By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Medical Components, Inc.
dba Medcomp
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

Digitally signed by Bolea Petru
Date: 2022.07.11 08:49:01 EEST
Reason: MoldSign Signature
Location: Moldova

Holds Certificate Number: **MD 636611**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, Development, Manufacturing, and Distribution of sterile catheter locking solution, sterile and nonsterile ECG-based peripherally inserted central catheter placement and tip location confirmation systems, dialysis, infusion, and drainage catheters for central and peripheral vascular and cavity access, and their associated repair, replacement, and adjunct accessories used in acute and chronic extracorporeal and maintenance therapies.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2015-07-16
Effective Date: 2020-09-29
Latest Revision Date: 2020-09-28
Expiry Date: 2022-09-28

...making excellence a habit.™

Certificate No: **MD 636611**

Location	Registered Activities
Medical Components, Inc. dba Medcomp 1499 Delp Drive Harleysville Pennsylvania 19438 USA	Design, Development, Manufacturing, and Distribution of sterile catheter locking solution, sterile and nonsterile ECG-based peripherally inserted central catheter placement and tip location confirmation systems, dialysis, infusion, and drainage catheters for central and peripheral vascular and cavity access, and their associated repair, replacement, and adjunct accessories used in acute and chronic extracorporeal and maintenance therapies.
Medical Components, Inc 3088 East 33rd Place Yuma Arizona 85365 USA	Warehousing, re-labeling, inventory control, shipping and customer service.

Original Registration Date: 2015-07-16

Effective Date: 2020-09-29

Latest Revision Date: 2020-09-28

Expiry Date: 2022-09-28

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Medical Components, Inc.
dba Medcomp
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

DUNS Number: 03-800-0253

Holds Certificate No: **MDSAP 691198**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, Development, Manufacture, and Distribution of sterile catheter locking solution, sterile and nonsterile ECG-based peripherally inserted central catheter placement and tip location confirmation systems, dialysis, infusion, and drainage catheters for central and peripheral vascular and cavity access, and their associated repair, replacement, and adjunct accessories used in acute and chronic extracorporeal and maintenance therapies.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-02-19 Effective Date: 2020-02-19 Expiry Date: 2022-09-28

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit.™

Certificate No: **MDSAP 691198**

Location	Registered Activities
Medical Components, Inc. dba Medcomp 1499 Delp Drive Harleysville Pennsylvania 19438 USA DUNS Number: 03-800-0253	Design, Development, Manufacture, and Distribution of sterile catheter locking solution, sterile and nonsterile ECG-based peripherally inserted central catheter placement and tip location confirmation systems, dialysis, infusion, and drainage catheters for central and peripheral vascular and cavity access, and their associated repair, replacement, and adjunct accessories used in acute and chronic extracorporeal and maintenance therapies.
Medical Components, Inc 3088 East 33rd Place Yuma Arizona 85365 USA DUNS Number: 08-075-7988	Warehousing, re-labeling, inventory control, shipping and customer service.

Original Registration Date: 2020-02-19 Effective Date: 2020-02-19 Expiry Date: 2022-09-28

bsi.

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

Gary E Slack, Senior Vice President Medical Devices

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

...making excellence a habit.™

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 616020

Issued To:

Medical Components, Inc.
dba Medcomp
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

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

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

...making excellence a habit.™

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 616020

Issued To:

Medical Components, Inc.
dba Medcomp
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

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.

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

...making excellence a habit.™

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 616020

Issued To:

Medical Components, Inc.
dba Medcomp
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

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

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

...making excellence a habit.™

bsi.

By Royal Charter

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 616020**
Date:	**2021-05-13**
Issued To:	**Medical Components, Inc.** **dba Medcomp** **1499 Delp Drive** **Harleysville** **Pennsylvania** **19438** **USA**

Subcontractor:	**Service(s) supplied**
Cosmed Group, Inc. dba Cosmed of NJ 19 Park Drive Franklin New Jersey 07416 USA	**ETO Sterilization**
HD Surgical – Spurrier Medical a Division of Harwood Design, Inc. 1507 Clyde Waite Drive Bristol Pennsylvania 19007 USA	**Crucial Supplier**
Isomedix Operations Inc. 43425 Business Park Drive Temecula California 92590 USA	**ETO Sterilization**

...making excellence a habit.™

bsi.

