EU Quality Management Certificate

This is to certify that the company

iRT Systems GmbH

Schlossstrasse 1
56068 Koblenz
Germany

SRN: DE-MF-000013778

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

For placing of devices of class IIa, IIb or III listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	519985 MDR2017Q
Certificate ID	170782574
Effective date	2023-10-11
Expiry date	2028-10-10
Frankfurt am Main,	2023-10-11

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000013778
Certificate ID: 170782574

Device categories covered by this certificate:

Device category:	**Active non-implantable devices utilising ionizing radiation**
Risk classification:	Class IIb
Intended purpose:	The IQM Integral Quality Monitor is a large-area ionization chamber intended to be used for quality assurance verification measurements and documentation of the treatment delivery accuracy (beam shape, position and dose) from medical linear accelerators used for intensity modulated radiation therapy.

Examinations and tests performed:
519985_A210777MED_01 dated 2023-10-05

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a