

EasyLyte EasyBloodGas EasyStat

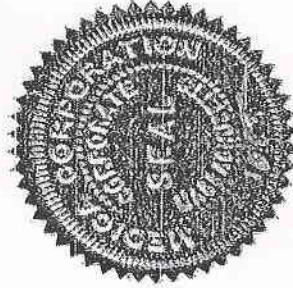
# Training Certificate

This is to certify that

Sergiu Sergiu  
Of Global Bioprocess Group

has completed training for the operation and service of the  
EasyLyte, EasyBloodGas, and EasyStat analyzers.

**MEDICA**

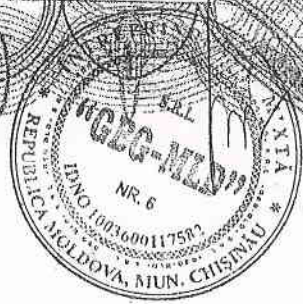


November 25, 2004

Date

Randall Rollins

Signed: Randall Rollins  
Technical Service Manager





# NSAI

## Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

**Monobind Inc.**  
**100 North Pointe Drive**  
**Lake Forest, CA 92630**  
**USA**

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

---

**The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents, Controls, and Semi-Manual and Automated Washers and Analyzers.**

**Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4585)**

Approved by:  
Geraldine Larkin  
Chief Executive Officer

Approved by:  
Caroline Dore Geraghty  
Director of Medical Devices /  
Head of Notified Body

---

Registration Number: MD19.4585  
Certification Granted: May 18, 2010  
Effective Date: September 25, 2019  
Expiry Date: September 24, 2022





# NSAI

## **Annex to Certificate Number: MD19.4585**

### **Scope of Registration:**

**The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents, Controls, and Semi-Manual and Automated Washers and Analyzers.**

#### **Activity**

#### **Location**

Headquarters, Administration,  
Design, Manufacturing,  
Distribution

Monobind Inc.  
100 North Pointe Drive  
Lake Forest, CA 92630  
USA  
File No.: MD19.4585

Manufacturing, Distribution

Monobind Inc.  
103 North Pointe Drive  
Lake Forest, CA 92630  
USA  
File No.: MD19.4585/A

**Verified by:  
Operations Manager**

Certificado ES16/20725

El sistema de gestión de



**DELTALAB GROUP**  
**DELTALAB, S.L., KEYLAB, S.L.U.,**  
**NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A.**

Pol. Ind. La Llana  
Plaza de la Verneda, 1  
08191 Rubí, Barcelona

ha sido evaluado y certificado en cuanto al cumplimiento de los requisitos de



**ISO 9001:2015**

Para las siguientes actividades

**Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis de microbiología, biología molecular, hematología, bioquímica, histología, microscopia y coloración, material general de laboratorio, envases y productos para el cuidado personal. Fabricación y comercialización de consumibles de laboratorio. Comercialización y distribución de equipos para el almacenamiento de muestras preparadas, almacenamiento de muestras para criogenización, jeringas, material general de laboratorio y envases industriales. Comercialización y distribución de equipos e instrumentación para laboratorio, reactivos para el diagnóstico, productos para el cuidado personal, productos cosméticos y productos dietéticos para uso médico especial. Comercialización, distribución, instalación y asistencia técnica de equipos e instrumentación para laboratorio.**

Este certificado es válido desde

11 de octubre de 2019 hasta 11 de octubre de 2022.

Edición 4. Organización certificada desde octubre de 2010.

Certificada con SGS desde 11 de octubre de 2016.

Este es un certificado multisede. Ver hoja(s) siguiente(s).

