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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

America

CERTIFICATE

No. QS6 073936 0011 Rev. 00

Certificate Holder: **Copan Italia S.p.a.**
Via F. Perotti, 10
25125 Brescia
ITALY

Certification Mark:

Scope of Certificate: **Design and Development, Manufacturing and Distribution of Medical and In-Vitro Diagnostic Devices for Collection, Preservation and Transport of Biological Specimens including Swabs, Media and Specimen Receptacles**

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 https://www.tuev-sued.de/product-testing/certificates

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

DUNS No: **42-898-1112**

Effective Date: **2019-02-12**

Expiry Date: **2022-02-11**

Date of Issue: 2019-02-25

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
-Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

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

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

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820
- 21 CFR Part 821

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

Facility(ies):

Copan Italia S.p.a.
Via F. Perotti, 10, 25125 Brescia, ITALY

COPAN ITALIA S.p.A.
Via F. Perotti 18, 25125 Brescia (BS), ITALY

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Facility Scopes:

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