

# 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 sterile and non-sterile medical tubing assemblies, contract manufacturing, specification development and distribution of sterile surgical instruments, catheters and electrodes.  
Extrusion and insert moulding of plastics for medical use.

Previous certificate expires on 28/02/2019  
Transition audit ended 21/02/2019



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2010-03-08

Latest Revision Date: 2019-02-28

Effective Date: 2017-12-24

Expiry Date: 2020-12-23

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Certificate No: **MD 560630**

Location

Registered Activities

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Indianapolis  
Indiana  
46278  
USA

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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



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