

Certificate

Certificate No.: MD 3032747 3241988-90

Manufacturer: Visage Imaging GmbH

Lepsiusstraße 70

12163 Berlin

Germany

D-U-N-S No.: 22-141-1577

Certification criteria ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance

Procedure

Canada Medical Devices Regulations - Part 1 - SOR 98/282

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 -

Subparts A to D

Scope: Design and development, manufacture, distribution, installation and

service of Picture Archiving Communications Systems (PACS), Advanced Visualization Software and Thin Client/Server Solutions.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 21235254 008

Issue Date: 2018-08-30

Effective Date: 2018-08-30

Expiry Date: 2021-08-24



Certification officer: Dipl.-Ing. S. Pane TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on www.certipedia.com, via the QR code or calling 1-888-743-4652.