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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 073934 0007 Rev. 00

Manufacturer	**Copan Diagnostics Inc.** 26055-26083 Jefferson Avenue Murrieta CA 92562 USA
EC-Representative:	Copan Flock Technologies S.r.l. Via F. Perotti, 18, 25125 Brescia, ITALY
Product Category(ies):	**Fiber swabs and flocked swabs for the collection of biological specimens**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:	ITA1101958
Valid from:	2018-10-05
Valid until:	2023-09-09

Date, 2018-10-05

I. Preiß

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Facility(ies):

Copan Diagnostics Inc.
26055-26083 Jefferson Avenue, Murrieta CA 92562, USA

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