

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

> ***** ***ZLC** * ****

Benannt durch/Designated by

Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten

BS-MDR-096

For the suing office
DNV MEDCERT GmbH – Notified Body 0482
Pilatus pool 2, 20355 Hamburg, Germany

Markus Bianchi Director Certification Body

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



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





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

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

