

Certificate

Full Quality Assurance

No. CE 548213



Issued to:

St. Jude Medical
14901 DeVeau Place
Minnetonka
Minnesota
55345-2126
USA

In respect of:

The Design and Manufacture of Electrophysiology (EP) Catheters, Cardiac Ablation Catheters, Occlusion Catheters, Transseptal Access System, Transseptal Needles, Introducers, Guidewires and Related Accessories

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 the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

A handwritten signature in black ink, appearing to read 'D. W. Ford', written over a horizontal line.

David W. Ford, Executive Director, Healthcare and Testing Services

First Issued: 1 Jul 2009

Date: 7 Mar 2011

Expiration Date: 21 Mar 2016

Page: 1 of 2

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.

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Supplementary Information to CE 548213

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Product

The following products are listed in conjunction with EC Certificate CE 548213:

Catheters, Introducers

Catheters, Introducers, Haemostasis Valve

Catheters, Cardiac, Electrophysiology

Catheters, Cardiac, Ablation

Catheters, Cardiac

Dilator, Vessel

Haemostasis Valve Adapter

Transseptal Access System

Catheters, Occlusion

Transseptal Needles

Guidewires

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Certificate

List of Significant Subcontractors

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

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Subcontractor	Service(s) supplied
MicroGroup 23530 University Avenue NW Bethel MN 55005 USA	Manufacture
Lake Region Medical Limited Butlersland New Ross Co. Wexford Ireland	Manufacture
St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem Belgium	EU Representative
UNIMED S.A. Grand-Pre 10 Lausanne Switzerland 1002	Manufacture

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Subcontractor

Service(s) supplied

STERIS Isomedix Services
380 90th Avenue NW
Minneapolis
Minnesota 55433
USA

ETO Sterilization

Lake Region Medical
340 Lake Hazeltine Drive
Chaska
MN 55318-1029
USA

Manufacture

History of Quality Assurance Certificate

Certificate No: **CE 548213**
Date: **07 March 2011**
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Date	Reference number	Action
01 July 2009	7339810	First issue – Transfer from another Notified Body (Phase 1 and 2)
01 October 2009	7441035	Transseptal Access System, Transseptal Needles and Occlusion Catheters added to scope – Transfer from another Notified Body (Phase 3)
26 November 2010	7607541	Add Guidewires to the scope
07 March 2011	7648853	Certificate Renewal Addition of MicroGroup as a significant subcontractor