





Certificate

No. Q6 073934 0009 Rev. 00

Holder of Certificate: Copan Diagnostics Inc.

26055-26083 Jefferson Avenue

Murrieta CA 92562

USA

Certification Mark:



Manufacture and distribution of non-active non-**Scope of Certificate:**

implantable Medical Devices for clinical sample collection, transport and preservation. Manufacture and distribution of in Vitro diagnostic medical devices and consumables for clinical sample transport and

preservation including media and receptacles.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 073934 0009 Rev. 00

Report No.: ITA200220002753

Valid from: 2024-09-02 Valid until: 2027-09-01

Christoph Dicks 2024-07-30 Date,

Head of Certification/Notified Body



Certificate

No. Q6 073934 0009 Rev. 00

Applied Standard(s): ISO 13485:2016

(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)

Medical devices - Quality management systems -

Requirements for regulatory purposes

Facility(ies): Copan Diagnostics Inc.

26055-26083 Jefferson Avenue, Murrieta CA 92562, USA

Manufacture and distribution of non-active non-implantable Medical Devices for clinical sample collection, transport and preservation. Manufacture and distribution of in Vitro diagnostic medical devices and consumables for clinical sample transport and preservation including media and receptacles.

Copan Diagnostics Inc

2728 Loker Avenue West, Carlsbad CA 92010, USA

Manufacture and distribution of non-active non-implantable Medical Devices for clinical sample collection, transport and preservation. Manufacture and distribution of in Vitro diagnostic medical devices and consumables for clinical sample transport and preservation including media and receptacles.

١