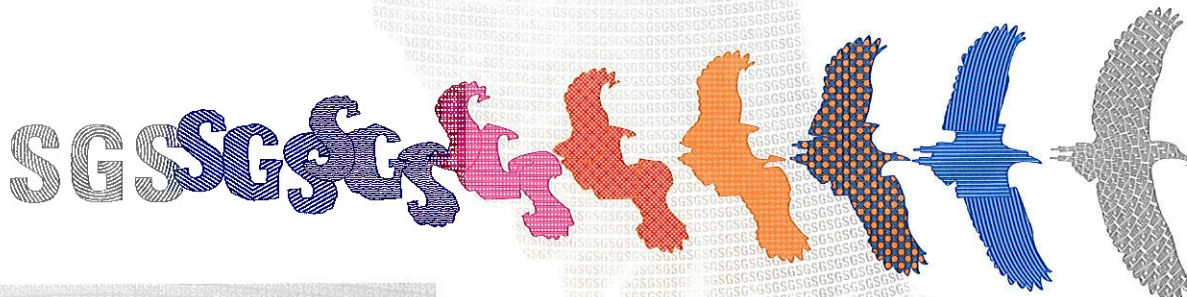
Autorizado por



Dirección de Certificación

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**DELTALAB GROUP**  
**DELTALAB, S.L., KEYLAB, S.L.U.,**  
**NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A.**

**ISO 9001:2015**

Edición 4



Emplazamientos en los que se realizan total o parcialmente dichas actividades

**DELTALAB, S.L.**  
Pol. Ind. La Llana, Plaza. de la Verneda, 1 - 08191 Rubí (Barcelona)

**Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis de microbiología, biología molecular, hematología, bioquímica, histología, microscopía y coloración. Comercialización de equipos para el almacenamiento de muestras preparadas, almacenamiento de muestras para criogenización, material general de laboratorio y envases industriales. Comercialización de Equipos e instrumentación para laboratorio, reactivos para el diagnóstico, productos para el cuidado personal, productos cosméticos y productos dietéticos para uso medico especial.**

**KEYLAB, S.L.U.**  
Pol. Ind. La Llana, Avda. de la Llana, 115-117 - 08191 Rubí (Barcelona)

**Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis de microbiología, biología molecular, hematología, bioquímica, histología, microscopía y coloración. Comercialización de equipos para el almacenamiento de muestras preparadas, almacenamiento de muestras para criogenización, material general de laboratorio y envases industriales. Comercialización de Equipos e instrumentación para laboratorio, reactivos para el diagnóstico, productos para el cuidado personal, productos cosméticos y productos dietéticos para uso médico especial.**



**NIRCO, S.L.**  
Pol. Ind. Expansión, Puerto de Navafría, 12 - 28935 Móstoles (Madrid)  
Pol. Ind. La Llana, Avda. de la Llana, 115-117 - 08191 Rubí (Barcelona)

**Fabricación y comercialización de consumibles para laboratorio  
Comercialización y distribución de reactivos para diagnóstico  
Comercialización, distribución, instalación y asistencia técnica de equipos e instrumentación para laboratorio.**

**ENVASES FARMACÉUTICOS, S.A.**  
C/ Paralela, 15 - 28860 Paracuellos de Jarama (Madrid)

**Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis, material general de laboratorio, envases y productos para el cuidado personal.  
Comercialización y distribución de material general de laboratorio, productos y equipos para el cuidado personal, jeringas y productos cosméticos.**

Certificat ES16/20725

SGS

El sistema de gestió de

**DELTALAB GROUP**  
**DELTALAB, S.L., KEYLAB, S.L.U.,**  
**NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A**

Pol. Ind. La Llana,  
Plaza de la Verneda, 1  
08191 Rubí, Barcelona

ha estat avaluat i certificat en quant al compliment dels requisits de

**ISO 9001:2015**

Per a les activitats següents

**Disseny, fabricació i comercialització de material de laboratori per a la presa, transport i conservació de mostres per anàlisis de microbiologia, biologia molecular, hematologia, bioquímica, histologia, microscòpia i coloració, material general de laboratori, envasos i productes per a la cura personal.**

