



America

CERTIFICATE

No. QS6 019692 0015 Rev. 01

Certificate Holder: NORAS MRI products GmbH
Leibnizstrasse 4
97204 Höchberg
GERMANY

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of MR Compatible Coils, MR Compatible Head Fixations, Patient Rests as well as Fixation and Biopsy Kits for the area of Radiology

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Health Canada, USA FDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: 31-284-4095

Effective Date: 2020-08-22

Expiry Date: 2023-08-21

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Date of Issue: 2020-10-21

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services



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Regulatory Requirements: **Audit/Certification Criteria**

Canada
- Medical Device Regulations – Part 1- SOR 98/282

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies): NORAS MRI products GmbH
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