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

Product Service

EC-CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 09 12 50497 015

Manufacturer:

Abbott Laboratories
Vascular Enterprises Ltd.
Dublin, Beringen Branch
(formerly: Ampthauptstrasse)
Anthoptstrasse
8222 Beringen
SWITZERLAND

Facility(ies):

Abbott Laboratories Vascular Enterprises Ltd. Dublin, Beringen Branch
(formerly: Ampthauptstrasse), Anthoptstrasse, 8222 Beringen, SWITZERLAND

Product Category(ies):

Biliary and Vascular Stents for Angioplasty, Class IIb:
•JOSTENT® SelfX product range
•Xpert
Balloon Dilatation Catheters for Angioplasty, Class IIa:
•FOX product range
•JOCATH® O.P.E.R.A.

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 products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

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Hans-Heiner Junker

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