

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No.**CE 540595**

Issued To:

**Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland**

In respect of:

The design and manufacture of non active digestive tract devices; non active gynecological devices; non active regional anaesthesia devices; non active respiratory devices; non active surgical devices; non active urology devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

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



Frank Lee, EMEA Compliance & Risk Director

First Issued: **13 January 2009**Date: **28 August 2015**Expiry Date: **07 September 2020**

...making excellence a habit.™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. 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.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No: **CE 540595**
 Date: **28 August 2015**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
Arrow International CR, a.s. Jamska 2359/47 59101 Zdar nad Sazavou Czech Republic	Control of Sterilization Design Manufacture
Arrow International CR, a.s. Prazska 209 50004 Hradec Kralove Czech Republic	Control of Sterilization Design Manufacture
Arrow Medical Ltd Hatton Gardens Industrial Estate Kington HR5 3RB United Kingdom	Crucial Supplier
CeMed GmbH Oberdorf 41 72419 Neufra Germany	Control of Sterilization Manufacture

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No: **CE 540595**
Date: **28 August 2015**
Issued To: **Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland**

Subcontractor:	Service(s) supplied
Chelle Medical Limited PO Box 221 Le Rocher Victoria Mahe Seychelles	Crucial Supplier
Forefront (Xiamen) Medical Devices Co., Ltd No 26 & 28 Haijing Dong Lu Haicang Xiamen Export Processing Zone 361026, Xiamen, Fujian China	Crucial Supplier
Forefront Medical Technology Pte Ltd 35 Joo Koon Circle, 6th Floor Singapore 629110 Singapore	Crucial Supplier

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No: **CE 540595**
 Date: **28 August 2015**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
M.E.M., Inc. 8 Bishop Lane Madison Connecticut 06443 USA	Crucial Supplier
Parker Medical Systems Division - Merrillville 1201 East 86th Place Merrillville Indiana 46410 USA	Crucial Supplier
Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II Zon Perdagangan Bebas 30020 Ipoh Perak Malaysia	Crucial Supplier

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No: **CE 540595**
 Date: **28 August 2015**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
SP Medical A/S Møllevvej 1 4653 Karise Denmark	Control of Sterilization Design Manufacture
Süddeutsche Feinmechanik GmbH (SFM) Brückenstrasse 5 D-63607 Wächtersbach Germany	Control of Sterilization Manufacture
Teleflex Medical Sdn. Bhd. Lot PT2577, Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	Control of Sterilization Design Manufacture
Teleflex Medical Asia Pte. Ltd. 6 Battery Road #07-02 049909 Singapore	Control of Sterilization Design Manufacture

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

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

Certificate No: **CE 540595**
 Date: **28 August 2015**
 Issued To: **Teleflex Medical**
IDA Business and Technology Park
Dublin Road
Athlone
Co. Westmeath
Ireland

Subcontractor:	Service(s) supplied
The Laryngeal Mask Company (Malaysia) Sdn. Bhd. Lot 19 & 1920 Industrial Zone Phase 1 Kulim Hi-Tech Park, Kulim 09000 Malaysia	Crucial Supplier
Tianjin Medis Medical Device Co. Ltd 10A Tianzhi Industrial Centre No 12 Hong Yuan Road Xiqing Economic Development Area 300385 Tianjin City China	Control of Sterilization Manufacture
Willy Rüsç GmbH Willy Rüsç-Strasse 4-10 D-71394 Kernern Germany	Control of Sterilization Design Manufacture

...making excellence a habit.™

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**
 Date: **28 August 2015**
 Issued To: **Teleflex Medical
 IDA Business and Technology Park
 Dublin Road
 Athlone
 Co. Westmeath
 Ireland**

Date	Reference Number	Action
13 January 2009	7245725	First issue
17 March 2009	7325719	Company address amended. Extension to scope. Addition of Willy Rüsck, Germany as subcontractor for design and manufacture
25 August 2009	7399879	Addition of 'epidural catheter Epistar and Epistar CSE' to scope. Addition of SFM as significant subcontractor for manufacture. Addition of 'design' to services supplied by Teleflex Medical Malaysia, Arrow International CR, a.s. and Arrow International Inc., Czech Republic
11 November 2009	7455515	Addition of CeMed GmbH for manufacturing to the list of significant subcontractors
20 April 2010	7497906	Laryngeal Mask added to scope. Addition of Tianjin Medis Medical Device Co. Ltd as significant subcontractor for manufacture
08 September 2010	7558508	Scope reworded in accordance with generic device groups. Certificate renewal
23 May 2012	7778467	Correction of significant subcontractor address and addition of new scope activities for subcontractors

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 540595**
 Date: **28 August 2015**
 Issued To: **Teleflex Medical
 IDA Business and Technology Park
 Dublin Road
 Athlone
 Co. Westmeath
 Ireland**

Date	Reference Number	Action
04 February 2013	7932588	The addition of a significant subcontractor SP Medical A/S
14 May 2014	8134266	Addition of peripheral angioplasty balloon catheters to product family, covered by scope expression 'non-active surgical devices'. Addition of significant subcontractors Hotspur Technologies, Inc and Teleflex Medical Asia Pte Ltd
09 March 2015	8293488	Addition of 8 crucial suppliers
28 August 2015	8406490	Certificate renewal. Removal of Hotspur Technologies, Inc. from list of significant subcontractors.