

# Certificate of Registration

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

This is to certify that:

Helena Laboratories (UK) Ltd  
trading as Helena Biosciences Europe  
Queensway South  
Team Valley Trading Estate  
Gateshead  
Tyne and Wear  
NE11 0SD  
United Kingdom

Holds Certificate Number:

**MD 69326**

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, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14

Expiry Date: 2024-04-13

Page: 1 of 2



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Certificate No: **MD 69326**

Location	Registered Activities
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Sunderland Enterprise Park Colima Avenue Sunderland SR5 3XB United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Queensway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 0SD United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.



Original Registration Date: 2002-10-25  
Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14  
Expiry Date: 2024-04-13

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.  
An electronic certificate can be authenticated [online](#).  
Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)

# Declaration of Conformity

**helena**  
Biosciences Europe

HL-7- 0135 DC DOI 2013/10 (6)

**In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.***

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

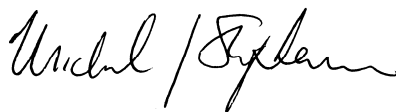
<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
5183	Routine Control SA	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 31<sup>st</sup> October 2013

**Tel** +44 (0)191 482 8440  
**Fax** +44 (0)191 482 8442  
info@helena-biosciences.com  
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# Declaration of Conformity

**helena**  
Biosciences Europe

HL-7-0136DC DOI 2015/07 (6)

## **In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.**

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

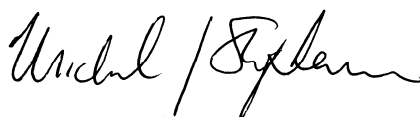
<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
5185	Calibration Plasma	55995

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 28 Jul 2015

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United Kingdom

# Declaration of Conformity

**helena**  
Biosciences Europe

HL-7- 0137 DC DOI 2013/10 (6)

**In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.***

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

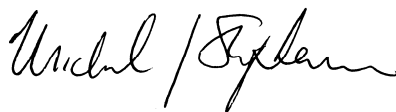
<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
5186	Routine Control N	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 31<sup>st</sup> October 2013

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United Kingdom

# Declaration of Conformity

**helena**  
Biosciences Europe

HL-7- 0138 DC DOI 2013/10 (6)

**In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.***

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

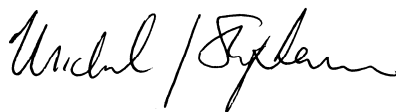
<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
5187	Routine Control A	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 31<sup>st</sup> October 2013

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# Declaration of Conformity

**helena**  
Biosciences Europe

HL-7- 0163 DC DOI 2014/05 (8)

## **In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.***

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
5265	Thromboplastin LI	55983
5265H	Thromboplastin LI	55983
5267	Thromboplastin LI	55983
5269	Thromboplastin LI	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 07 May 2014

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Gateshead, Tyne and Wear, NE11 0SD,

United Kingdom

# Declaration of Conformity

**helena**  
Biosciences Europe

HL-7- 0512 DC DOI 2013/08 (4)

## **In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.***

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

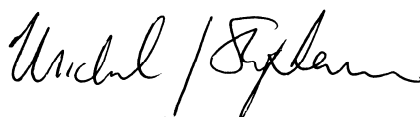
<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
5556	Clauss Fibrinogen 50	55997
5556H	Clauss Fibrinogen 50	55997

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 05 Aug 2013

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United Kingdom



# Declaration of Conformity

**helena**  
Biosciences Europe

HL-7-0664DC DOI 2015/08 (1)

## **In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.**

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

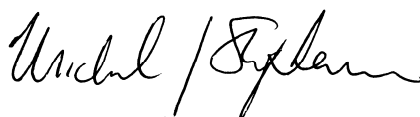
<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
5267L	Thromboplastin L	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:



Date: 06 Aug 2015

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United Kingdom

# Certificate

**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG  
Neumann-Neander-Str. 6-8  
52355 Düren  
Germany

Scope: Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine, gastric and vaginal fluid analysis, as well as in vitro diagnostic products for bioanalytical sample preparation.

(see attachment for sites included)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 3309079-90

Effective date: 2020-05-29

Expiry date: 2023-05-28

Issue date: 2020-05-28



Dipl.-Ing. S. Hoffmann  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

# Certificate

**Quality Management System**  
**EN ISO 13485:2016**

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG  
Neumann-Neander-Str. 6-8  
52355 Düren  
Germany

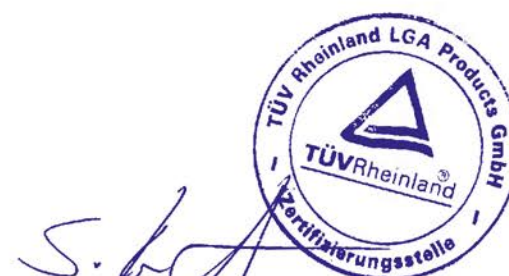
No.	Facility	Scope
/02	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design and development, manufacture, quality control, distribution and customer service
/03	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 3309079-90

Effective date: 2020-05-29

Expiry date: 2023-05-28

Issue date: 2020-05-28



Dipl.-Ing. S. Hoffmann  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

Certificate Holder: **MACHEREY-NAGEL GmbH & Co. KG**

Neumann-Neander-Str. 6-8  
52355 Düren  
Germany

including the locations according to annex

Scope:

Design and development, production and distribution  
of products for filtration, rapid tests, water analysis,  
chromatography and bioanalysis

Proof has been furnished by means of an audit that the  
requirements of ISO 9001:2015 are met.

Validity:

The certificate is valid from 2020-05-29 until 2023-05-28.

2020-05-25



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

No.	Location	Scope
/01	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design, development and production of products for chromatography and bioanalysis
/02	MACHEREY-NAGEL GmbH & Co. KG Valenciennener Str. 11 52355 Düren Germany	Design, development, production and distribution of products for filtration, rapid tests, water analysis. Service and administration
/03	MACHEREY-NAGEL GmbH & Co. KG Papiermühle 50 52349 Düren Germany	Waste disposal
/04	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Storage
/05	MACHEREY-NAGEL GmbH & Co. KG Monschauer Str. 64 52355 Düren Germany	Production

2020-05-25

  
TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln