



Product Service

CERTIFICATE

No. Q1N 16 06 73936 007

Holder of Certificate: Copan Italia S.p.a.

Via F. Perotti, 10
25125 Brescia
ITALY

Certification Mark:



Scope of Certificate: Design and development, manufacturing and distribution of swabs, applicators and media for sample collection and preservation of clinical specimens. Design and development, manufacturing, distribution and servicing of automated equipment for pre-analytical phases of analysis of clinical specimens

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: ITA270189

Valid from: 2016-09-02

Valid until: 2019-09-01



Date, 2016-07-14

Stefan Preiß

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Applied Standard(s): EN ISO 13485:2012 + AC:2012
 Medical devices - Quality management systems -
 Requirements for regulatory purposes
 (ISO 13485:2003 + Cor. 1:2009)
 DIN EN ISO 13485:2012

Facility(ies):

- Copan Italia S.p.a.
Via F. Perotti, 10, 25125 Brescia, ITALY
- Copan Flock Technologies S.r.l.
Via F. Perotti, 18, 25125 Brescia, ITALY
- Copan Diagnostics Inc.
26055 Jefferson Avenue, Murrieta CA 92562, USA
- Copan Wasp S.r.l.
Via F. Perotti, 18, 25125 BRESCIA, ITALY
- NEWLAB ENGINEERING S.r.l.
Via Perotti 16, 25125 BRESCIA BS, ITALY

