

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Catheter Research, Inc.
D.B.A. Thomas Medical
6102 Victory Way
Indianapolis
Indiana
46278
USA

Holds Certificate No:

FM 45439

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

The design and manufacture of single-use sterile medical devices including: catheters and kits, LLETZ/LEEP electrodes, and wound surgical suction tip. Contract manufacturing and specification development of medical devices, distribution of surgical instruments, and extrusion and insert molding of plastics. Manufacture of medical balloons (non-sterile) to customer specifications.

For and on behalf of BSI:



Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 1999-03-31

Effective Date: 2017-11-07

Expiry Date: 2018-12-31



CMDCAS
Recognized
Registrar



Page: 1 of 2

...making excellence a habit.™

Certificate No: **FM 45439**

Location	Registered Activities
Catheter Research, Inc. dba. Thomas Medical 6102 Victory Way Indianapolis Indiana 46278 USA	The design and manufacture of single-use sterile medical devices including: catheters and kits, LLETZ/LEEP electrodes, and wound surgical suction tip. Contract manufacturing and specification development of medical devices, distribution of surgical instruments, and extrusion and insert molding of plastics.
Catheter Research, S.R.L. Edificio 22-23 D Zona Franca Parque Industrial Zeta Cartago, Costa Rica Costa Rica	The contract manufacture of medical tubing assemblies.
CRI Wexford Wexford Enterprise Centre Strandfield Business Park Kerlogue Rosslare Road Wexford Ireland	Manufacture of medical balloons to customer specifications.



Original Registration Date: 1999-03-31

Effective Date: 2017-11-07

Expiry Date: 2018-12-31

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.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.