**Fabricació i comercialització de consumibles per a laboratori.**

**Comercialització i distribució d'equips per l'emmagatzematge de mostres preparades, emmagatzematge de mostres per criogenització, xeringues, material general de laboratori i envasos industrials. Comercialització i distribució d'equips i instrumentació per a laboratori, reactius per al diagnòstic, productes per a la cura personal, productes cosmètics i productes dietètics per a ús mèdic especial. Comercialització, distribució, instal·lació i assistència tècnica d'equips i instrumentació per laboratori.**

Aquest certificat és vàlid des del  
11 d'octubre de 2019 fins 11 d'octubre de 2022.  
Edició 4. Organització certificada des d'octubre de 2010.  
Certificada amb SGS des de 11 d'octubre de 2016.

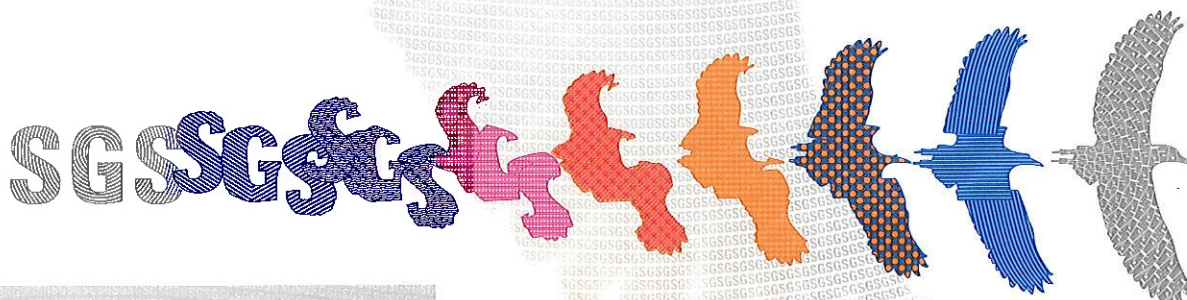
Aquest és un certificat multiemplaçament.  
Els detalls dels emplaçaments addicionals són al full annex.

Autoritzat per

Direcció de Certificació

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C/Trespaderne, 29 28042 Madrid España  
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**DELTALAB GROUP**  
**DELTALAB, S.L., KEYLAB, S.L.U.,**  
**NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A**

**ISO 9001:2015**

Edició 4



Emplaçaments en els quals es duen a terme, total o parcialment, les esmentades activitats

**DELTALAB, S.L.**  
Pol. Ind. La Llana, Plaça de la Verneda, 1 - 08191 Rubí (Barcelona)

Disseny, fabricació i comercialització de material de laboratori per a la presa, transport i conservació de mostres per anàlisi de microbiologia, biologia molecular, hematologia, bioquímica, histologia, microscòpia i coloració. Comercialització d'equips per a l'emmagatzematge de mostres preparades, emmagatzematge de mostres per criogenització, material general de laboratori i envasos industrials.

Comercialització d'equips i instrumentació per a laboratori, reactius per al diagnòstic, productes per a la cura personal, productes cosmètics i productes dietètics per a ús mèdic especial.

**KEYLAB, S.L.U.**  
Pol. Ind. La Llana, Avda. de la Llana, 115-117 - 08191 Rubí (Barcelona)

Disseny, fabricació i comercialització de material de laboratori per a la presa, transport i conservació de mostres per anàlisi de microbiologia, biologia molecular, hematologia, bioquímica, histologia, microscòpia i coloració. Comercialització d'equips per a l'emmagatzematge de mostres preparades, emmagatzematge de mostres per criogenització, material general de laboratori i envasos industrials.

Comercialització d'equips i instrumentació per a laboratori, reactius per al diagnòstic, productes per a la cura personal, productes cosmètics i productes dietètics per a ús mèdic especial.