By Royal Charter

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 616020**
Date:	**2021-05-13**
Issued To:	**Medical Components, Inc.** **dba Medcomp** **1499 Delp Drive** **Harleysville** **Pennsylvania** **19438** **USA**

Subcontractor:	**Service(s) supplied**
Isomedix Operations, Inc. 9 Apollo Drive Whippany New Jersey 07981 USA	**Radiation (Gamma Sterilization)**
Martech Medical Products S. de R.L. de C.V. Calle Mercurio N 46 Parque Industrial Mexicali 1 Mexicali Baja California C.P. 21210 Mexico	**Manufacture** **Packaging**
MPS Medical Product Service GmbH Borngasse 20 Braunfels 35619 Germany	**EU Representative**

...making excellence a habit.™

bsi.

By Royal Charter

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 616020**
Date:	**2021-05-13**
Issued To:	**Medical Components, Inc.** **dba Medcomp** **1499 Delp Drive** **Harleysville** **Pennsylvania** **19438** **USA**

Subcontractor:	**Service(s) supplied**
Point Medical Corporation 891 East Summit Street Crown Point Indiana 46307 USA	**Crucial Supplier**
Sterigenics US, LLC 5725 W. Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**

...making excellence a habit.™

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 616020**

Date: **2021-05-13**

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

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.

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 616020**

Date: **2021-05-13**

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

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.

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 616020**

Date: **2021-05-13**

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

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.

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 616020**

Date: **2021-05-13**

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

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.

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 616020**

Date: **2021-05-13**

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

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.

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 616020**

Date: **2021-05-13**

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

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.

By Royal Charter

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 616020**

Date: **2021-05-13**

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

Date	Reference Number	Action
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.

bsi.

Inspiring trust for a more resilient world.

10 September 2021

Medical Components, Inc.
dba Medcomp
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

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	3508453	Remove "Dignity Dual Port" (CE 640747) from the Device Table.

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,

Gary Slack
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl

By Royal Charter

EC Certificate - Production Quality Assurance

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

No. **CE 616021**

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

In respect of:

Manufacture of accessories of short-term and long-term vascular access catheters and accessories for short-term and long term haemodiaylsis, dialysis and short-term and long-term infusion devices.
Those aspects of Annex V concerned with securing and maintaining sterile conditions of class Is accessories.

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 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-08-11** Date: **2020-06-17** Expiry Date: **2024-05-26**

...making excellence a habit.™

EC Certificate - Production Quality Assurance

Supplementary Information to CE 616021

Issued To:

Medical Components, Inc.
dba Medcomp
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

Number	Device Name	Intended purpose per IFU
Class IIa		
MD0106	Dilators and Sheaths	To widen the vessel prior to catheter insertion to allow easy passage to target vein.
MD0106	Guidewires	To act as a "path" for vessel dilators, holds access to the vein and helps with catheter tip positioning and to measure the length of the catheter for ideal placement.
MD0106	Introducers	To enable vascular access.
MD0106	Needles	To gain access to selected vein and for the percutaneous introduction of guidewires.
MD0106	Picks	Instrument designed to facilitate catheter placement into vessel.
MD0106	Caps and Plugs	To keep clean and protect catheter luer between treatments.
MD0106	Clamps	To temporarily occlude a catheter.

First Issued: **2016-08-11** Date: **2020-06-17** Expiry Date: **2024-05-26**

EC Certificate - Production Quality Assurance

Supplementary Information to CE 616021

Issued To:

Medical Components, Inc.
dba Medcomp
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

Number	Device Name	Intended purpose per IFU
Class IIa		
MD0106	Scalpels	A cutting device during surgical, pathology and minor medical procedures.
MD0106	Stylets	To facilitate catheter insertion.
MD0302	Sutures	To secure catheter.
MD0102	Syringes	To inject fluids into or withdraw fluids.
MD0106	Tearaway	To enable vascular access.

First Issued: **2016-08-11** Date: **2020-06-17** Expiry Date: **2024-05-26**

EC Certificate - Production Quality Assurance

Supplementary Information to CE 616021

Issued To:

Medical Components, Inc.
dba Medcomp
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

Number	Device Name	Intended purpose per IFU
Class Is		
MD 0100	Tourniquets	A constricting or compressing device used to control venous and arterial circulation to an extremity for a period of time.
MD 0301	Dressings	Adhesive wound dressing intended to protect the catheter from contamination when not in use.
MD 0106	Scissors	A cutting device for the catheter.
MD 0100	Drapes	To preserve sterility of the catheter during repair or insertion.
MD 0106	Anchoring Devices	Stabilization device for compatible winged catheters.
MD 0100	Wraps	Kits are placed in a CSR wrap to help maintain the sterility of the products inside.
MD 0301	Gauzes	Intended to soak up blood or fluid that may be on or around the catheter insertion site during catheter placement.

