



America

CERTIFICATE

No. QS6 117142 0004 Rev. 00

Certificate Holder:

Thales AVS France SAS
75-77 Avenue Marcel Dassault
33700 Mérignac
FRANCE

Certification Mark:



Scope of Certificate:

Design, Manufacturing and Servicing of X-Ray Imaging Detectors, Equipped with the Electronics and Associated Devices, and Medical Imaging Solutions

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

**Australia TGA, Brazil ANVISA, 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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6 117142 0004 Rev. 00

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

REPs Facility ID:

F007143

Report No.:

713305236

Effective Date:

2024-02-20

Expiry Date:

2027-02-19

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Date of Issue: 2024-02-22

(Renee Walker)
Director, US Certification Body, MHS



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Regulatory Requirements: Audit/Certification Criteria

Australia

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

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

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):

Thales AVS France SAS

75-77 Avenue Marcel Dassault, 33700 Mérignac, FRANCE

Thales AVS France SAS

Rue du Pommarin 460, 38430 Moirans, FRANCE

Facility Scopes:

Thales AVS France SAS

75-77 Avenue Marcel Dassault, 33700 Mérignac, FRANCE

Head Office - Management

REPs Facility ID: F007143

Thales AVS France SAS

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Design, Manufacturing and Servicing of X-Ray Imaging Detectors,
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REPs Facility ID: F007151

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