EC Certificate - Full Quality Assurance System

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

No. **CE 565719**

Issued To: **Argon Medical Devices, Inc.**
also trading as Becton Dickinson
Infusion Therapy Systems Inc.
1445 Flat Creek Road
Athens
Texas
75751
USA

In respect of:

The design and manufacture of single use instruments, catheters and access devices for intravascular and non-vascular applications, biopsy devices, fluid administration and pressure monitoring 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 0086):

Gary Fenton, Global Assurance Director

First Issued: **28/02/2011** Date: **19/02/2014** Expiry Date: **01/12/2017**

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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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.

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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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Subcontractor:	**Service(s) supplied**
Becton Dickinson Infusion Therapy Systems, Inc. 9450 South State Street Sandy Utah 84070 USA	**Control of Sterilization** **Manufacture** **Packaging**
Argon Critical Care Systems Singapore Pte. Ltd. 198 Yishun Avenue 7 Singapore 768926 Singapore	**ETO Sterilization** **Manufacture** **Packaging**
Shanghai Greenway Medical Apparatus Co., Ltd. (Supplied through International Medsurg Connection) No. 3899, Puxing Road Shanghai 201112 China	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Ningbo Shengyurui Medical Appliances Co., Ltd. (Supplied through International Medsurg Connection) No. 138, Binhaisi Road, Hangzhou Bay New Zone Cixi City, Zhejiang Province China	**Manufacture**
Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands	**EU Representative**
Medron, Inc. 1518 South Gladiola St. Salt Lake City Utah 84104 USA	**Manufacture**
Greatbatch Medical 2300 Berkshire Lane North Minneapolis Minnesota 55441 USA	**Manufacture**
B. Braun Medical, Inc. 824 Twelfth Avenue Bethlehem Pennsylvania 18018 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
M/s Ribbel International Ltd. (Supplied through International Medsurg Connection) 20th Mile G.T. Road, Jatheri Road P.O. RAI Sonepat 131029 Haryana India	**Manufacture**
Martech Medical Products, Inc. 1500 Delp Drive Harleysville Pennsylvania 19438 USA	**Manufacture**
Aspen Surgical Puerto Rico Corp. Road 183, KM 20.3 Las Piedras 00771 Puerto Rico	**Manufacture**
Accellent, Inc. 45 Lexington Laconia New Hampshire 03246 USA	**Manufacture**
Lemco Enterprises P.O. Box 1407 3204 Hale Road Ardmore 73402 Oklahoma USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Halkey-Roberts Corp. 2700 Halkey-Roberts Place N St. Petersburg FL 33716 USA	**Manufacture**
Rex Medical, L.P. 1100 East Hector Street, Suite 245 Conshohocken PA 19428 USA	**Design**
Aspen Surgical Products, Inc. 6945 Southbelt Drive, SE Caledonia Michigan 49316 USA	**Manufacture**
Becton Dickinson Infusion Therapy Systems, Inc. S.A. de C.V. Periferico L. D. Colosio #579 Nogales, Sonora C.P. 84048 Mexico	**Control of Sterilization** **Manufacture** **Packaging**
3M Health Care dba 3M Consumer Health Care 3M Center, Building 275 St Paul Minnesota 55144-1000 USA	**Manufacture**

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Subcontractor:	**Service(s) supplied**
Wenzhou KLF Medical Plastics Co., Ltd. (Supplied through International Medsurg Connection) No. 258, Tongqiang West Road Wenzhou 325024 China	**Manufacture**
Synergy Health AST, LLC 500 West 4th Street Lima OH 45804 USA	**E beam Sterilization**
Manan Medical Products Inc also dba Angiotech 241 W. Palantine Road Wheeling Illinois 60090 USA	**Manufacture**
Sterigenics US, LLC 1302 Avenue T Grand Prairie Texas 75050 USA	**ETO Sterilization**

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Subcontractor:	**Service(s) supplied**
Pelham Plastics Inc 42 Dick Tracy Drive P.O. Box 997 Pelham New Hampshire 03076-0967 USA	**Manufacture**
STERIS Isomedix Services 2072 Isomedix Services Spartanburg South California 92590 USA	**ETO Sterilization**

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
28 February 2011	7561304	First Issue - Transfer from another Notified Body
11 October 2011	7752883	"Also trading as Becton Dickinson Infusion Therapy Systems Inc." added to the manufacture name. Becton Dickinson Infusion Therapy Systems, Inc. S.A. de C.V., Becton Dickinson Infusion Therapy Systems, Inc., Argon Critical Care Systems Singapore Pte. Ltd. and B.Braun Medical Inc. added to the list of significant subcontractors.
25 January 2012	7791401	3M Health Care, Aspen Surgical Products, Medron, Greatbatch Medical and Martech Medical Products added to the list of significant subcontractors.
03 August 2012	7807038	Rex Medical, Aspen Surgical Puerto Rico and Halkey-Roberts added to the list of significant subcontractors.
31 October 2012	7842537	Certificate Renewal. Address change for Ningbo Shengyurui Medical Appliances and M/s Ribbel International.
19 February 2014	8108569	Scope extension to include biopsy devices and access devices for non-vascular applications. List of subcontractors updated to include the significant suppliers involved in the manufacturing of the new products.

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