

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Biomerics FMI
1605 Enterprise Street
Athens
Texas
75751
USA

Holds Certificate No:

FM 39737

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

Design and contract manufacturing of Urological products including balloon catheters, stents, and urological access devices; PTA balloon catheters, angiography catheters, and drainage catheters. Devices are either packaged bulk or for sterilization and are either sterile or non sterile.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 1998-06-04

Latest Revision Date: 2014-04-14

Effective Date: 2021-04-24

Expiry Date: 2024-04-23

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Certificate No: **FM 39737**

Location

Biomerics FMI
1605 Enterprise Street
Athens
Texas
75751
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Registered Activities

Design and contract manufacturing of Urological products including balloon catheters, stents, and urological access devices; PTA balloon catheters, angiography catheters, and drainage catheters. Devices are either packaged bulk or for sterilization and are either sterile or non sterile.

Biomerics FMI
1704 Enterprise Street
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Extrusion and Molding operations.



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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.