

EU Quality Management System Certificate

Certificate no.
3420GB448240326

Final Assessment Report no.
3420AU20F

Effective date
2024-03-26

Expiry date
2028-02-14

This is to certify that the quality system of

IMAGE Information Systems Europe GmbH

Lange Straße 16, 18055 Rostock, Germany

SRN: DE-MF-000004979

For design, production, and final product inspection/testing of
Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX Chapter I and III of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date
Hamburg, 2024-03-26

For the issuing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatuspool 2, 20355 Hamburg, Germany



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-096

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact info@medcert.de

Markus Bianchi
Director Certification Body



Certificate no.: 3420GB448240326
Place and date: Hamburg, 2024-03-26

Sites covered by this certificate

IMAGE Information Systems Europe GmbH, Lange Straße 16, 18055 Rostock, Germany





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Products covered by this certificate

Class IIb medical devices

Category	EMDN code	Medical devices/groups of medical devices
MDA 0315	Z110603	Picture archiving and communication systems

Intended purpose

Picture archiving and communication system (PACS) for the management, retention, routing, analysis and review of medical images stored in proper DICOM format.

