Declaration of Conformity

IDEV Technologies, Inc. hereby declares that the products specified below conform to the applicable sections of the Council Directive concerning medical devices – 93/42/EEC and 2007/47/EC.

Manufacturer: IDEV Technologies, Inc., a wholly owned subsidiary of Abbott Laboratories

Facility Address: 253 Medical Center Blvd., Webster, Texas 77598

Medical Devices: SUPERA® Peripheral Stent System

SUPERA® Peripheral Stent System Model Numbers:

SE-04-040-120-G3, SE-04-060-120-G3, SE-04-080-120-G3, SE-04-100-120-G3, SE-04-120-120-G3, SE-04-150-120-G3, SE-05-040-120-G3, SE-05-060-120-G3, SE-05-080-120-G3, SE-05-100-120-G3, SE-05-120-120-G3, SE-05-150-120-G3, SE-05-180-120-G3, SE-05-200-120-G3, SE-06-040-120-G3, SE-06-060-120-G3, SE-06-080-120-G3, SE-06-100-120-G3, SE-06-120-120-G3, SE-06-150-120-G3, SE-06-180-120-G3, SE-06-200-120-G3, SE-07-040-120-G3, SE-07-060-120-G3, SE-07-080-120-G3, SE-07-100-120-G3, SE-08-020-120-G3, SE-08-030-120-G3, SE-08-040-120-G3, SE-08-060-120-G3, SE-08-080-120-G3, SE-08-100-120-G3

Application of Council Directives: 93/42/EEC & 2007/47/EC

Device Classification: Classified as IIb under Rule 8 of Annex IX of the Medical Devices Directive 93/42/EEC

Supporting Certificates:
EC Quality Management System, ISO 13485:2003 Certificate Number: FM76862
Annex II Certificate Number: CE 70454

Issue Date of Original EC Certificate: January 29, 2003

Notified Body: BSI America, Inc. - #0086

IDEV Technologies, Inc. | 253 Medical Center Boulevard, Webster, TX 77598 | Phone 281.525.2000 • Fax 281.525.2001 | www.idevmd.com

Standards to which Conformity is Declared:	AAMI TIR No. 14:2009, AAMI TIR 16:2009, AAMI TIR No. 28:2009, ANSI/AAMI/ISO 11737-1:2006, ANSI/AAMI/ISO 11135-1:2007, ANSI/AAMI/ISO TIR11135-2:2008, ASTM F756:2008, ASTM 2096-04:2012, ASTM F2119:2007, ASTM F2129:2008, ASTM F2182:11a: 2011, ASTM F2514:2008, BS EN 980:2008, BS EN 1041:2008 (A1:2013), EN ISO 14971:2012, BS EN 13485:2012, ISO 10555-1: 2012, ISO 10993-1:2009, ISO 10993-4: 2009, ISO 10993-5:2009, ISO 10993-7:2008, ISO 10993-10:2010, ISO 10993-11:2006, ISO 10993-12:2012, ISO 13485:2003, ISO 25539-2:2008, ISTA-3A:2008, MEDDEV 2.12-1, Rev.8, USP<151>, USP<788>
Authorized EU Representative:	Medical Device & QA Services Ltd 76, Stockport Road, Timperley Cheshire, WA15 7SN United Kingdom

Katherine Cox, Director of Quality Assurance
IDEV Technologies, Inc.

09/04/14
Date

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