

16/02/2021

**LETTER OF DISTRIBUTION**

To Whom It May Concern,

This letter is to serve notice that GBG-MLD SRL Global Biomarketing Group, located at str. Tighina, 65, of. 607 MD2001 Chisinau, Municipiul Chisinau, Moldova is authorized to distribute the Helena Biosciences Europe Haemostasis and Electrophoresis range of products in the whole Republic of Moldova territory. As such, GBG-MLD SRL Global Biomarketing Group is responsible for promotion, support, installation, and after-sales service for Helena Biosciences Europe products.

GBG-MLD SRL Global Biomarketing Group will maintain appropriate, up-to-date and accurate records to enable the immediate recall of any Products or batches of Products. These records shall include records of deliveries to customers (including batch numbers, expiry dates, delivery date, name and address of customer, telephone number, fax number and e-mail address). These records should be kept for a minimum of one year past the expiry of the product that has been delivered.

This agreement is effective for a period of 3 years from the date of this letter, unless terminated by either party by giving 90 days notice, and can be extended through the mutual agreement of both parties based on sales performance.

Sincerely,

Dmitri Alexandrov

International Business Manager



# 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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...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

Latest Revision Date: 2021-04-13

Effective Date: 2021-04-14

Expiry Date: 2024-04-13

# 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.

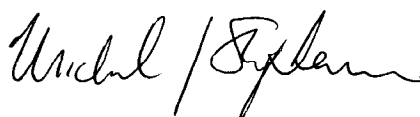
Product Code	Description	GMDN Classification Code
200100	SAS-1 SP-24 Kit	53967

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

Tel +44 (0)191 482 8440

Fax +44 (0)191 482 8442

[info@helena-biosciences.com](mailto:info@helena-biosciences.com)

[www.helena-biosciences.com](http://www.helena-biosciences.com)

Helena Biosciences Europe

Queensway South, Team Valley Trading Estate,  
Gateshead, Tyne and Wear, NE11 0SD,

United Kingdom



# Training certificate

helena  
Biosciences Europe

This is to certify that

**Sergiu Sorocovici**

from

**IM Global Biomarketing Group**

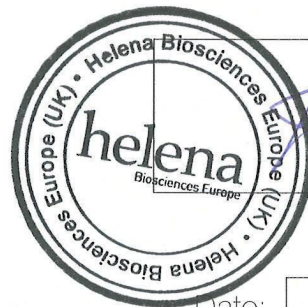
has received training on the following:

Electrophoresis products: SAS-1/2,V8

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

Service training: AC-4

Signed:



*[Handwritten signature]*

Date: 31st October - 4th November 2011

Tel +44 (0)191 482 8440

info@helena-biosciences.com

Queensway South, Team Valley Trading Estate,

Fax +44 (0)191 482 8442

techsupport-hs@helena-biosciences.com

Gateshead, Tyne and Wear, NE11 0SD, United Kingdom

[www.helena-biosciences.com](http://www.helena-biosciences.com)

## Declaration of Conformity

**Certificate Identification:** SC-08H59

**Legal Manufacturer's Name:** Abbott Laboratories  
Diagnostics Division



**Legal Manufacturer's Address:** Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08H59-01	55866	CELL-DYN 26 Plus Control, Full Pack	Self-declared
08H59-02	55866	CELL-DYN 26 Plus Control, Half Pack	Self-declared

<b>Authorized European Representative (Name and Address)</b>	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
<b>Storage site of technical documentation (Name and Address)</b>	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
<b>Harmonized Standards</b>	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

**This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.**

<p>Signature: </p> <p>Full Name: <u>Barry Simpson</u></p> <p>Position: <u>Site Quality Manager</u></p> <p>Date of Approval: <u>18 June 2015</u></p> <p>Date Issued: <u>JUN 30 2015</u></p> <p>Supersedes: <u>IRIS V5</u> <u>February 26, 2015</u></p>	<p>Signature: </p> <p>Full Name: <u>Marcy Jaqua</u></p> <p>Position: <u>Director, Regulatory Affairs</u></p> <p>Date of Approval: <u>30 June 2015</u></p> <p>Place Issued: <u>Abbott Santa Clara</u></p> <p>Effective (Date or Lot Number): <u>JUL 06 2015</u></p>
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## Declaration of Conformity

**Certificate Identification:** SC-01H73  
**Legal Manufacturer's Name:** Abbott Laboratories  
Diagnostics Division  
**Legal Manufacturer's Address:** Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
01H73-01	58237	CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/SHEATH	Self-declared