First Issued: **2016-08-11** Date: **2020-06-17** Expiry Date: **2024-05-26**

...making excellence a habit.™

By Royal Charter

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 616021**
Date:	**2020-06-17**
Issued To:	**Medical Components, Inc.** **dba Medcomp** **1499 Delp Drive** **Harleysville** **Pennsylvania** **19438** **USA**

Subcontractor:	**Service(s) supplied**
Bard Access Systems, Inc. 605 North 5600 West Salt Lake City Utah 84116 USA	**Crucial Supplier**
Becton Dickinson & Co. North American Shared Services Center 5859 Farinon Drive, Suite 200 San Antonio TX 78249 USA	**Crucial Supplier**
Cosmed Group, Inc. dba Cosmed of NJ 19 Park Drive Franklin New Jersey 07416 USA	**ETO Sterilization**

...making excellence a habit.™

By Royal Charter

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 616021**
Date:	**2020-06-17**
Issued To:	**Medical Components, Inc.** **dba Medcomp** **1499 Delp Drive** **Harleysville** **Pennsylvania** **19438** **USA**

Subcontractor:	**Service(s) supplied**
Galt Medical Corp 2220 Merritt Drive Garland, TX 75041 USA	**Crucial Supplier**
Guangdong Baihe Medical Technology Co., Ltd No 89 Taoyuan East Road Nanhai, Foshan 528225 Guandong Province China	**Crucial Supplier**
Heraeus Components SRL Parque Industrial Zona Franca La Lima Guadalupe Building 29 Cartago 30106 Costa Rica	**Crucial Supplier**

...making excellence a habit.™

By Royal Charter

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 616021**
Date:	**2020-06-17**
Issued To:	**Medical Components, Inc.** **dba Medcomp** **1499 Delp Drive** **Harleysville** **Pennsylvania** **19438** **USA**

Subcontractor:	**Service(s) supplied**
ICU Medical, Inc. 951 Calle Amanecer San Clemente California 92673 USA	**Crucial Supplier**
Isomedix Operations Inc. 43425 Business Park Drive Temecula California 92590 USA	**ETO Sterilization**
Lake Region Medical 340 Lake Hazeltine Drive Chaska Minnesota 55318 USA	**Crucial Supplier**

...making excellence a habit.™

By Royal Charter

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 616021**
Date:	**2020-06-17**
Issued To:	**Medical Components, Inc.** **dba Medcomp** **1499 Delp Drive** **Harleysville** **Pennsylvania** **19438** **USA**

Subcontractor:	**Service(s) supplied**
Martech Medical Products S. de R.L. de C.V. Calle Mercurio N 46 Parque Industrial Mexicali 1 Mexicali Baja California C.P. 21210 Mexico	**Manufacture**
Medline Industries, Inc. Three Lakes Drive Northfield Illinois 60093 USA	**Crucial Supplier**
Micro Moldings, Inc. 65 Howard Street Phillipsburg New Jersey 08865 USA	**Crucial Supplier**

...making excellence a habit.™

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 616021**
Date:	**2020-06-17**
Issued To:	**Medical Components, Inc.** **dba Medcomp** **1499 Delp Drive** **Harleysville** **Pennsylvania** **19438** **USA**

Subcontractor:	**Service(s) supplied**
MPS Medical Product Service GmbH Borngasse 20 Braunfels 35619 Germany	**EU Representative**
Neomedical Inc. 1375 Greg Street #108 Sparks Nevada 89431 USA	**Crucial Supplier**
Qosina Corporation 2002-Q Orville Drive North Ronkonkoma New York 11779 USA	**Crucial Supplier**

...making excellence a habit.™

By Royal Charter

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 616021**
Date:	**2020-06-17**
Issued To:	**Medical Components, Inc.** **dba Medcomp** **1499 Delp Drive** **Harleysville** **Pennsylvania** **19438** **USA**

Subcontractor:	**Service(s) supplied**
Sklar Instruments 889 South Matlack Street West Chester Pennsylvania 19382 USA	**Crucial Supplier**
Southmedic Inc. 50 Alliance Blvd Barrie Ontario L4M 5K3 Canada	**Crucial Supplier**
Sterigenics US, LLC 5725 West Harold Gatty Drive Salt Lake City Utah 84116 USA	**ETO Sterilization**

