

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Catheter Research, Inc.
dba.Thomas Medical
6102 Victory Way
Indianapolis
Indiana
46278
USA

Holds Certificate Number:

MD 560630

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design and manufacture of single-use sterile catheters and kits, LLETZ/LEEP electrodes and wound surgical suction tips.

Contract manufacturing of non-sterile medical tubing assemblies, contract manufacturing, specification development and distribution of sterile catheters and electrodes.

Extrusion of plastics for medical use.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2010-03-08

Latest Revision Date: 2020-12-22

Effective Date: 2020-12-24

Expiry Date: 2021-06-23

Page: 1 of 2



003

...making excellence a habit.™

Certificate No: **MD 560630**

Location

Catheter Research, Inc.
6102 Victory Way
Indianapolis
Indiana
46278
USA

Registered Activities

The design and manufacture of single-use sterile catheters and kits, LLETZ/LEEP electrodes and wound surgical suction tips.

Contract manufacturing of non-sterile medical tubing assemblies, contract manufacturing, specification development and distribution of sterile catheters and electrodes.

Extrusion of plastics for medical use.

Catheter Research, S.R.L.
Edificio 22-23 D Zona Franca
Parque Industrial
Zeta Cartago, Costa Rica
Costa Rica

Contract manufacturing of non-sterile medical tubing assemblies



Original Registration Date: 2010-03-08

Latest Revision Date: 2020-12-22

Effective Date: 2020-12-24

Expiry Date: 2021-06-23

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.