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

Digitally signed by Ceaicovschi Tudor
Date: 2021.11.12 14:24:30 EET
Reason: MoldSign Signature
Location: Moldova

**Helena Biosciences Europe**
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD, United Kingdom
**Tel** +44 (0)191 482 8440
**Fax** +44 (0)191 482 8442
**info**@helena-biosciences.com
**www**.helena-biosciences.com

By Royal Charter

# 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



...making excellence a habit.™

Certificate No: **MD 69326**

| Location | Registered Activities |
|---|---|
| Helena Laboratories (UK) Ltd<br>trading as Helena Biosciences Europe<br>Sunderland Enterprise Park<br>Colima Avenue<br>Sunderland<br>SR5 3XB<br>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<br>trading as Helena Biosciences Europe<br>Queensway South<br>Team Valley Trading Estate<br>Gateshead<br>Tyne and Wear<br>NE11 0SD<br>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: 2021-04-14

Latest Revision Date: 2021-04-13

Expiry Date: 2024-04-13

# Declaration of Conformity

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
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:

Helena Biosciences Europe (UK) • Helena Biosciences Europe (UK) • helena Biosciences Europe

Date: 31st October - 4th November 2011


Tel +44 (0)191 482 8440 info@helena-biosciences.com
Fax +44 (0)191 482 8442 techsupport-hs@helena-biosciences.com
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD, United Kingdom

www.helena-biosciences.com

Abbott

# 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** |

| | |
|---|---|
| **Authorized European Representative (Name and Address)** | ABBOTT<br>Max-Planck-Ring-2<br>65205 Wiesbaden, Germany |
| **Storage site of technical documentation (Name and Address)** | Abbott Laboratories<br>4551 Great America Parkway<br>Santa Clara, CA 95054 |
| **Harmonized Standards** | 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: | 18 June 2015 | Date of Approval: | 30 June 2015 |
| Date Issued: | JUN 30 2015 | Place Issued: | Abbott Santa Clara |
| Supersedes: | IRIS V5<br>February 26, 2015 | Effective (Date or Lot Number): | JUL 06 2015 |

Abbott

# 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** |

| | |
|---|---|
| **Authorized European Representative (Name and Address)** | ABBOTT<br>Max-Planck-Ring-2<br>65205 Wiesbaden, Germany |
| **Storage site of technical documentation (Name and Address)** | Abbott Laboratories<br>4551 Great America Parkway<br>Santa Clara, CA 95054 |
| **Harmonized Standards** | 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<br>January 10, 2014 | Effective (Date or Lot Number): | JUL 06 2015 |

Abbott

# Declaration of Conformity

**Certificate Identification:** SC-99644

**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 |
|---|---|---|---|
| 99644-01 | 59058 | CELL-DYN ENZYMATIC CLEANER CONCENTRATE | **Self-declared** |
| 93641-01 | 59058 | CELL-DYN ENZYMATIC CLEANER CONCENTRATE | **Self-declared** |

| | |
|---|---|
| **Authorized European Representative (name and address)** | ABBOTT<br>Max-Planck-Ring 2<br>65205 Wiesbaden, Germany |
| **Storage site of technical documentation (name and address)** | Abbott Laboratories<br>4551 Great America Parkway<br>Santa Clara, CA 95054 USA |
| **Harmonized Standards** | 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: | Quality Manager | Position: | Regulatory Affairs , Director |
| Date of Approval: | 04. Sept. 2015 | Date of Approval: | 04 Sep 2015 |
| Date Issued: | SEP 04 2015 | Place Issued: | Abbott Santa Clara |
| Supersedes: | IRIS V4,<br>January 10, 2014 | Effective (Date or Lot Number): | SEP 11 2015 |

Abbott

# 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<br>CN-FREE HGB/NOC LYSE | **Self-declared** |

| | |
|---|---|
| **Authorized European Representative (Name and Address)** | ABBOTT<br>Max-Planck-Ring-2<br>65205 Wiesbaden, Germany |
| **Storage site of technical documentation (Name and Address)** | Abbott Laboratories<br>4551 Great America Parkway<br>Santa Clara, CA 95054 |
| **Harmonized Standards** | 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<br>January 10, 2014 | Effective (Date or Lot Number): | JUL 06 2015 |

Abbott

# Declaration of Conformity

| | |
|---|---|
| **Certificate Identification:** | SC-08H52 |
| **Legal Manufacturer's Name:** | Abbott Laboratories<br>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<br>WBC LYSE | **Self-declared** |

| | |
|---|---|
| **Authorized European Representative (Name and Address)** | ABBOTT<br>Max-Planck-Ring-2<br>65205 Wiesbaden, Germany |
| **Storage site of technical documentation (Name and Address)** | Abbott Laboratories<br>4551 Great America Parkway<br>Santa Clara, CA 95054 |
| **Harmonized Standards** | 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,<br>January 10, 2014 | Effective (Date or Lot Number): | JUL 06 2015 |

Abbott

A Promise for Life

This document certifies that:

*Sergiu Sorocovici*

has completed

# Ruby

## Service Training

TSOBANIDIS VLASSIS

Trainer.....

Athens, 29-31/10/2014