...making excellence a habit.™

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 616021**
Date:	**2020-06-17**
Issued To:	**Medical Components, Inc.** **dba Medcomp** **1499 Delp Drive** **Harleysville** **Pennsylvania** **19438** **USA**

Subcontractor:	**Service(s) supplied**
Surgical Specialties Mexico, S.DE R.L. DE C.V. also trading as Surgical Specialties Corporation Corredor Tijuana-Rosarito 2000, #24702-B, Ejido Francisco Villa, Tijuana, B.C., C.P., 22235 Mexico	**Crucial Supplier**
Teleflex Medical, Inc. 50 Plantation Drive Jaffrey New Hampshire 03452 USA	**Crucial Supplier**
TIDI Products, LLC 570 Enterprise Drive Neenah Wisconsin 54956 USA	**Crucial Supplier**

...making excellence a habit.™

By Royal Charter

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 616021**
Date:	**2020-06-17**
Issued To:	**Medical Components, Inc.** **dba Medcomp** **1499 Delp Drive** **Harleysville** **Pennsylvania** **19438** **USA**

Subcontractor:	**Service(s) supplied**
Viscot Medical, LLC 32 West Street East Hanover New Jersey 07936 USA	**Crucial Supplier**

...making excellence a habit.™

By Royal Charter

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 616021**

Date: **2020-06-17**

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

Date	Reference Number	Action
11 August 2016	8177222	First issue.
02 November 2016	8623845	Addition of subcontractor North American Sterilization Packaging Company, Franklin, USA for the activity of ETO Sterilisation.
26 October 2018	9664323	Extension to scope to include: Short Term Haemodialysis Catheter and accessories, Short Term Infusion Catheters and Accessories and Accessories for Acute and Long-Term Vascular Access Catheters and Those aspects of Annex V concerned with securing and maintaining sterile conditions of class Is accessories. Addition of the Accessories Critical Suppliers in Subcontractor list.
26 February 2019	8958818	Traceable to NB 0086.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 616021**
Date: **2020-06-17**
Issued To: **Medical Components, Inc.**
dba Medcomp
1499 Delp Drive
Harleysville
Pennsylvania
19438
USA

Date	Reference Number	Action
21 October 2019	9714913	Transfer error correction: Amendment of Scope statement to update devices that were incorrectly added to the Production Quality Assurance Certificate issued by previous Notified Body and aligned devices and suppliers with the correct certificates. Administrative update to product table format, clarified products per updates to scope statement above as follows: ▪ Rename device in the IIa Table: Tearaway (was Valved Tearaways). ▪ Remove devices from the IIa Table: Midline Catheter (to CE 616020), Short Term Infusion Catheter and Accessories (Discontinued), Short Term Haemodialysis Catheter and Accessories (To CE 616020), Adaptors (Included with Luers and Adaptors), Extension Sets (in scope of CE 616022), Luers and Adaptors (to CE 616020), Connectors (to CE 616020), Surgical Gloves (Discontinued), Tunnelers (to CE 616020), 3-Way Stopcock (Discontinued), Micro Stick Introducer Set (to CE 616020), Valves (Included with Tearaways). ▪ Move devices from Class Is to Class IIa Table: Caps and Plugs, Clamps. ▪ Add Intended Purpose for each device in IIa and Is Tables.

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 616021**

Date: **2020-06-17**

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

Date	Reference Number	Action
21 October 2019 (continued)	9714913	Updated suppliers: Added Heraeus Components SRL-Costa Rica, Micro Molding Inc.-NJ, Qosina Corporation-NY, Isomedix Operations-Temecula CA, Surgical Specialties Corporation-Mexico, TIDI Products LLC-WI, and Viscot Medical LLC-NJ. Updated Name from Steris Isomedix Operations to Isomedix Operations, Inc. Updated Address for Becton Dickinson to San Antonio TX. Removed B. Braun Medical PA, Greatbatch Inc MN, Halkey-Roberts Corp. FL, HD Surgical-Spurrier Medical-a Division of Harwood Design Inc. PA, Heraeus Components LLC MN, Industrie Borla Inc. Italy, Medron Inc. UT, PHS Medical GmbH Germany, and Spectra Medical Devices Inc MA.
23 April 2020	3061343	Certificate Renewal. Corrected subcontractor addresses for: Micro Moldings, Surgical Specialties, TIDI Products

By Royal Charter

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 616021**

Date: **2020-06-17**

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

Date	Reference Number	Action
Current	3152698	Remove Centurion as EtO sterilization supplier.

...making excellence a habit.™