

# EC Certificate - Full Quality Assurance System

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

**No.**

**CE 66263**

**Issued To:**

**ACIST Medical Systems, Inc.  
7905 Fuller Road  
Eden Prairie  
Minnesota  
55344  
USA**

In respect of:

**The design and manufacture of Contrast Injection Systems including EDA module and sterile disposable kits used in diagnostic and interventional imaging procedures, and intravascular diagnostic systems including sterile 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, Senior Vice President Medical Devices

First Issued: **2002-04-26**

Date: **2021-03-15**

Expiry Date: **2024-05-26**

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## Supplementary Information to CE 66263

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NBOG Code	Device Name	Intended purpose per IFU
<b>Class IIb</b>		
MD 1101	CVi system	Controlled infusion of radiopaque contrast media for angiographic procedures.
<b>Class IIa</b>		
MD 1301	Rapid Exchange (RXi) System	N/A
MD 1202	High Definition (HDi) System	N/A
MD 0102	CVi Consumables/Disposables	N/A

First Issued: **2002-04-26**Date: **2021-03-15**Expiry Date: **2024-05-26**

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## List of Significant Subcontractors

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

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 Date: **2021-03-15**  
 Issued To: **ACIST Medical Systems, Inc.**  
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Subcontractor:	Service(s) supplied
Acist Europe BV Argonstraat 3 6422 PH Heerlen The Netherlands	EU Representative Labelling
Forte Grow Medical (Vietnam) Co. Ltd. 20 Tu Do Blvd Vietnam-Singapore, Industrial Park Thuan An Town, Binh Duong Province Vietnam	ETO Sterilization
Freudenberg Medical, LLC 2301 Centennial Boulevard Jeffersonville Indiana 47130 USA	Manufacture

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Subcontractor:	Service(s) supplied
FUJIKURA FIBER OPTICS VIETNAM LTD. No.9 VSIP Street 6, Vietnam Singapore Industrial Park, Binh Hoa Ward, Thuan An Town, Binh Duong Province, Vietnam	<b>Manufacture</b>
Isomedix Operations, Inc. 7685 Saint Andrews Avenue San Diego California 92154 USA	<b>ETO Sterilization</b>
Medical Product Service GmbH Borngasse 20 35619 Braunfels Germany	<b>EU Representative</b>

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Subcontractor:	Service(s) supplied
NPA de México S. de R.L. de C.V. Sor Juana Ines de la Cruz #20150, Interior 5 Cd. Industrial Tijuana Baja California CP 22444 Mexico	Manufacture
Sterigenics US, LLC 1401 Morgan Circle Tustin California 92780 USA	Radiation (Gamma Sterilization)
Sterigenics US, LLC 4900 Gifford Avenue Los Angeles California 90058 USA	ETO Sterilization

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### Subcontractor:

### Service(s) supplied

Sterigenics US, LLC  
 344 Bonnie Circle  
 Corona  
 California  
 92880  
 USA

**Radiation (Gamma Sterilization)**

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Date	Reference Number	Action
26 April 2002	4309960	First Issue.
08 February 2005	4658177	Tyco Healthcare (Mexico) removed and Nypro Precision Assemblies (Mexico) added to list of subcontractors. IBA name changed to Sterigenics.
21 July 2006	4823884	Extension of scope to include syringe pumps for delivery of contrast agent for Ultrasound Echography Addition of subcontractors 'AP Technologies SA' and 'SIDAM s.a.s' for the manufacture of VueJect infusion device Addition of EU Representative as a subcontractor activity for Medical Product Service GmbH.
11 September 2006	4843449	Extension of scope to include Infusion Pumps for delivery of Rubidium-82 Addition of subcontractors: RbM Services LLC for the manufacture of the Infusion pumps for the delivery of Rubidium-82 and B Braun Medical, Inc for the manufacture of sterilized disposable accessories for Infusion pumps for the delivery of Rubidium-82.
20 March 2007	7001464	5-year certificate renewal. Editorial changes to list of significant subcontractors.
24 July 2007	7061535	Company address change from 7450 Flying Cloud Drive, Suite 150, Eden Prairie, MN 55344, USA to 7905 Fuller Road, Eden Prairie, MN 55344, USA Addition of Steris Isomedix Services for ETO Sterilization.

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Date	Reference Number	Action
23 May 2008	7213217	Change of name of significant sub-contractor AP Technologies SA to Valtronics Technologies SA.
24 September 2008	7279847	Change of scope to 'The design and manufacture of contrast injection systems including EDA module and sterile disposable kits used in diagnostic and interventional imaging procedures, Infusion pumps for delivery of contrast agent used in ultrasound echography, and syringe pumps for delivery of Rudidium-82 Addition of the following significant sub-contractors: 1) Smiths Healthcare Manufacturing, S.A. de C.V., Carretera Miguel Aleman KM 21.7, Parque. Industrial Monterrey Apodaca N.L., CP 66603, Mexico for the activity of Sterile. Manufacture 2) Coeur Medical, a Division of Coeur Inc, 209 Creekside Drive, Washington, North Carolina, 27889, USA for the activity of sterile manufacture 3) Ludlow Technical Products Canada Ltd, 215 Herbert Street, Gananoque, Ontario, K7G 2Y7, Canada for the activity of manufacture 4) Acist Europe BV, Renier Nafzgerstraat 114, 6221 KL Maastricht, The Netherlands for the activity of EU representative.

