</td>
<td><a href="https://www.dicomstandard.org/">https://www.dicomstandard.org/</a></td>
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<tr>
<td>IHE</td>
<td><a href="https://www.ihe.net/">https://www.ihe.net/</a></td>
</tr>
<tr>
<td>IHE-RO</td>
<td><a href="https://www.ihe.net/ihe_domains/radiation">https://www.ihe.net/ihe_domains/radiation</a>_ oncology/</td>
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1.5 DEFINITIONS

<table>
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<th>Term</th>
<th>Meaning</th>
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<tbody>
<tr>
<td>CE</td>
<td>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)</td>
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<tr>
<td>DICOM</td>
<td>Digital Imaging and Communications in Medicine</td>
</tr>
<tr>
<td>EEC</td>
<td>European Economic Community</td>
</tr>
<tr>
<td>IHE</td>
<td>Integrating the Healthcare Enterprise</td>
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<tr>
<td>IHE-RO</td>
<td>Integrating the Healthcare Enterprise Radiation Oncology</td>
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<tr>
<td>BRTO-II</td>
<td>Basic RT Object Interoperability-II (IHE-RO Profile)</td>
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<tr>
<td>MMRO-III</td>
<td>Multi-Modality Registration in Radiation Oncology-III (IHE-RO Profile)</td>
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# 1.6 INTEGRATION STATEMENT

<table>
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<tr>
<th>Integration Profiles Implemented</th>
<th>Actors Implemented</th>
<th>Options Implemented</th>
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<tr>
<td>MMRD-III</td>
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<td>Retain Original Treatment Records</td>
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<td></td>
<td>Object Storage</td>
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**Links to Standards Conformance Statements for the Implementation**

**DICOM**


**IHE**

**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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