**NIRCO, S.L.**  
Pol. Ind. Expansión, Puerto de Navafria, 12 - 28935 Móstoles (Madrid)  
Pol. Ind. La Llana, Avda. de la Llana, 115-117 - 08191 Rubí (Barcelona)

Fabricació i comercialització de consumibles per a laboratori.  
Comercialització i distribució de reactius de diagnòstic.  
Comercialització, distribució, instal·lació i assistència tècnica d'equips i instrumentació per a laboratori.

**ENVASES FARMACÉUTICOS, S.A.**  
C/ Paralela, 15 - 28860 Paracuellos de Jarama (Madrid)

Disseny, fabricació i comercialització de material de laboratori per a la presa, transport i conservació de mostres per a anàlisis, material general de laboratori, envasos i productes per a la cura personal. Comercialització i distribució de material general de laboratori, productes i equips per a la cura personal, xeringues i productes cosmètics.





Certificate ES16/20725

The management system of

**DELTALAB GROUP**  
**DELTALAB, S.L., KEYLAB, S.L.U.,**  
**NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A.**

Pol. Ind. La Llana  
Plaza de la Vermeda, 1  
08191 Rubí, Barcelona

has been assessed and certified as meeting the requirements of



**ISO 9001:2015**

For the following activities

**Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis, general labware, containers and healthcare products. Manufacture and commercialization of consumables for the laboratory. Commercialization and distribution of equipment for the storage of prepared samples, cryogenic stored samples, syringes, general labware and industrial packages. Commercialization and distribution of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes. Commercialization, distribution, installation and technical service of equipment and instrumentation for the laboratory.**

This certificate is valid from  
11 October 2019 until 11 October 2022.  
Issue 4. Company certified since October 2010.  
Certified with SGS since 11 October 2016.

This is a multisite certification. See following page(s).

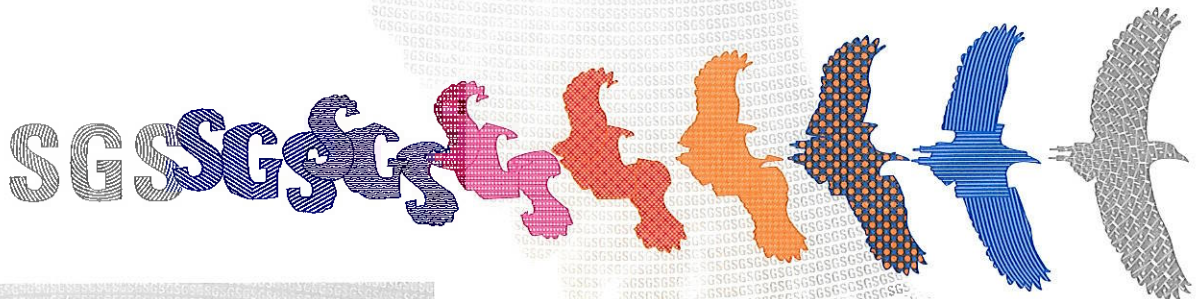
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**DELTALAB GROUP**  
**DELTALAB, S.L., KEYLAB, S.L.U.,**  
**NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A.**

**ISO 9001:2015**

Issue 4



Sites where these activities are totally or partially carried out

**DELTALAB, S.L.**

**Pol. Ind. La Llana, Plaza de la Verneda, 1 – 08191 Rubí, Barcelona (España)**

**Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis. Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.**

**Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes.**

**KEYLAB, S.L.U.**

**Pol. Ind. La Llana, Avda. de la Llana, 115-117 – 08191 Rubí -Barcelona (España)**

**Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis. Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.**

**Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes.**

**NIRCO, S.L.**

**Pol. Ind. Expansión, Puerto de Navafria, 12 - 28935 Móstoles -Madrid (España)**  
**Pol. Ind. La Llana, Avda. de la Llana, 115-117 – 08191 Rubí -Barcelona (España)**

**Manufacture and commercialization of consumables for the laboratory.**

**Commercialization and distribution of diagnostic kits**

**Commercialization, distribution, installation and technical service of equipment and instrumentation for the laboratory.**

