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

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 073936 0014 Rev. 03

Manufacturer: **Copan Italia S.p.A.**
Via F. Perotti, 10
25125 Brescia
ITALY

Product Category(ies): **Fiber swabs and flocked swabs for the collection of biological specimens with or without transport medium**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: ITA1287929

Valid from: 2020-03-13
Valid until: 2024-05-26

Date, 2020-03-13

Christoph Dicks
Head of Certification/Notified Body

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

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD
A4 / 07.17

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(Devices in Class IIa, IIb or III)

No. G1 073936 0014 Rev. 03

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, ITALY

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

Copan Medical Shanghai
1st Floor, Building A, N°6 plant, N° 258 Zhijiang Road, Feng Xian District,
201415 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Copan Industries Inc.
Carr. 110 KM. 28.6 San Antonio Industrial Park, 00603 Aguadilla,
PUERTO RICO USA

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

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