bsi.

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 540596**

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

In respect of:

See certificate scope page.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III 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**

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Certificate No: CE 540596

Certificate Scope:

Those aspects of Annex V relating to securing and maintaining sterility in the manufacture of non-active respiratory devices; non active gynaecological devices; non active regional anaesthesia devices; non active surgical devices; non active urology devices.

Those aspects of manufacturing relating to obtaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.

The manufacture of non-active and active surgical devices for adult and paediatric intraosseous infusion, bone marrow aspiration, bone marrow biopsy and bone lesion biopsy.

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

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

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

Certificate No:	**CE 540596**
Date:	**28 August 2015**
Issued To:	**Teleflex Medical** **IDA Business and Technology Park** **Dublin Road** **Athlone** **Co. Westmeath** **Ireland**

Subcontractor:	**Service(s) supplied**
ArcRoyal Ltd. Virginia Road Kells, Co. Meath Ireland	**Control of Sterilization** **Manufacture**
Arriol International Corporation Zona Franca San Isidro Carreta San Isidro Km.17 Santo Domingo Dominican Republic	**Crucial Supplier**
Arrow International CR, a.s. Jamska 2359/47 59101 Zdar nad Sazavou Czech Republic	**Control of Sterilization** **Manufacture**
Arrow International CR, a.s. Prazska 209 50004 Hradec Kralove Czech Republic	**Control of Sterilization** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Bidoia SAS Di Gianfranco Didoia E C. Peraga di Vigonza (PD) Via dell' Artigianato, 18 35010 Italy	**Control of Sterilization** **Manufacture**
Coastal Life Technologies, Inc 1803 Grandstand Drive, Suite 101 San Antonio Texas 78238 USA	**Crucial Supplier**
Foremount Enterprise Co., Ltd. Head Office No. 17, Alley 15, Lane 5 Shenan Street Shengang Dist Taichung City Taiwan	**Control of Sterilization** **Manufacture**

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Subcontractor:	**Service(s) supplied**
Lake Region Medical 2052 West 11th Street Upland California 91786 USA	**Crucial Supplier**
Sparton Onyx. LLC 2920 Kelly Avenue Watertown South Dakota 57201 USA	**Crucial Supplier**
Süddeutsche Feinmechanik GmbH (SFM) Brückenstrasse 5 D-63607 Wächtersbach Germany	**Control of Sterilization** **Manufacture**

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Directive 93/42/EEC on Medical Devices, Annex V

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Subcontractor:	**Service(s) supplied**
Teleflex Medical Sdn. Bhd. Lot PT2577, Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	**Control of Sterilization** **Manufacture**
Vidacare LLC 4350 Lockhill Selma Rd., Suite 150 Shavano Park Texas 78249 USA	**Control of Sterilization** **Manufacture**
Willy Rüsch GmbH Willy Rüsch-Strasse 4-10 D-71394 Kernen Germany	**Control of Sterilization** **Manufacture**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 540596**

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Date	Reference Number	Action
13 January 2009	7245725	First issue
17 March 2009	7325720	Company address amended. Extension to scope. Addition of Willy Rüsch, Germany as subcontractor for design and manufacture
25 August 2009	7399908 7439096	Addition of SFM as significant subcontractor for manufacture. Addition of 'design' services supplied by Teleflex Medical, Malaysia, Arrow International CR, a.s. and Arrow International, Inc., Czech Republic. Correction of History page header. Intrauterine catheter added to scope
08 September 2010	7558507	Scope reworded in accordance with generic device groups. Activity of 'Design' removed from all subcontractors and 'Control of Sterilisation' added. Certificate renewal

EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
23 February 2011	7635647	Scope extended to include, 'Those aspects of manufacturing relating to securing and maintaining sterility in the assembly of procedure packs in accordance with Article 12 of the Medical Devices Directive.' Addition of subcontractor, 'ArcRoyal Ltd., Virginia Road, Kells, Co. Meath, Ireland' for Manufacture and Control of Sterilization activities
23 May 2012	7778468	Correction of significant subcontractor address
04 February 2013	7932595	The addition of significant subcontractors Foremount Enterprise Co Ltd and Bidoia SAS Di Gianfranco Didia EC
13 July 2015	8334933	Extension to scope to include 'The manufacture of non-active and active surgical devices for adult and paediatric intraosseous infusion, bone marrow aspiration, bone marrow biopsy and bone lesion biopsy.' Significant subcontractor changes: Addition of Vidacare LLC, Lake Region Medical, Arriol International Corporation, Coastal Life Technologies, Inc & Sparton Onyx. LLC

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28 August 2015	8406492	Certificate renewal. Removal from scope of 'those aspects of Annex V relating to securing and maintaining sterility in the manufacture of non-active digestive tract devices' and 'Those aspects of Annex V related to metrology in the manufacture of non-active respiratory devices'.