

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Becton Dickinson Infusion
Therapy Systems Inc.
9450 South State Street
Sandy
Utah
84070
USA

Holds Certificate No:

FM 71665

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 for the following scope:

The design, development, manufacture and distribution of disposable, sterile medical devices including needles, catheter for peripheral and central vascular access and insertion procedure trays, catheter introducers, catheter adapters, catheter flush valves and connector/adaptor tubing, catheter injection ports, extension tubing, stopcocks and catheter accessories. The design, development, manufacture and distribution of surgical scrub brushes and anti-microbial solution dispensers. The manufacture of microbiological reagent droppers, culture collection and transport devices, disposable environmental chambers and syringe assemblies. On-Site EO Sterilization, including contract sterilization, for medical devices. The design, development, manufacture and distribution of sterile cannula products.

For and on behalf of BSI:

Reg Blake, VP Regulatory Affairs, BSI Group America Inc.

Original Registration Date: 12/17/2002

Effective Date: 11/11/2015

Expiry Date: 11/10/2018



CMDCAS
Recognized
Registrar



Page: 1 of 2

...making excellence a habit.™

Certificate No: **FM 71665**

Location	Registered Activities
Becton Dickinson Infusion Therapy Systems Inc. 9450 South State Street Sandy Utah 84070 USA	The design, development, manufacture and distribution of disposable, sterile medical devices including needles, catheter for peripheral and central vascular access and insertion procedure trays, catheter introducers, catheter adapters, catheter flush valves and connector/adaptor tubing, catheter injection ports, extension tubing, stopcocks and catheter accessories. The design, development, manufacture and distribution of surgical scrub brushes and anti-microbial solution dispensers. The manufacture of microbiological reagent droppers, culture collection and transport devices, disposable environmental chambers and syringe assemblies. On-Site EO Sterilization, including contract sterilization, for medical devices. The design, development, manufacture and distribution of sterile cannula products.
Becton Dickinson Infusion Therapy Systems Inc. S.A. de C.V. Periferico Luis Donaldo Colosio#579 Nogales Sonora C.P.84048 Mexico	The manufacture of disposable sterile and non-sterile medical devices including needles, catheters for peripheral and central vascular access and insertion procedure trays; the manufacture of microbiological reagent droppers, culture collection and transport devices, disposable environmental chambers and syringe assemblies. Support processes including design transfer and validation activities for the BD Infusion Therapy Systems facility at Utah.
Becton Dickinson Infusion Therapy Systems, Inc. 745 North Target Range Road Nogales Arizona 85621 USA	The manufacture of disposable sterile and non-sterile medical devices including needles, catheters for peripheral and central vascular access and insertion procedure trays; the manufacture of microbiological reagent droppers, culture collection and transport devices, disposable environmental chambers and syringe assemblies. Support processes including design transfer and validation activities for the BD Infusion Therapy Systems facility at Utah.

Original Registration Date: 12/17/2002

Effective Date: 11/11/2015

Expiry Date: 11/10/2018

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.



This is to certify that the Quality Management System of:

RR Donnelley - Global Turnkey Solutions

6315 West by Northwest Blvd.
Houston TX 77040

Central function listed above. See appendix for additional locations

applicable to:

Supply Chain Management, Turnkey Manufacturing and Order Fulfillment Services.

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 9001: 2008

For and on behalf of NQA, USA

Certificate Number: 15436

EAC Code: 29

Certified Since: September 18, 2001

Valid Until: September 14, 2018

Reissued: April 7, 2016

Cycle Issued: April 7, 2016





Appendix to Certificate Number: 15436

Includes Facilities Located at:

RR Donnelley - Global Turnkey Solutions

Certificate Number 15436
6315 West by Northwest Blvd.
Houston TX 77040
United States of America

Supply Chain Management, Turnkey Manufacturing
and Order Fulfillment Services.

**RR Donnelley Global Turnkey
Solutions Mexico S.DE.R.L DE D.V.**

Certificate Number 15436
Boulevard Internacional #881 San Jeronimo
Chihuahua, C.P. 32505
Mexico

Assembly, Test, Configuration, Services of the Hard
Disk.



Certified Since: September 18, 2001

Valid Until: September 14, 2018

Reissued: April 7, 2016

Cycle Issued: April 7, 2016