

Certificate

Certificate

P000515542CRT02**kiwa**

First issue	30-Jul-2019 by DQS MED	Re-certification	29-Jul-2025
Reissued	22-May-2026	Technical Area	1.2
Valid until	29-Jul-2028		

Quality Management System Certificate

EN-ISO 13485:2016

For the Quality Management System of

MedCom GmbH

Regarding the scope Design & Development, manufacturing and distribution of treatment planning software in the field of radiotherapy, transmission, processing and visualization of medical image data, 3D ultrasound imaging software devices and mobile medical workstation with image and navigation interfaces. Direct sale, distribution and import of associated medical devices.

This certificate is based on the following documents:
24M00300RPT01

Kiwa Assurance B.V. hereby declares that it has audited the quality management system in accordance with EN-ISO 13485:2016 + AC:2018 + A11:2021 and that all requirements of the standard and its implementation are fulfilled.

The certificate validity is three years and includes the surveillance obligations of EN-ISO/IEC 17021-1:2015.

Signed by:

*Joe Petersen*8A265E04DD41483...
Mr. J. Petersen

Certification Decision Maker

Signed by:

*Dennis van der Vlugt*4E831C843C0B4EA...
Ing. D. van der Vlugt
Director

This certificate consists of 2 page(s)
Disclosure of the certificate is permitted



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Appendix of EN-ISO 13485 Certificate



For the certificate P000515542CRT02

Organizational Boundary(ies)

Certified additional locations and/or organizations	Scope
MedCom GmbH X-Ray Test Laboratory Hilpertstraße 31 64295 Darmstadt Germany	Verification and Validation activities

Revision history

Version	Changes
P000515542CRT01	Renewed certificate
P000515542CRT02	Correction of scope

The certificate P000515542CRT02