**ENVASES FARMACÉUTICOS, S.A.**

**C/ Paralela, 15 - 28860 Paracuellos de Jarama (Madrid)**

**Design, manufacture and commercialization of laboratory material for the collection, transport and conservation of samples for analysis, laboratory material for general use, containers and products for personal care**

**Commercialisation and distribution of laboratory material for general use, products and equipment for personal care, syringes and cosmetic products.**



Certificado ES16/20725.01



# DELTALAB, S.L.

Pol. Ind. La Llana  
Plaza de la Verneda, 1  
08191 Rubí, Barcelona

ha sido evaluado como parte del sistema de gestión de DELTALAB GROUP  
organización certificada en cuanto al cumplimiento de los requisitos de

## ISO 9001:2015

Para las siguientes actividades

**Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis de microbiología, biología molecular, hematología, bioquímica, histología, microscopía y coloración. Comercialización de equipos para el almacenamiento de muestras preparadas, almacenamiento de muestras para criogenización, material general de laboratorio y envases industriales. Comercialización de Equipos e instrumentación para laboratorio, reactivos para el diagnóstico, productos para el cuidado personal, productos cosméticos y productos dietéticos para uso medico especial.**

en/desde los siguientes emplazamientos

**Pol. Ind. La Llana, Plaza de la Verneda, 1 - 08191 Rubí (Barcelona)**

Válido desde

11 de octubre de 2019 hasta 11 de octubre de 2022.

Edición 1.

El presente documento es parte del certificado nº ES16/20725.

La vigencia de este documento queda supeditada a la de este certificado.

Autorizado por

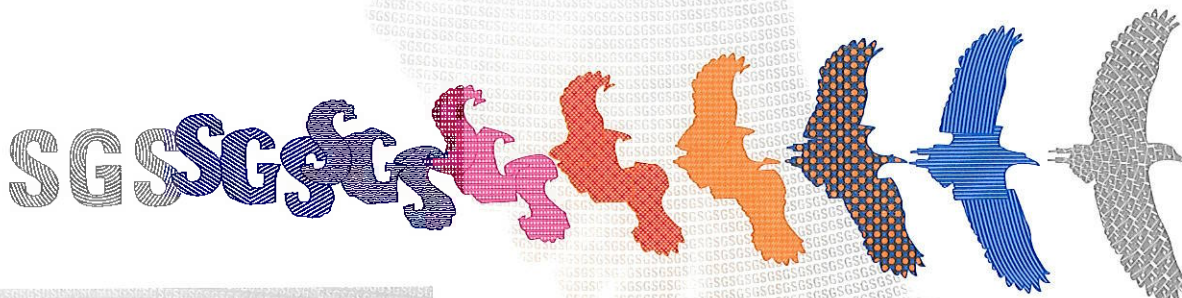
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# SGS

Certificat ES16/20725.01

## DELTALAB, S.L.

Pol. Ind. La Llana,  
Plaza de la Verneda, 1  
08191 Rubí, Barcelona

Ha estat avaluat com a part del sistema de Gestió de DELTALAB GROUP  
organització certificada en quant a l'acompliment dels requisits de

### ISO 9001:2015

Per a les activitats següents

**Disseny, fabricació i comercialització de material de laboratori per a la presa, transport i conservació de mostres per anàlisi de microbiologia, biologia molecular, hematologia, bioquímica, histologia, microscòpia i coloració. Comercialització d'equips per a l'emmagatzematge de mostres preparades, emmagatzematge de mostres per criogenització, material general de laboratori i envasos industrials. Comercialització d'equips i instrumentació per a laboratori, reactius per al diagnòstic, productes per a la cura personal, productes cosmètics i productes dietètics per a ús mèdic especial.**

a/des dels següents emplaçaments

**Pol. Ind. La Llana, Plaza de la Verneda, 1 - 08191 Rubí (Barcelona)**

Vàlid des del  
11 d'octubre de 2019 fins 11 d'octubre de 2022.

