

bsi.

Certificate

Full Quality Assurance

No. CE 70454



Issued to:

**IDEV Technologies, Inc.
253 Medical Center Blvd.
Webster
Texas
77598
USA**

In respect of:

The design, development and manufacture of devices for palliative treatment of Biliary strictures produced by malignant neoplasms and for use in peripheral vasculature for failed PTA, and for peripheral guidewires

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex II, Section 3.2.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **29 Jan 2003**

Date: **25 Jan 2013**

Expiration Date: **28 Jan 2018**

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

...making excellence a habit.™



List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No. **CE 70454**
Date: **25 Jan 2013**
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Webster
USA

Subcontractor**Service(s) supplied**

NeoMetrics, Inc.
2605 Fernbrook Lane North, Suite J
Plymouth
MN 55447
USA

Manufacture

Medical Device & QA Services
76 Stockport Road
Timperley
Altrincham
Cheshire
WA15 7SN
United Kingdom

EU Representative

NovoSci Corp.
Sterilization Facility
2613 Industrial Lane
Conroe
TX 77301
USA

ETO Sterilization



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Subcontractor**Service(s) supplied**

Lemco Enterprises, Inc
3204 Hale Road
PO Box 1407
Ardmore
Oklahoma 73402
USA

ETO Sterilization



Certificate

History of Quality Assurance Certificate

Certificate No: CE 70454
Date: 25 Jan 2013
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Date	Reference Number	Action
29 January 2003	4400765	First Issued
26 April 2006	4815713	Scope changed to add: "for palliative treatment of Biliary strictures produced by malignant neoplasms and for use in peripheral vasculator for failed PTA"
28 January 2008	7117904	Certificate Renewal
29 April 2009	7361037	Addition of NovoSci Corp as an ETO Sterilization subcontractor
26 January 2010	7481003	Change legal manufacturers address from "1120 NASA Road 1" to "253 Medical Centre Blvd" and remove Steris Isomedix. Add EU Representative to list of significant subcontractors
12 August 2010	7559841	Addition of Lemco Enterprises as an alternative ETO Sterilization Subcontractor and amendment to scope to remove products which are no longer manufactured.
30 November 2012	7917367	Addition of peripheral guidewires to the certification scope and addition of NeoMetrics, Inc. in Plymouth, MN as a significant subcontractor.
25 January 2013	7945569	Certificate Renewal.