CERTIFICATE

This is to certify that the company

iRT Systems GmbH

Schlossstrasse 1
56068 Koblenz
Germany

with the organizational units/sites as listed in the annex

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), 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	170780835
Effective date	2022-07-16
Expiry date	2024-09-20
Frankfurt am Main	2022-07-16

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Marc Goedecke
Product Manager

Annex to certificate
Certificate registration No.: 519985 MDSAP16
Certificate unique ID: 170780835
Effective date: 2022-07-16

iRT Systems GmbH

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56068 Koblenz
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Audited site	REPs FEI No.: site scope and country-specific requirements
519985 **iRT Systems GmbH** Schlossstrasse 1 56068 Koblenz Germany	Design and development, manufacture, distribution, installation and servicing of devices and software for radiation therapy and radiology. -**AUS (a), CND, USA (a, b, c, d)** **REPs FEI No.: F004966**

Annex to certificate
Certificate registration No.: 519985 MDSAP16
Certificate unique ID: 170780835
Effective date: 2022-07-16

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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