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Date	Reference Number	Action
05 October 2009	7446088	Change of address of the significant sub-contractor Nypro Precision Assemblies de Mexico S.A. de C.V. from Blvd. Bella Artes #20181, Cd. Industrial Nuvea Tijuana Otay, Tijuana, Baja California, Mexico, 22509 to Sor Juana Ines de la Cruz #20150, Cd. Industrial, Tijuana, Baja California, CP 22444, Mexico.
28 January 2011	7522042	Certificate reissue due to extension to scope to include 'computer aided reporting systems for diagnostic imaging'. Addition of significant subcontractor CADMEI Software-Entwicklung für Medizinsysteme GmbH for the activities of software, design and manufacture. Addition of BYTEC Medizintechnik GmbH as the significant subcontractor for design and manufacture.

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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.

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Date	Reference Number	Action
8 March 2012	7650560	Certificate renewal incorporating the following certificate changes: Scope reduction Syringe pumps for delivery of Rubidium 82 and computer aided reporting systems removed List of Significant Subcontractors -RbM Services LLC removed -B. Braun Medical, Inc. removed -CADMEI Software-Entwicklung fur Medizinsysteme GmbH removed -Smiths Healthcare Manufacturing, S.A. de C.V. removed - Activities corrected to 'sterile manufacture' for Nypro Precision Assemblies de Mexico S.A. de C.V. - Address changed to 'Hermann-Hollerith-Str. 11, 52249 Eschweiler' for BYTEC Medizintechnik GmbH SIDAM s.a.s. Di Azzolini Graziano & Co corrected to SIDAM S.r.l.
25 June 2012	7848206	Addition of Phillips Plastics Corporation as a significant subcontractor for sterile manufacture.

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Date	Reference Number	Action
30 October 2012	7910887	Addition of Sterigenics US, LLC, Tustin, as a significant subcontractor for gamma sterilization.
26 September 2013	7960273	Addition of MedVenture and Sterigenics (Willowbrook facility) to the list of significant subcontractors. Scope extension to include intravascular diagnostic systems including sterile catheters.
27 June 2015	8347634	Amendment to scope, removal of subcontractors, 'Valtronics Technologies SA' and 'SIDAM S.r.l.'.
06 April 2016	8498637	Addition of Fujikura Fiber Optics Vietnam (FOV) Limited, Forte Grow Medical (FGM) (Vietnam) Co. Ltd. and Acist Medical Systems Inc., to the list of significant subcontractors. Change of address for Acist Europe BV. Identification of Ludlow Technical products as A division of Covidien. Amendment of services provided by Medventure from "Manufacture, Assembly and Testing" to "Sterile Manufacture".
24 April 2017	8676113	Certificate renewal. Removal of BYTEC Medizintechnik GmbH, Coeur Medical and Ludlow Technical Products Canada Ltd as significant subcontractors. Change of name of sub-contractor from MedVenture Technology Corporation to Freudenberg Medical MIS, Inc.

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Date	Reference Number	Action
7 July 2018	8750368	Removal of subcontractor ACIST Medical Systems, Inc., 47621 Westinghouse Drive, Fremont, California, 94539, USA.
15 February 2019	8935986	Traceable to NB 0086. Administrative Subcontractor Service wording update for: Freudenberg Medical MIS, Inc, IN 47130, USA from "Sterile Manufacture" to "Manufacture". FUJIKURA FIBER OPTICS VIETNAM LTD, No.9 VSIP Street 6, Singapore Industrial Park, Binh Hoa Ward, Thuan An Town, Vietnam from "Sterile Manufacture" to "Manufacture". NPA De México S. de R.L. de C.V., Sor Juana Ines de la Cruz, #20150, Interior 5, Cd. Industrial, Tijuana, CP 22444, Mexico from "Sterile Manufacture" to "Manufacture" Phillips Plastics Corporation, Philips Medical, 409 Technology Drive, Menomonie, Wisconsin, 54751, USA from "Sterile Manufacture" to "Manufacture"

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Date	Reference Number	Action
Current	3297413	Certificate renewal. Administrative typo errors corrected. Removal of subcontractors 'Philips Plastics Corporation' and 'Sterigenics US, LLC, Willowbrook, Illinois'. Amendment of name of 'Steris Isomedix Services, Inc' to 'Isomedix Operations, Inc'. Service 'Labelling' added to the subcontractor 'Acist Europe BV'. Device table added.

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