ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 15 07 73936 008

Manufacturer:

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

Facility(ies):

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.: ITA262911

Valid from: 2015-09-02
Valid until: 2020-09-01

Date, 2015-07-31

Hans-Heiner Junker

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

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