

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

Peter Brasseler Holdings, LLC  
also trading as Brasseler U.S.A. Dental, LLC  
also trading as Brasseler U.S.A. Medical, LLC  
also trading as Brasseler Canada, Inc.  
also trading as Brasseler USA® Dental Instrumentation  
also trading as Brasseler USA® Surgical Instrumentation  
also trading as BUSA®  
also trading as Brasseler USA®  
1 Brasseler Boulevard  
Savannah  
Georgia  
31419  
USA

Holds certificate No:

**FM 606418**

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

**Please see scope page.**

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2013-10-22

Latest Revision Date: 2019-02-22

Effective Date: 2019-01-01

Expiry date: 2020-12-19

Page: 1 of 4

...making excellence a habit.™



Certificate No:

**FM 606418**

## Registered Scope:

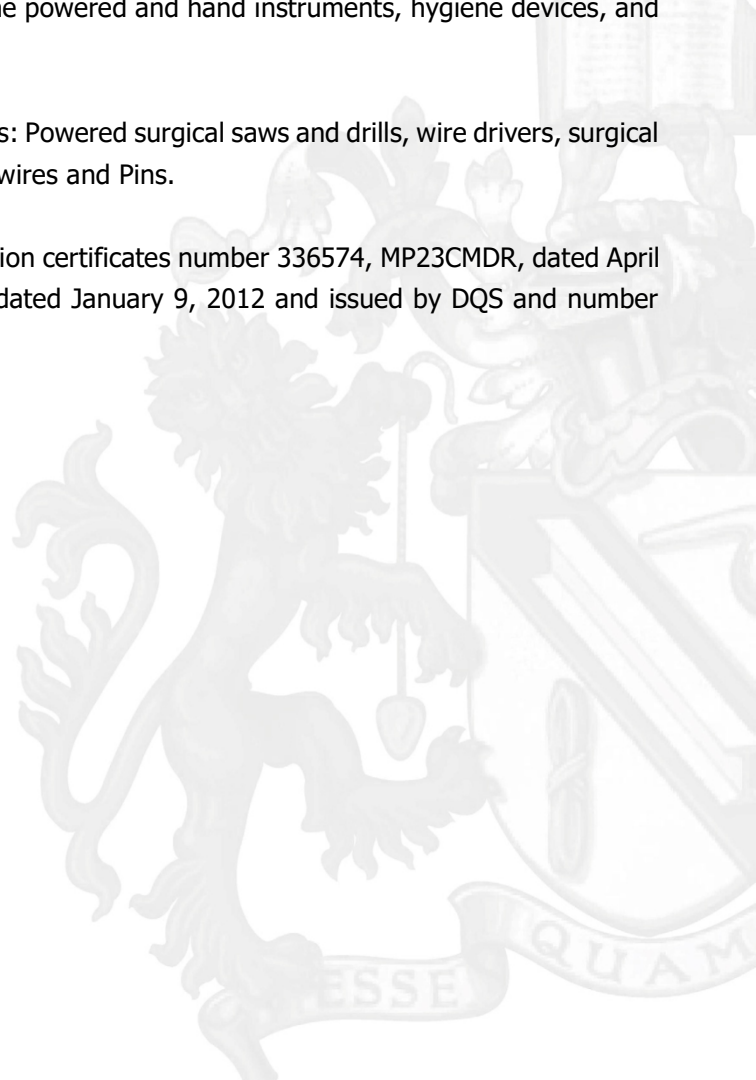
The design and development, manufacture and distribution of powered dental diamond, carbide, steel, abrasive and polishing instruments, endodontic powered and hand files, reamers and broaches, and sterilization cassettes for the area of dental applications.

Servicing of dental hand engines.

Private-Labeling and distribution of endodontic paper points, gutta percha, cements, build-up materials, endodontic pins and points, powered dental hand engines, dental hygiene powered and hand instruments, hygiene devices, and vision enhancements.

Design, manufacture, distribute and assemble Medical Devices: Powered surgical saws and drills, wire drivers, surgical burs, surgical saw blades, drills, craniotome attachments, K-wires and Pins.

The certificate is traceable to the company's original registration certificates number 336574, MP23CMDR, dated April 27, 2012 and issued by DQS, number 336597, MP23CMDR dated January 9, 2012 and issued by DQS and number 336597, MP23SCC dated April 27, 2012 and issued by DQS.



Original Registration Date: 2013-10-22

Latest Revision Date: 2019-02-22

Effective Date: 2019-01-01

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Page: 2 of 4

This certificate remains the property of BSI and shall be returned immediately upon request.  
To be read in conjunction with the scope above or the attached appendix.

Managed by: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.

Certificate No: **FM 606418**

Location	Registered Activities
<p>Peter Brasseler Holdings, LLC also trading as Brasseler U.S.A. Dental, LLC also trading as Brasseler U.S.A. Medical, LLC also trading as Brasseler Canada, Inc. also trading as Brasseler USA® Dental Instrumentation also trading as Brasseler USA® Surgical Instrumentation also trading as BUSA® also trading as Brasseler USA® 1 Brasseler Boulevard Savannah Georgia 31419 USA</p>	<p>Headquarters, Sales and Administration.</p> <p>The design and development, manufacture and distribution of powered dental diamond, carbide, steel, abrasive and polishing instruments, endodontic powered and hand files, reamers and broaches, and sterilization cassettes for the area of dental applications. Servicing of dental hand engines. Private-Labeling and distribution of endodontic paper points, gutta percha, cements, build-up materials, endodontic pins and points, powered dental hand engines, dental hygiene powered and hand instruments, hygiene devices, and vision enhancements.</p>
<p>Brasseler Canada, Inc., a wholly-owned subsidiary of Peter Brasseler Holdings, LLC 4500 Blvd., Henri Bourassa, Suite 230 Quebec City Québec G1H 3A5 Canada</p>	<p>Sales and Administration.</p> <p>Distribution of powered dental diamond, carbide, steel, abrasive and polishing instruments, endodontic powered and hand files, reamers and broaches, sterilization cassettes for the area of dental applications, endodontic paper points, gutta percha, cements, build-up materials, endodontic pins and points, powered dental hand engines, dental hygiene powered and hand instruments, hygiene devices, and vision enhancements.</p>
<p>Brasseler USA Medical, LLC, a wholly-owned subsidiary of Peter Brasseler Holdings, LLC, also trading as Brasseler USA® Surgical Instrumentation also trading as Brasseler USA® also trading as BUSA® 2188 Knoll Drive Ventura California USA</p>	<p>Manufacture: Surgical saw blades, surgical burs and drills, K-wires and pins.</p>

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Page: 3 of 4

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Location	Registered Activities
Brasseler USA Medical, LLC, a wholly-owned subsidiary of Peter Brasseler Holdings, LLC, also trading as Brasseler USA® Surgical Instrumentation also trading as Brasseler USA® also trading as BUSA® 4837 McGrath Street Ventura California 93003 USA	Design, Manufacture, Distribute and Assemble: Powered surgical saws, drills, wire drivers, and craniotome attachments.

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Page: 4 of 4

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