

# 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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2009-01-13**

Date: **2020-06-09**

Expiry Date: **2024-05-26**

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## Supplementary Information to CE 540595

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Number	Device Name	Intended purpose per IFU
<b>Class III</b>		
---	EpiStar CSE - Spinal-Epidural Anaesthesia Kits	See CE 544836
---	Spinostar Spinal Needles	See CE 560441
<b>Class IIb</b>		
10735	Sterile Percutaneous Nephrostomy Catheter	Puncture and dilation of percutaneous approaches into the upper urinary tract.
35404	Sterile Tracheostomy Tube	Cannulation of tracheostomised patients through an existing tracheostoma.
14099	Sterile Tracheostomy Tube	Cannulation of tracheostomised patients, in whom the stoma was created by percutaneous dilative tracheostomy.
58005	Sterile Ureter Stent	Routine drainage of the renal pelvis via the ureter or a ureter-skin stoma to an external collection site.
34924	Sterile Suprapubic Cystotomy Set	Routine suprapubic drainage of the bladder
31074	Sterile Ureterocutaneostomy Catheter	Routine drainage of urine through a ureterocutaneous stoma site.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD 0106	Sterile Transurethral Catheter	---
MD 0101	Sterile Tracheostomy Retainer Set	---
MD 0106	Sterile Rectal Tube	---
MD 0101 MD 1102	Sterile Breathing Circuit	---
MD 0101 MD 1102	Non-sterile Breathing Circuit	---
MD 0101	Sterile Cricothyrotomy Set	---
MD 0102	Sterile Epidural Set	---
MD 0101	Sterile EZ Blocker Kit	---
MD 0106	Sterile Guidewire	---
MD 0106	Sterile Kidney Stone Extractor	---
MD 0101	Sterile Tracheal Tube	---
MD 0101	Non-sterile Tracheal Tube	---
MD 0101	Sterile Laryngeal Mask	---
MD 0101	Non-sterile Laryngeal Mask	---

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Number	Device Name	Intended purpose per IFU
<b>Class IIa</b>		
MD 0106	Sterile Laparoscopy Bag	---
MD 0101	Sterile Bronchial Tube	---
MD 0101	Sterile Suprapubic Cystotomy Set	---
MD 0303	Sterile Drainage Tube	---
MD 0101	Sterile Tracheostomy Tube, Inner cannula	---
MD 0106	Sterile Ureter Catheter	---
MD 0102	Sterile Needle Introducer	---
MD 0101	Sterile Percutaneous Nephrostomy Catheter	---
MD 0106	Non-sterile Temperature Sensor	---
MD 0101	Sterile Breathing Bag	---
MD 0101 MD 0106	Sterile Irrigation System for Ureterocutaneostomy	---

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# 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:

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Arrow International CR, a.s. Jamska 2359/47 Zdar Nad Sazavou 59101 Czech Republic	<b>Design</b> <b>Manufacture</b>
Arrow International CR, a.s. Prazska 209 Hradec Kralove 50004 Czech Republic	<b>Design</b>
Arrow Medical Ltd Hatton Garden Industrial Estate Kington Hereford HR5 3RB United Kingdom	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
BBF Sterilisationsservice GmbH Willy-Rüsch-Straße 10/1 71394 Kernen Germany	<b>Radiation (Gamma Sterilization)</b>
Chelle Medical Limited Le Rocher P.O Box 221 Victoria Mahe Seychelles	<b>Manufacture</b>
Chemiczna Spółdzielnia Pracy Technochemia ul. Fabryczna 3 05-600 Grójec Poland	<b>ETO Sterilization</b>
Contract Medical International, spol. sr.o. Vážní 848 500 03 Hradec Králové Czech Republic	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Daqing Medical Device (Tianjin) Co., Ltd 10A & 11A Tianzhi Industrial Center No.12 Hong Yuan Road Xiqing Economic Development Area 300385 Tianjin People's Republic of China	<b>Manufacture</b>
Degania Silicone Limited Kibbutz 1513000 Degania Bet Israel	<b>Manufacture</b>
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 People's Republic of China	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Forefront Medical Technology (Pte) Ltd 35 Joo Koon Circle Singapore 629110 Singapore	<b>Manufacture</b>
M.E.M., Inc. 8 Bishop Lane Madison Connecticut 06443 USA	<b>Manufacture</b>
Medicoplast International GmbH Heusweilerstrasse 100 DE-66557 Ilingen Germany	<b>ETO Sterilization</b>
Parker Hannifin CSS Merrillville 1201 East 86th Place Merrillville IN, 46410 United States	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Plaxtron Industrial (M) Sdn. Bhd. Plot 28, Kawasan Perusahaan Jelapang II Zon Perdagangan Bebas, Ipoh Perak 30020 Malaysia	<b>Manufacture</b>
Professional Contract Sterilization Inc. 40 Myles Standish Blvd Taunton Massachusetts 02780-1026 USA	<b>ETO Sterilization</b>
safemed medical devices s.r.o Trabantská 292 19015 Praha 9 Czech Republic	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
sfm medical devices GmbH Brückenstraße 5 63607 Wächtersbach Germany	<b>ETO Sterilization Manufacture</b>
SINA-SterilGamma Sdn. Bhd. LOT 88077, Jalan Perigi Nenas 7/1 Taman Perindustrian Pulau Indah 42907 Pelabuhan Klang, Selangor Malaysia	<b>ETO Sterilization</b>
SP Medical A/S Møllevej 1 4653 Karise Denmark	<b>Design Manufacture</b>
SP Medical Sp. z o.o. Ul. Ceramiczna 2K 98-220 Zduńska Wola Poland	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
STERIS AST CZ s.r.o. Prumyslová Zona Kosikov 80 Velka Bites 59501 Czech Republic	<b>ETO Sterilization</b>
Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	<b>ETO Sterilization</b>
Synergy Sterilisation Kulim (M) Sdn. Bhd Lot 71, Kulim Industrial Estate Kulim Kedah 09000 Malaysia	<b>ETO Sterilization</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Teleflex Medical Asia Pte. Ltd. 21 Merchant Road #04-01 Royal Merukh S.E.A 058267 Singapore	<b>Design Manufacture</b>
Teleflex Medical Sdn. Bhd. Lot PT 2577, Jalan Perusahaan 4 34600 Kamunting Perak Malaysia	<b>Design ETO Sterilization Manufacture</b>
The Laryngeal Mask Company (Malaysia) Sdn. Bhd. Lot 19 & 1920 Industrial Zone Phase 1 Kulim Hi-Tech Park Kulim 09000 Malaysia	<b>Manufacture</b>

