

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## RaySearch Laboratories AB (publ)

(F000942)

Main Site: Eugeniavägen 18C,  
Stockholm, SE-113 68, 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:** RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

**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:**

0080663-05

**Initial Certification Date:**

2018-09-06

**Date of Certification Decision:**

2024-02-09

**Certification Effective Date:**

2024-02-09

**Certification Expiry Date:**

2024-09-05



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