

CERTIFICATE

Certificate Number
PR 08 08 0022 003

Date of Issue
28 August 2008

Expiration Date
NONE

Test Report Number/s
E-0022-2619-00 MG
S-0022-2128-01 BT
S-0022-2128-02 BT

Product Description
Coagulometer

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Holder of Certificate :

Helena Laboratories (UK) Ltd trading as
Helena Biosciences Europe
Queensway South, Team Valley Trading
Estate, Gateshead, Tyne & Wear,
NE11 9SD, United Kingdom

Manufacturer :

Helena Laboratories (UK) Ltd trading as
Helena Biosciences Europe
Queensway South, Team Valley Trading
Estate, Gateshead, Tyne & Wear,
NE11 9SD, United Kingdom

Type/Model Name/s:

Helena C-1, C-2, C-4

Directive/s: 2004/108/EC
2006/95/EC

Standard/s: EN 61326-1:2006
EN 61000-3-2:2000
EN 61000-3-2:2006
EN 61000-3-3:1995+A1:2001+A2:2005
EN 61010-1:2001 (2nd Edition)
EN 61010-2-101:2002 (1st Edition)

The certificate is issued after testing of the named product/s and/or audit of the technical documentation and confirms that the tested product complies with the essential protection requirements of the mentioned directives on a voluntary basis.

2008-08-28

Date

Signature



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GERMANY

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After preparation of the necessary technical documentation as well as the conformity declaration the required marking can be affixed to the product. Other relevant directives have to be observed. See also notes overleaf.

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:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2018-11-28

Effective Date: 2018-04-14

Expiry Date: 2021-04-13



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Certificate No: **MD 69326**

Location

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Sunderland Enterprise Park
Colima Avenue
Sunderland
SR5 3XB
United Kingdom

Registered Activities

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: 2018-11-28

Effective Date: 2018-04-14

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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

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
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Declaration of Conformity

helena
Biosciences Europe

HL-7-0408DC DOI 2015/08 (3)

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.


Product Code	Description	GMDN Classification Code
200100	SAS-1 SP-24 Kit	53967

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: 14 Aug 2015

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