

Certificate of Registration

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

This is to certify that:

VistaMed Limited
IDA Business & Technology Park
Carrick-on-Shannon
Co. Leitrim
Ireland

Holds Certificate Number:

MD 80941

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, development and manufacture of medical grade tubing, balloon catheters, balloons, medical plastic components and devices. The contract manufacture and primary packaging of coronary stent systems including drug eluting stents to customer specifications. Distribution of medical devices.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2004-01-26

Latest Revision Date: 2019-01-15

Effective Date: 2016-11-02

Expiry Date: 2019-11-01

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Certificate No: **MD 80941**

Location	Registered Activities
VistaMed Limited IDA Business & Technology Park Carrick-on-Shannon Co. Leitrim Ireland	The design, development and manufacture of medical grade tubing, balloon catheters, balloons, medical plastic components and devices. The contract manufacture and primary packaging of coronary stent systems including drug eluting stents to customer specifications. Distribution of medical devices.
VistaMed Limited Rooskey Co. Leitrim Ireland	The development and manufacture of medical grade tubing, balloon catheters, balloons, medical plastic components and devices.
VistaMed R&D Centre Attirory Business Park Carrick-on-Shannon Co. Leitrim Ireland	The design and development of medical grade tubing, balloon catheters, balloons, medical plastic components and devices.



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Printed copies can be validated at www.bsigroup.com/ClientDirectory

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