

# Certificate of Registration

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

This is to certify that:

HemoSonics LLC  
400 Preston Avenue  
Suite 250  
Charlottesville  
Virginia  
22903  
USA

Holds Certificate Number:

**MD 683030**

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 in-vitro diagnostic devices (analyzers, software, reagents, quality control materials) and accessories used to aid in the evaluation of blood coagulation properties.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2018-06-29

Latest Revision Date: 2018-10-29

Effective Date: 2018-06-29

Expiry Date: 2021-06-28

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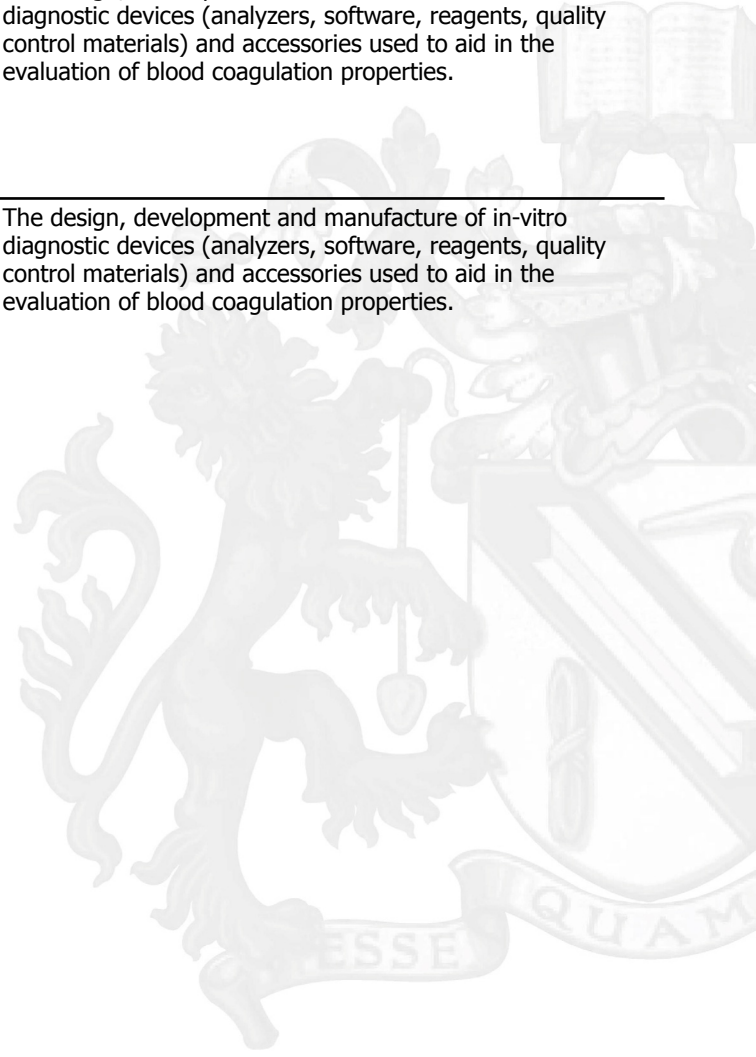


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...making excellence a habit.™

Certificate No: **MD 683030**

Location	Registered Activities
HemoSonics LLC 400 Preston Avenue Suite 250 Charlottesville Virginia 22903 USA	Company headquarters, regulatory compliance and design.
HemoSonics LLC 4020 Stirrup Creek Suite 112 Durham North Carolina 27703 USA	The design, development and manufacture of in-vitro diagnostic devices (analyzers, software, reagents, quality control materials) and accessories used to aid in the evaluation of blood coagulation properties.
HemoSonics LLC 323 Foster Street Suite 300 Durham North Carolina 27701 USA	The design, development and manufacture of in-vitro diagnostic devices (analyzers, software, reagents, quality control materials) and accessories used to aid in the evaluation of blood coagulation properties.



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An electronic certificate can be authenticated [online](#).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

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