By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 616020**

Issued To: **Medical Components, Inc.**
dba Medcomp
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

In respect of:

Design, Development and manufacture of sterile power injectable implantable infusion ports, sterile short-term and long-term haemodialysis catheters, peritoneal dialysis catheters, sterile short-term and long-term Peripherally Inserted Central Vein Catheters (PICCs), sterile long-term infusion catheters (CVCs), Sterile Peripherally Inserted Midline Catheters for intravenous therapies, blood sampling and power injection of contrast media, short-term infusion catheters, sterile short-term infusion sets, catheter locking solutions, and accessories for short-term and long-term haemodiaylsis, dialysis, short-term and long-term infusion devices and short-term and long-term vascular access catheters.

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: **2015-05-15** Date: **2021-05-13** Expiry Date: **2024-05-26**

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Supplementary Information to CE 616020

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Class III	
Device Name	**Intended Purpose Per IFU**
Symetrex Long Term Hemodialysis Catheter	See CE 653207
Dignity Dual Port	See CE 640747
Split Cath Long Term Hemodialysis Catheter	See CE 616022
Step Tip Long Term Hemodialysis Catheter	See CE 616077
Tesio Long Term Hemodialysis Catheter	See CE 658964
Hemodialysis Catheter Repair Kit	See CE 658965
Dignity, Profuse and Jet CT Ports	See CE 662596
Pro-Line and Vascu-Line CVC Infusion Catheters	See CE 662598
LT Silicone CVC Infusion Catheters	See CE 662601
Pro-PICC, Valved Pro-PICC and Jet-PICC	See CE 662604
Vascu-PICC and Valved Vascu-PICC	See CE 662605
Hemo-Cath Long Term Hemodialysis Catheter	See CE 663428
Jet-Flow XF Long Term Hemodialysis Catheter	See CE 678677

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Class IIb		
GMDN Code	**Device or Generic Device Group**	**Intended Purpose per IFU**
47085	Catheter – Peritoneal Dialysis	The Medcomp PD Catheters are indicated for acute and chronic peritoneal dialysis.
61840	Catheter Locking Solutions	Maintain patency of Hemodialysis Catheters.

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Class IIa		
NBOG Code	**Device or Device Subcategory**	**Intended Purpose**
MD0102	Infusion Sets	N/A
MD0102	Midline Catheters	N/A
MD0102	Short Term Haemodialysis Catheters and accessories	N/A
MD0106	Tunnelers	N/A
MD0106	Stylets	N/A
MD0106	Dilators and Sheaths	N/A
MD0106	Needles	N/A
MD0106	Luers and Adaptors	N/A
MD0106	Introducers	N/A
MD0106	Micro Stick Introducer Set	N/A

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Date	Reference Number	Action
15 May 2015	8177168	First Issue.
11 September 2015	8360908	Addition of significant subcontractors; The Electronic Assembly Company for Manufacture, Martech East for Manufacture, VPI Technology Group for software, and Lextech Global Services for software.
14 July 2016	8410522	Expanded certificate scope to include sterile power injectable implantable infusion ports. Addition of Centurion Medical Products as significant subcontractor for ETO Sterilisation.
05 September 2016	8555366	Removal of subcontractor Nostix, LLC, Colorado, USA.

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Date	Reference Number	Action
04 October 2016	8535863	Extension to scope to include sterile long term hemodialysis catheters. Addition of subcontractors Pelham Plastics, Pelham NH 03076; Medron, Inc., Salt Lake City, UT 84104; Galt Medical Corp, Garland, TX 75041, Greatbatch Medical, Minneapolis, MN 55441; all for the activity of Crucial supplier. Additional of subcontractors Phase 2 Medical Manufacturing, Inc., Rochester NH 03867 for the activity of Secondary packaging, iuvo BioScience, Erie, PA 16510 for the activity of ETO sterilization.
16 August 2017	8747861	Removal of subcontractor iuvo BioScience. Addition of subcontractor Martech Medical Products for the activity of packaging. Addition of subcontractor North American Sterilization Packaging Company for the activity of ETO Sterilization.
17 November 2017	8576505	Addition of manufacture to the services supplied by Martech Medical Products. Addition of peritoneal dialysis catheters to the scope. Subcontractor Martech Medical name correction.

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Date	Reference Number	Action
23 February 2018	8898159	Remove Phase 2 Medical Manufacturing, Inc from subcontractor list. Change subcontractor name from North American Sterilization Packaging Company to Cosmed.
11 October 2018	8886900	Extension to scope to include; sterile short and long term Peripherally Inserted Central Vein Catheters (PICCs), short and long term sterile infusion catheters (CVCs), sterile short term infusion sets, catheter locking solutions. Removal of subcontractor Martech Medical Products (1500 Delp Drive, US) for the activity of Manufacture. Addition of subcontractor Steris (Isomedix Operations, Inc. 9 Apollo Drive Whippany US) for the activity of Gamma Sterilization.
26 February 2019	8958818	Traceable to NB 0086.

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Date	Reference Number	Action
21 October 2019	9714917	Transfer error correction: Amendment of Scope statement to update devices that were incorrectly added to the Full Quality Assurance Certificate issued by previous Notified Body and aligned devices and suppliers with the correct certificates. Administrative update to product table format and clarified products per updates to scope statement above as follows: ▪ Add devices to the IIa Table from CE 616021: Midline Catheters, Short Term Haemodialysis Catheters and Accessories, Tunnelers, Suture Wings, Stylets, Dilators and Sheaths, Needles, Luers and Adaptors, Introducers, Clamps, Connectors, Anchoring Sleeves, and Micro Stick Introducer Set. ▪ Add device to Is Table: Tourniquet (Silicone). ▪ Add Intended Purpose for each device in IIa and Is Tables. Updated NBOG code for Catheter Locking Solutions from MDS 7001 to MD 0106 per manufacturer. Updated Scope Statement to remove "short-term" infusion catheters (CVC's) due to product discontinuation.

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Date	Reference Number	Action
21 October 2019 (continued)	9714917	Updated suppliers: Added HD Surgical – Spurrier Medical a Division of Harwood Design, Inc.-Bristol PA, Martech Medical Products-Baja California, Mexico, Point Medical-Crown Point IN, Isomedix Operations-Whippany NJ, and Isomedix Operations, Inc. Temecula, CA. Updated Name for HD Surgical (Tecomet) to HD Surgical – Spurrier Medical a Division of Harwood Design, Inc. Removed Galt Medical-Garland TX, Greatbatch Inc.-Minneapolis MN, Industrie Borla-Italy, Martech Medical Products-Harleysville PA, Medron Inc.-Salt Lake City UT, and Southmedic Inc.-Canada.

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Date	Reference Number	Action
27 April 2020	9773903	Certificate Renewal. Update Lextech address to 3025 Highland Pkwy Suite 275. Update Sterigenics US, LLC name at 5725 West Harold Gatty Drive location. Update device table format to remove indications for use from IIa and Is. Correct Class III device name listings to align with design exam certificate scopes. Correct classification of Catheter Locking Solutions to IIb. Correct GMDN code of Peritoneal Dialysis Catheters to 47085. Correct device tables to remove Suture Wings, Clamps, Connectors, Anchoring Sleeves and Tourniquet (Silicone). Correct class Is device table to include ECG Accessory Packs as per scope. Correct prior certificate history entry 9714917 to indicate the addition of Isomedix Operations, Inc. Temecula, CA.
17 June 2020	3152698	Remove Centurion as EtO sterilization supplier. Updated scope of CE 662604 to include the Jet-PICC.
17 September 2020	3221763	Remove Pelham Plastics Inc. as Crucial Supplier.

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13 May 2021	3442623	Remove ECG tip positioning system (Class IIb) and ECG accessories (Class Is) from device tables and scope. Remove Lextech Global Services and VPI Technology Group as crucial suppliers. Remove The Electronics Assembly Company as critical subcontractor.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
10 September 2021	3508453	Remove "Dignity Dual Port" (CE 640747) from the Device Table.
19 May 2022	3664212	Administrative removal of Cosmed Group, Inc (19 Park Drive, Franklin, NJ) as ETO Sterilization subcontractor.
22 February 2023	3846612	Remove all subcontractor pages. Addition of sterilization subcontractor.

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22 February 2023

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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	**Directive and Annex**	**Reference Number**	**Changes approved**
CE 616020	93/42/EEC Annex II excluding Section 4	3846612	Addition of sterilization subcontractor.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices