

Certificate



Certificate No.: MD 3350313-90
Manufacturer: **Visage Imaging GmbH**
Lepsiusstraße 70
12163 Berlin
Germany

REPs Facility ID: F001080
Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
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 System (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.: 3350313-150
Issue Date: 2021-08-18
Effective Date: 2021-08-25
Expiry Date: 2024-08-24



A handwritten signature in black ink, appearing to read "S. Pane", positioned above a horizontal line.

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

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/CERTIPEDIA_ID?locale=en
or calling 1-888-743-4652.

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The scope of certification includes the following additional site: :

No.	Location	Scope
/01	Visage Imaging Inc. 12625 High Bluff Drive, Suite 205 San Diego, CA 92130 USA	Distribution, installation and service of Picture Archiving Communications Systems (PACS), Advanced Visualization Software and Thin Client/Server Solutions REPs ID: F005749



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