SGS

The management system of

ev3, Inc.

4600 Nathan Lane North,
Plymouth, MN, 55442, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2012 until 16 December 2017
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 15 December 2015
Issue 17. Certified since 17 June 2001

Certification is based on reports numbered WW/PCI 201110

This is a multi-site certification.
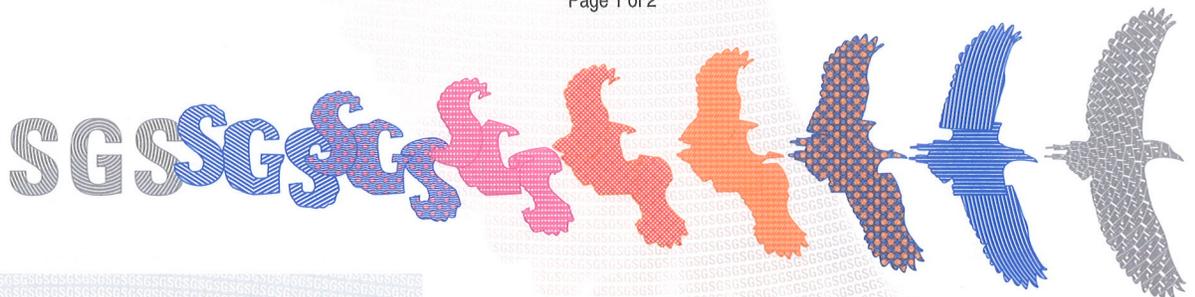Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 01 0311 M2

ev3, Inc.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 17

Detailed scope

Guidewires; Snares, Microsnares, Snare Catheters and Microcatheters; Endovascular Catheters; Rotating Y-Connectors; Thrombectomy Devices; Atherectomy Systems; Percutaneous Transluminal Angioplasty (PTA) Catheters; Peripheral Vascular, Cardiovascular and Neurovascular Filtration Systems and Embolic Protection Devices. Self-expanding biliary stent systems; Self-expanding peripheral stent systems; Pre-mounted and unmounted balloon expandable stents, Crossing Catheters, Re-entry Catheters.

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

Additional facilities

Europalaan 25, 6199 AB, Maastricht Airport, The Netherlands

14005 13th Avenue North, Plymouth, MN, 55441, United States

3033 Campus Drive, Plymouth, MN, 55441, United States