

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

RaySearch Laboratories AB (publ)

(F000942)

Main Site: Sveavägen 44, SE-111 34 Stockholm, Sweden

has been registered by Intertek, an MDSAP recognized auditing organization,
as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012; RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act

The management system is applicable to:

Design, development, manufacture, distribution, installation and servicing of medical device software for analysis, planning and follow-up of radiation therapy, medical oncology and surgery

Certificate Number:

0080663-02

Initial Certification Date:

2018-09-06

Date of Certification Decision:

2021-08-12

Certification Effective Date:

2021-09-05

Certification Expiry Date:

2024-09-05



intertek

A handwritten signature in black ink, appearing to read 'Calin Moldoveanu', is written over a horizontal line.

Calin Moldoveanu

President, Business Assurance

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