<b>Authorized European Representative (Name and Address)</b>	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
<b>Storage site of technical documentation (Name and Address)</b>	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
<b>Harmonized Standards</b>	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

**This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.**

Signature: 


Full Name: Barry Simpson

Position: Site Quality Manager

Date of Approval: 29 Jun. 2015

Date Issued: JUN 30 2015

Supersedes: IRIS V2  
January 10, 2014

Signature: 

Full Name: Marcy Jaqua

Position: Director, Regulatory Affairs

Date of Approval: 30 June 2015

Place Issued: Abbott Santa Clara

Effective (Date or Lot Number): JUL 06 2015



## Declaration of Conformity

<b>Certificate Identification:</b>	SC-99644
<b>Legal Manufacturer's Name:</b>	Abbott Laboratories Diagnostics Division
<b>Legal Manufacturer's Address:</b>	Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
99644-01	59058	CELL-DYN ENZYMATIC CLEANER CONCENTRATE	Self-declared
93641-01	59058	CELL-DYN ENZYMATIC CLEANER CONCENTRATE	Self-declared

<b>Authorized European Representative (name and address)</b>	ABBOTT Max-Planck-Ring 2 65205 Wiesbaden, Germany
<b>Storage site of technical documentation (name and address)</b>	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 USA
<b>Harmonized Standards</b>	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

**This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.**

<p>Signature: </p> <p>Full Name: <u>Barry Simpson</u></p> <p>Position: <u>Quality Manager</u></p> <p>Date of Approval: <u>04. Sept. 2015</u></p> <p>Date Issued: <u>SEP 04 2015</u></p> <p>Supersedes: <u>IRIS V4, January 10, 2014</u></p>	<p>Signature: </p> <p>Full Name: <u>Marcy Jaqua</u></p> <p>Position: <u>Regulatory Affairs , Director</u></p> <p>Date of Approval: <u>04 Sep 2015</u></p> <p>Place Issued: <u>Abbott Santa Clara</u></p> <p>Effective (Date or Lot Number): <u>SEP 11 2015</u></p>
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## Declaration of Conformity

**Certificate Identification:** SC-03H80  
**Legal Manufacturer's Name:** Abbott Laboratories  
Diagnostics Division  
**Legal Manufacturer's Address:** Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
03H80-02	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems CN-FREE HGB/NOC LYSE	Self-declared

<b>Authorized European Representative (Name and Address)</b>	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
<b>Storage site of technical documentation (Name and Address)</b>	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
<b>Harmonized Standards</b>	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

**This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.**

Signature:



Signature:



Full Name:

Barry Simpson

Full Name:

Marcy Jaqua

Position:

Site Quality Manager

Position:

Director, Regulatory Affairs

Date of Approval:

29 Jun. 2015

Date of Approval:

30 June 2015

Date Issued:

JUN 30 2015

Place Issued:

Abbott Santa Clara

Supersedes:

IRIS V2  
January 10, 2014

Effective (Date or  
Lot Number):

JUL 06 2015

## Declaration of Conformity

**Certificate Identification:** SC-08H52  
**Legal Manufacturer's Name:** Abbott Laboratories  
Diagnostics Division  
**Legal Manufacturer's Address:** Abbott Park, IL 60064 USA

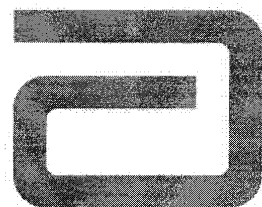
List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08H52-01	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems WBC LYSE	Self-declared

<b>Authorized European Representative (Name and Address)</b>	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
<b>Storage site of technical documentation (Name and Address)</b>	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
<b>Harmonized Standards</b>	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

**This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.**

<p>Signature: <u></u></p> <p>Full Name: <u>Barry Simpson</u></p> <p>Position: <u>Site Quality Manager</u></p> <p>Date of Approval: <u>29. Jun. 2015</u></p> <p>Date Issued: <u>JUN 30 2015</u></p> <p>Supersedes: <u>IRIS V2,</u> <u>January 10, 2014</u></p>	<p>Signature: <u></u></p> <p>Full Name: <u>Marcy Jaqua</u></p> <p>Position: <u>Director, Regulatory Affairs</u></p> <p>Date of Approval: <u>30 June 2015</u></p> <p>Place Issued: <u>Abbott Santa Clara</u></p> <p>Effective (Date or Lot Number): <u>JUL 06 2015</u></p>
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# Abbott

A Promise for Life

This document certifies that:

***Sergiu Sorocovici***

has completed

**Ruby**

**Service Training**

TSOBANIDIS VLASSIS

Trainer.....

Athens, 29-31/10/2014

