



America

CERTIFICATE

No. QS6 051199 0013 Rev. 02

Certificate Holder: **SCANCO Medical AG**
 Fabrikweg 2
 8306 Brüttisellen
 SWITZERLAND

Certification Mark:



Scope of Certificate: **Design and Development, Manufacturing and Distribution of Computed Tomography System for the In Vivo Determination of Bone Density and Bone Architecture at Peripheral Sites**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Health Canada, Japan MHLW / PMDA, 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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_051199_0013_Rev_02

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F005643**
Report No.: **713351852**
Effective Date: **2025-06-30**
Expiry Date: **2028-06-29**

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Date of Issue: 2025-04-28

(Renee Walker)
 Director, US Certification Body, MHS



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Regulatory Requirements: **Audit/Certification Criteria**

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

Japan
 - MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
 - Japan PMD Act (as applicable)

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

Facility(ies): **SCANCO Medical AG**
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