



CERTIFICATE



This is to certify that the company

iRT Systems GmbH

Schlossstrasse 1
56068 Koblenz
Germany

has implemented and maintains a **Quality Management System**.

Scope of certification:

Design and development, manufacture, distribution, installation and servicing of devices and software for radiation therapy and radiology.

-AUS (a), BRA, CND, USA (a, b, c, d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

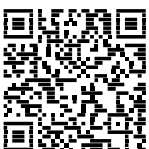
| | |
|------------------------------|----------------|
| Certificate registration no. | 519985 MDSAP16 |
| Certificate unique ID | 1000168498 |
| Effective date | 2024-05-04 |
| Expiry date | 2027-05-03 |
| Frankfurt am Main | 2024-05-04 |



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager



August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, info-med@dqs.de

DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.

Visit <https://www.dqs.de/en/customer-database/> to validate this certificate.

The validity of this certificate can only be verified by the QR-code.



Annex to certificate
Certificate registration No.: 519985 MDSAP16
Certificate unique ID: 1000168498
Effective date: 2024-05-04

iRT Systems GmbH

Schlossstrasse 1
56068 Koblenz
Germany

Audited site

519985
iRT Systems GmbH
Schlossstrasse 1
56068 Koblenz
Germany

REPs FEI No.: site scope and country-specific requirements

Design and development, manufacture,
distribution, installation and servicing of
devices and software for radiation therapy and
radiology.
-AUS (a), BRA, CND, USA (a, b, c, d)
REPs FEI No.: F004966



Annex to certificate
Certificate registration No.: 519985 MDSAP16
Certificate unique ID: 1000168498
Effective date: 2024-05-04

iRT Systems GmbH

Schlossstrasse 1
56068 Koblenz
Germany

Full references of country-specific requirements of MDSAP participating Regulatory Authorities

| Abbreviation | Jurisdiction | Reference |
|---------------------|---------------------|--|
| AUS | Australia | (a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure |
| BRA | Brazil | RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009 |
| CND | Canada | Medical Device Regulations SOR/98-282, Part 1 |
| JPN | Japan | MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable) |
| USA | United States | (a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821 |