



America

CERTIFICATE

No. QS6 084922 0007 Rev. 00

Certificate Holder: Copan Wasp S.r.l.
Via A. Grandi 32
25125 BRESCIA
ITALY

Certification Mark:



Scope of Certificate: Design and Development, Manufacture, Installation and Servicing of In-Vitro Diagnostic Analyzers and Software and Design and Development, Manufacture of In-Vitro Reagents, used in the Detection of Transmissible Agents

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. 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.

REPs Facility ID: F005494

Effective Date: 2022-01-07

Expiry Date: 2025-01-06

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Date of Issue: 2022-01-19

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services



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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. 16/2013
 - RDC ANVISA n. 23/2012
 - RDC ANVISA n. 67/2009

Canada

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

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
 - PMD Act

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820
 - 21 CFR Part 821

Facility(ies):

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