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: **09 January 2017** Expiry Date: **07 September 2020**

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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:

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Date:	**09 January 2017**
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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**

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Subcontractor:	**Service(s) supplied**
Chelle Medical Limited PO Box 221 Le Rocher Victoria Mahe Seychelles	**Crucial Supplier**
Contract Medical International spol. sr.o. Vazni 848 50003 Hradec Kralove Czech Republic	**Control of Sterilization** **Manufacture**
Forefront (Xiamen) Medical Devices Co., Ltd No 28 Haijing East Road & No 61 Haijing South Road Xiamen area of china (Fujian) pilot free trade zone 361026, Xiamen, Fujian China	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
Forefront Medical Technology Pte Ltd 35 Joo Koon Circle, 6th Floor Singapore 629110 Singapore	**Crucial Supplier**
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**

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Subcontractor:	**Service(s) supplied**
Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II Zon Perdagangan Bebas Ipoh Perak 30020 Malaysia	**Crucial Supplier**
SP Medical A/S Møllevej 1 4653 Karise Denmark	**Control of Sterilization** **Design** **Manufacture**
Süddeutsche Feinmechanik GmbH (SFM) Brückenstrasse 5 D-63607 Wächtersbach Germany	**Control of Sterilization** **Manufacture**

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Subcontractor:	**Service(s) supplied**
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**
The Laryngeal Mask Company (Malaysia) Sdn. Bhd. Lot 19 & 1920 Industrial Zone Phase 1 Kulim Hi-Tech Park, Kulim 09000 Malaysia	**Crucial Supplier**

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Subcontractor:	**Service(s) supplied**
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 Rüsch GmbH Willy Rüsch-Strasse 4-10 D-71394 Kernen Germany	**Control of Sterilization** **Design** **Manufacture**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
13 January 2009	7245725	First issue.
17 March 2009	7325719	Company address amended. Extension to scope. Addition of Willy Rüsch, 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.

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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.
05 August 2016	8571081	Addition of Contract Medical International, spol. sr.o. to the list of significant subcontractors. Addition of EZ Blocker non-active respiratory device.
09 January 2017	8665617	Change to the address of subcontractor (Forefront).