

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 Sterile Peripherally Inserted Midline Catheters for intravenous therapies, blood sampling and power injection of contrast media, Short Term Haemodialysis Catheters and Accessories, Short Term Infusion Catheters and Accessories and Accessories for Acute and Long-Term Vascular Access Catheters.
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):



Albert Roossien, Regulatory Lead

First Issued: **2016-08-11**

Date: **2019-02-26**

Expiry Date: **2021-08-10**

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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:

**Medical Components, Inc.
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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0102	Midline Catheter	N/A
MD 0102	Short term infusion catheter and accessories	N/A
MD 0102	Short Term Haemodialysis Catheter and accessories	N/A
MD 0106	Adaptors	N/A
MD 0106	Dilator & Sheaths	N/A
MD 0106	Extension Sets	N/A
MD 0106	Guidewires	N/A
MD 0106	Introducers	N/A
MD 0106	Luers and Adaptors	N/A
MD 0106	Needles	N/A
MD 0106	Picks	N/A

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

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

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Scalpels	N/A
MD 0106	Stylets	N/A
MD 0106	Surgical gloves	N/A
MD 0302	Sutures	N/A
MD 0102	Syringes	N/A
MD 0106	Tunnelers	N/A
MD 0106	3-Way Stopcock	N/A
MD 0106	Micro Stick Introducer Set	N/A

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Number	Device Name	Intended purpose per IFU
Class Is		
MD 0106	Tourniquets	N/A
MD 0301	Dressings	N/A
MD 0106	Scissors	N/A
MD 0106	Drapes	N/A
MD 0106	Anchoring Devices	N/A
MD 0106	Wraps	N/A
MD 0106	Gauzes	N/A
MD 0106	Caps and Plugs	N/A
MD 0106	Clamps	N/A

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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
B. Braun Medical Inc. 824 12th Avenue Bethlehem Pennsylvania 18018 USA	Crucial Supplier
Bard Access Systems, Inc. 605 North 5600 West Salt Lake City Utah 84116 USA	Crucial Supplier
Becton Dickinson & Co. BD Medical Surgical Systems 1 Becton Drive Franklin Lakes New Jersey 07417 USA	Crucial Supplier

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Subcontractor:	Service(s) supplied
Centurion Medical Products Corporation 3173 East 43rd Street Yuma Arizona 85365 USA	ETO Sterilization
Cosmed Group, Inc. d.b.a Cosmed of NJ 19 Park Drive, Franklin New Jersey 07416 USA	ETO Sterilization
Galt Medical Corp 2220 Merritt Drive Garland, TX 75041 USA	Crucial Supplier

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Subcontractor:	Service(s) supplied
Greatbatch Medical 2300 Berkshire Lane North Minneapolis MN 55441 USA	Crucial Supplier
Guangdong Baihe Medical Technology Co., Ltd No 89 Taoyuan East Road Nanhai, Foshan 528225 Guandong Province China	Crucial Supplier
Halkey-Roberts Corp. 2700 Halkey-Roberts Place N St Petersburg Florida 33716 USA	Crucial Supplier

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Subcontractor:	Service(s) supplied
HD Surgical – Spurrer Medical a Division of Harwood Design, Inc. 1507 Clyde Waite Drive Bristol Pennsylvania 19007 USA	Crucial Supplier
Heraeus Medical Components, LLC 2605 Fernbrook Lane North, Suite J Plymouth Minnesota 55447 USA	Crucial Supplier
ICU Medical, Inc. 951 Calle Amanecer San Clemente California 92673 USA	Crucial Supplier

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Subcontractor:	Service(s) supplied
Industrie Borla S.P.A. Via G. di Vittorio, 7 bis 10024 Moncalieri (TO) Italy	Crucial Supplier
Lake Region Medical 340 Lake Hazeltine Drive Chaska Minnesota 55318 USA	Crucial Supplier
Martech Medical Products S. de R.L. de C.V. Calle Mercurio No. 46 Parque Industrial Mexicali 1 Mexicali, Baja California 21210 Mexico	Manufacture

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Subcontractor:	Service(s) supplied
Medline Industries, Inc. Three Lakes Drive Northfield Illinois 60093 USA	Crucial Supplier
Medron, LLC 1518 South Gladiola Street Salt Lake City Utah 84104 USA	Crucial Supplier
MPS Medical Product Service GmbH Borngasse 20 Braunfels 35619 Germany	EU Representative

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Subcontractor:	Service(s) supplied
Neomedical Inc. 1375 Greg Street #108 Sparks Nevada 89431 USA	Crucial Supplier
PHS Medical GmbH Ederweg 3 34277 Fuldabrück Germany	Crucial Supplier
Sklar Instruments 889 South Matlack Street West Chester Pennsylvania 19382 USA	Crucial Supplier

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Subcontractor:	Service(s) supplied
Southmedic Inc. 50 Alliance Blvd Barrie Ontario L4M 5K3 Canada	Crucial Supplier
Spectra Medical Devices, Inc. 260-H Fordham Road Wilmington Massachusetts 01887 USA	Crucial Supplier
Sterigenics US, LLC 5725 West Harold Gatty Drive Salt Lake City Utah 84116 USA	ETO Sterilization

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Subcontractor:

Service(s) supplied

Teleflex Medical, Inc.
50 Plantation Drive
Jaffrey
New Hampshire
03452
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.
Current	8958818	Traceable to NB 0086.