ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

# CERTIFICATE

## No. QS6 074115 0019 Rev. 04

**Certificate Holder:** **Christie Medical Holdings, Inc.**
200 Technology Park, Suites 1040
Lake Mary FL 32746
USA

**Certification Mark:**

**Scope of Certificate:** **Design and Development, Production, Distribution and Service of Vein Imaging Systems**

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

**Regulatory Authority(ies):** **Australia TGA, Brazil ANVISA, 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 074115 0019 Rev. 04
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F002934**
**Report No.:** **721001193**
**Effective Date:** **2025-02-22**
**Expiry Date:** **2028-02-21**


**Date of Issue:** 2024-12-20

( Renee Walker )
Director, US Certification Body, MHS

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# C E R T I F I C A T E

## No. QS6 074115 0019 Rev. 04

**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

**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):** **Christie Medical Holdings, Inc.**
200 Technology Park, Suites 1040, Lake Mary FL 32746, USA

**Facility Scopes:** Design and Development, Production, Distribution and Service of Vein Imaging Systems
REPs Facility ID: F002934


**Date of Issue:** 2024-12-20

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