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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 Rüsç, 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).
16 July 2018	8939923	Addition of Daqing Medical Device (Tianjin) Co., Ltd to the list of significant subcontractors.

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Date	Reference Number	Action
4 March 2019	7779566	Traceable to NB 0086.
Current	3124666	<p>Certificate renewal.</p> <p>Addition of supplementary product information table.</p> <p>Removal of Control of Sterilization from Service(s) supplied for Arrow International CR, a.s. (Zdar), Arrow International CR, a.s. (Hradec Kralove), Contract Medical International spol. sr.o., SP Medical A/S, sfm medical devices GmbH, Teleflex Medical Asia Pte. Ltd. and Teleflex Medical Sdn. Bhd.</p> <p>Removal of Crucial Supplier from Service(s) supplied for Arrow Medical Ltd, Chelle Medical Limited, Forefront (Xiamen) Medical Devices Co., Ltd, Forefront Medical Technology (Pte) Ltd, Parker Hannifin CSS Merrillville, Plaxtron Industrial (M) Sdn. Bhd. and The Laryngeal Mask Company (Malaysia) Sdn. Bhd.</p> <p>Addition of Manufacture to Service(s) supplied for Arrow Medical Ltd, Chelle Medical Limited, Forefront (Xiamen) Medical Devices Co., Ltd, Forefront Medical Technology (Pte) Ltd, M.E.M., Inc., Parker Hannifin CSS Merrillville, Plaxtron Industrial (M) Sdn. Bhd., and The Laryngeal Mask Company (Malaysia) Sdn. Bhd.</p> <p>Removal of Manufacture from Service(s) supplied for Arrow International CR, a.s. (Hradec Kralove)</p> <p>Addition of Degania Silicone Limited, safemed medical devices s.r.o and SP Medical Sp. z.o.o. as subcontractors for Manufacture.</p>

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Date	Reference Number	Action
		<p>Addition of STERIS AST CZ s.r.o., Synergy Sterilisation (M) Sdn Bhd., Synergy Sterilisation Kulim (M) Sdn Bhd., Chemiczna Spółdzielnia, Medicoplast International GmbH, Professional Contract Sterilization Inc., SINA-SterilGamma Sdn Bhd and Teleflex Medical Sdn. Bhd. as subcontractors for ETO Sterilization.</p> <p>Addition of BBF Sterilisationservice GmbH as subcontractor for Gamma Sterilization.</p> <p>Removal of CeMed GmbH, Tianjin Medis Medical and Willy Rüschi GmbH</p> <p>Administrative correction of details for Arrow Medical Ltd, Chelle Medical Limited, Contract Medical International spol. sr.o., Daqing Medical Device (Tianjin) Co., Ltd, Forefront (Xiamen) Medical Devices Co., Ltd and SP Medical A/S.</p> <p>Change of address for Teleflex Medical Asia Pte. Ltd.</p> <p>Name change from Süddeutsche Feinmechanik GmbH (SFM) to sfm medical devices GmbH</p> <p>Name change from Parker Medical Systems Division - Merrillville to Parker Hannifin CSS Merrillville</p>

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