

EC Certificate - Full Quality Assurance System

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

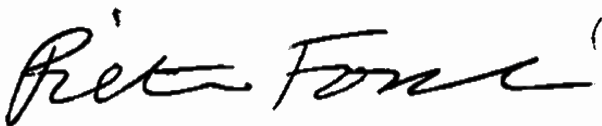
No. CE 543532
Issued To: **Bayer Medical Care Inc.**
Also doing business as Medrad, Inc.
1 Bayer Drive
Indianola
Pennsylvania
15051-0780
USA

In respect of:

The design, development and manufacture of vascular injection systems, sterile disposable syringes, sterile disposable administration sets, MRI endo-rectal coils, vital signs monitors and infusion pump systems. Those aspects of Annex II concerned with securing and maintaining sterile conditions of disposable accessories for vascular injection systems.

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):



Pietro Foschi - Strategic Delivery Director

First Issued: **11 December 2008**

Date: **04 March 2015**

Expiry Date: **20 March 2020**

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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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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	Service(s) supplied
Availmed S.A. de C.V. Av. Paseo Reforma No. 8950 Interior B1,C1,E1,E2,F2,G1 (Local A,B,C,G,H) La Mesa Tijuana C.P. 22116 Mexico	Sterile Manufacture
B. Braun Medical, Inc. 824 Twelfth Avenue Bethlehem Pennsylvania 18018 USA	Sterile Manufacture
B. Braun of Dominican Republic Inc. Z. Franca, Ind'l Las Américas Las Américas, KM #22 Santo Domingo Dominican Republic	Manufacture

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Subcontractor:	Service(s) supplied
Bayer Medical Care Inc. 625 Alpha Drive Pittsburgh Pennsylvania 15238 USA	Manufacture
Bayer Medical Care Saxonburg, Inc. 150 Victory Road Saxonburg Pennsylvania 16056 USA	Manufacture Sterile Manufacture
Bayer Medical Care, B.V. Horsterweg 24 6199 AC Maastricht Airport Netherlands	EU Representative
Caesarea Medical Electronics Ltd 16 Shacham Street Industrial Park Caesarea North 38900 Caesarea Israel	Manufacture

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Subcontractor:	Service(s) supplied
Criticare Systems, Inc. N7 W22025 Johnson Drive Waukesha Wisconsin 53186 USA	Manufacture
Merit Medical Systems Inc. 1600 West Merit Parkway South Jordan Utah 84095 USA	Sterile Manufacture
Microtek Dominicana, S.A. Zona Franca, # 2 La Romana Dominican Republic	Sterile Manufacture
Sterigenics US, LLC 10811 Withers Cover Park Drive Charlotte North Carolina 28278 USA	Gamma Sterilization

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Subcontractor:	Service(s) supplied
Sterigenics US, LLC 305 Enterprise Drive Westerville Ohio 43081 USA	Gamma Sterilization
Sterigenics US, LLC 7775 South Quincy Willowbrook Illinois 60527 USA	ETO Sterilization
Struckmyer, LLC Also trading as Strukmyer Medical 1801 Big Town Blvd, Suite 100 Mesquite Texas 75149 USA	Sterile Manufacture

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Subcontractor:	Service(s) supplied
Synergy Health Americas 500 West 4th Street Lima Ohio 45804 USA	E beam Sterilization
Synergy Health AST, LLC 7225 North Noah Drive Saxonburg Pennsylvania 16056 USA	E beam Sterilization
Vincent Medical (Dong Guan) Manufacturing Co., Ltd. 45-46 ShaBu Industrial Zone Qiao Long District, Tang Xia Town Dong Guan City Guangdong China	Sterile Manufacture

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Date	Reference Number	Action
11 December 2008	7287824	First Issue – transfer from another Notified Body
20 August 2009	7371981	Merger of BSI EC Certificates CE 543532 and CE 76721 resulting in the following: Extension to scope of CE 543532 to include 'minimally invasive tissue and thrombus removal devices, and vascular occlusion devices' Addition to the list of significant sub-contractors: STERIS Isomedix Services for ETO Sterilization. Minnetronix Inc for Manufacture and Testing. Medrad, Inc for Manufacture. STERIS Isomedix Services for Gamma Sterilization, Heraeus Medical Components for Manufacture and Testing. Removal of MRI Surface Coils, Oximeters and Multigas Monitors from the scope. Addition to the list of significant subcontractors: Sterigenics US, LLC for EO Sterilization Sterigenics US, LLC for Gamma Sterilization Merit Medical Systems Inc, for Sterile Manufacture and Brady Precision Converting for Sterile Manufacture Addition of Sterile Manufacture as an activity for the sub-contractor 'MEDRAD Saxonburg, Inc'.

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Date	Reference Number	Action
29 February 2010	7480635	Addition of BeamOne LLC as a significant sub-contractor for E Beam sterilization. Certificate renewal.
16 April 2010	7521260	Addition of Sterigenics US, LLC, 10811 Withers Cover Park Drive, Charlotte, North Carolina, 28278, USA as a significant subcontractor for the activity of Gamma Sterilization.
25 November 2010	7602702	Addition of Beam One LLC, 7225 North Noah Drive, Saxonburg, PA 16056, USA as a significant subcontractor for the activity of E Beam Sterilization
03 February 2012	7794530	Addition of Pathway Medical Technologies, Inc. as a significant subcontractor for design, manufacture and sterile manufacture and change of name of significant subcontractor BeamOne LLC to Synergy Health AST, LLC
20 December 2012	7932272	Addition of Microtek Dominicana, S.A., B. Braun Medical Inc., B. Braun of Dominican Republic Inc. and Availmed S.A. de C.V. as significant subcontractors for manufacture. Removal of Medegen MMS as a significant subcontractor.

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Date	Reference Number	Action
12 February 2014	8110074	Change of legal manufacturer name from MEDRAD Inc. to Bayer Medical Care Inc. and of address from One Medrad Drive to 1 Bayer Drive. Change of name of other MEDRAD sites listed as significant subcontractors to Bayer Medical Care. Addition of Bayer Medical Care Inc., 8880 Evergreen Blvd. NW Minneapolis, Minnesota 55433, USA as a significant subcontractor for design and manufacture, and Lake Region Medical as a significant subcontractor for manufacture. Change of name of significant subcontractor from Brady Precision Converting to Struckmyer, LLC. Removal of Pathway Medical Technologies, Inc. and Sterigenics, Glens Falls, New York as significant subcontractors.
07 November 2014	82251920	Change of Company name from Bayer Medical Care Inc to Bayer Medical Care Inc also doing business as Medrad, Inc. Removal of 3 significant subcontractors:- Avail Medical for Sterile Manufacture. STERIS Isomedix Services Inc. for Gamma Sterilization. Heraeus Medical Components for Manufacture and Testing. Change of address of significant subcontractor Bayer Medical Care, B.V. from P.O. Box 205, 6190 AE Beek, Netherlands to Horsterweg 24, 6199 AC Maastricht Airport Netherlands.

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Date	Reference Number	Action
04 March 2015	8283498	Certificate renewal. Transfer of 'minimally invasive tissue and thrombus removal devices' to CE 631845. Removal of the following significant subcontractors: Bayer Medical Care Inc. sites in Minneapolis, Minnesota and Warrendale, Pennsylvania, Lake Region Medical, STERIS Isomedix Services in Minneapolis, Minnesota, and Minnetronix, Inc. Change of address for significant subcontractor Criticare Systems, Inc. Clarification to scope to separate Class I sterile disposable accessories for vascular injection systems.