Certificate

TÜVRheinland®

Certificate No.:	MD 3208197 3232442-90
Manufacturer:	**HICAT GmbH** Brunnenallee 6 53177 Bonn Germany
D-U-N-S No.:	31-254-5378
Certification criteria	ISO 13485:2016 Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009 Canada Medical Devices Regulations – Part 1 – SOR 98/282 Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act (as applicable) United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope:	Design and Development, Manufacture and Distribution of PACS Software

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.:	21234710 008
Issue Date:	2018-09-04
Effective Date:	2018-09-04
Expiry Date:	2021-08-15

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: X. Ren
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.

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
Tel: (925) 249-9123, Fax: (925) 249-9124

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Manufacturer:

HICAT GmbH

Brunnenallee 6

53177 Bonn

Germany

Scope: The scope of Certification also includes the following additional site:

HICAT GmbH

Am Fronhof 10

53177 Bonn, Germany

D-U-N-S No.: NA

Scope: Distribution

Project No.: 21234710 008

Issue Date: 2018-09-04

Effective Date: 2018-09-04

Expiry Date: 2021-08-15

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