

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 haemodialysis, 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**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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Supplementary Information to CE 616021

Issued To:

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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.

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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.

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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.

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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:

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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

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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 Guangdong Province China	Crucial Supplier
Heraeus Components SRL Parque Industrial Zona Franca La Lima Guadalupe Building 29 Cartago 30106 Costa Rica	Crucial Supplier

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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

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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

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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

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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

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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

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Subcontractor:

Service(s) supplied

Viscot Medical, LLC
 32 West Street
 East Hanover
 New Jersey
 07936
 USA

Crucial Supplier

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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.

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Date	Reference Number	Action
21 October 2019	9714913	<p>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.</p> <p>Administrative update to product table format, clarified products per updates to scope statement above as follows:</p> <ul style="list-style-type: none"> ▪ 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.

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Date	Reference Number	Action
21 October 2019 (continued)	9714913	<p>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.</p> <p>Updated Name from Steris Isomedix Operations to Isomedix Operations, Inc.</p> <p>Updated Address for Becton Dickinson to San Antonio TX.</p> <p>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.</p>
23 April 2020	3061343	<p>Certificate Renewal.</p> <p>Corrected subcontractor addresses for: Micro Moldings, Surgical Specialties, TIDI Products</p>

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

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