



COAGULOMETRU Helena C-Series



Caracteristici și specificații

- Platformă flexibilă cu 1, 2 sau 4 canale
- Analiză optică de înaltă performanță, fără cerință de agitare mecanică
- Detectare sensibilă cu volume mici de probă
- Măsurare optică de înaltă rezoluție, chiar și cu un volum de probă și reactiv de numai 75 μ L
- Operare ușor de utilizat

Fluxul de lucru cu ecran tactil permite programarea simplă și pornirea automată

- Reglare optică automată

Asigură rezultate fiabile pe toate canalele atunci când calitatea probei variază

- Conectivitate puternică
- Urmărirea ID-ului pacientului și al probei cu scanner de coduri de bare opțional
- Construcție de înaltă calitate

Platformă analitică testată, proiectată și fabricată în UE

Display tactil colorat

Zona completă este preîncălzită la 37°C

1 x Poziție reactiv Ø24mm

2 x Poziție reactiv Ø22mm

(1 poziție pentru agitare pe Helena C-2 și Helena C-4)

2 x poziții de reactiv Ø13mm

10 x poziții de incubare cuvetă (x20 pe Helena C-2 și Helena C-4)

1 x poziții de măsurare a cuvei (x2 pentru Helena C-2, x4 pentru Helena C-4)

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



emitel AG
Ohmstrasse 1
94342 Strasskirchen
GERMANY

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☎ + 49 (0) 9424 9482-640
🌐 www.emitel.de
✉ germany@emitel.de



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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-10-25

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

Page: 1 of 2



...making excellence a habit.™

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

Effective Date: 2024-04-14

Latest Revision Date: 2024-03-26

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Page: 2 of 2

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.
A Member of the BSI Group of Companies.

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.

Product Code	Description	GMDN Classification Code
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: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
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www.helena-biosciences.com

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United Kingdom

Declaration of Conformity

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HL-7- 0511 DC DOI 2013/08 (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
5376	Clauss Fibrinogen 100	55997
5376H	Clauss Fibrinogen 100	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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Declaration of Conformity

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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.

Product Code	Description	GMDN Classification Code
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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Declaration of Conformity

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HL-7-DC-0814 Rev. 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.

Product Code	Description	GMDN Classification Code
5560	APTT Si L Minus	55981

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

Full Name: C.J. Sandercock

Title: QA and Regulatory Affairs Officer

Signed:



Date: 24 Nov 2020



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Tel +44 (0)191 482 8440

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www.helena-biosciences.com

EC REP

Prince Technologies B.V.
Waanderweg 62,
7812 HZ Emmen,
The Netherlands

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.

Product Code	Description	GMDN Classification Code
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:

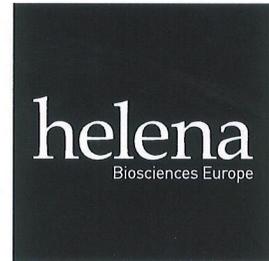


Date: 31st October 2013

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Training certificate



This is to certify that

Sergiu Sorocovici

from

IM Global Biomarketing Group

has received training on the following:

Electrophoresis products: SAS-1/2,V8

Haemostasis products: C-series, AC-4, AggRAM and reagents

Service training: AC-4

Signed:



Sergiu Sorocovici

Date: **31st October - 4th November 2011**

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