



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Creganna Medical S.R.L. 400m Este de Holcim, Zona Industrial Flexipark Bodega G6 San Rafael Costa Rica

Holds Certificate No:

FM 680418

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

Manufacture of Guidewires and Catheters.

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For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-12-22 Latest Revision Date: 2021-02-17





Effective Date: 2020-12-22

Expiry Date: 2023-12-21

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...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. 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.