Edició 1.

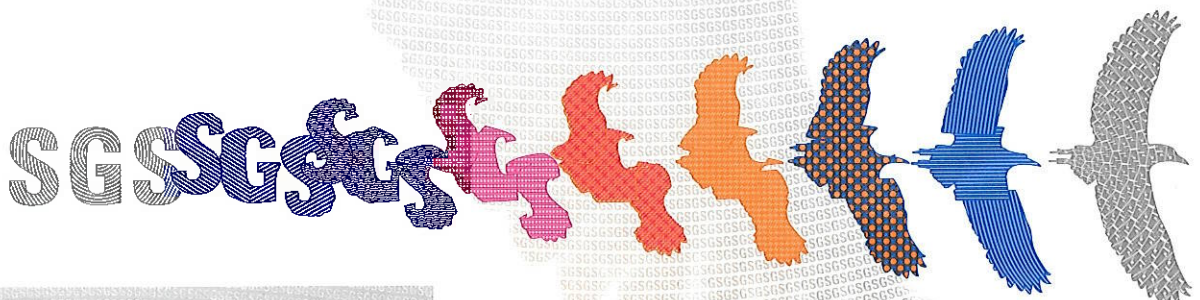
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Autoritzat per

Direcció de Certificació

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t 34 91 313 8115 f 34 91 313 8102 [www.sgs.com](http://www.sgs.com)  
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Certificate ES16/20725.01



# DELTALAB, S.L.

Pol. Ind. La Llana  
Plaza de la Vereda, 1  
08191 Rubí, Barcelona

has been assessed as part of the management system of DELTALAB GROUP  
certified organization as meeting the requirements of

## ISO 9001:2015

For the following activities



**Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, hematology, biochemistry, histology, microscopy and colorimetric analysis. Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages. Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes.**

in / from the following sites

**Pol. Ind. La Llana, Plaza de la Vereda, 1 - 08191 Rubi (Barcelona)**

Valid from  
11 October 2019 until 11 October 2022.  
Issue 1.

This document is part of Certificate ES16/20725.  
The validity of this document is subject to the certificate.

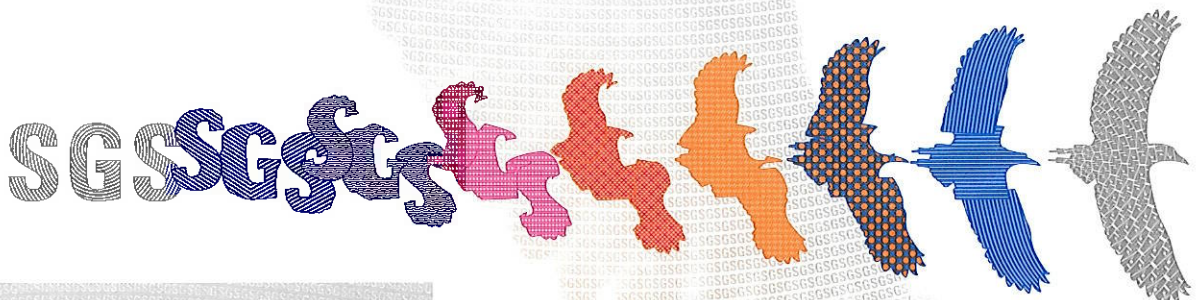


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# Declaration of Conformity

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  
www.helena-biosciences.com

Helena Biosciences Europe  
Queensway South, Team Valley Trading Estate,  
Gateshead, Tyne and Wear, NE11 0SD,  
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.

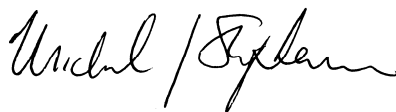
<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
5186	Routine Control N	30590

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

**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

# 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.

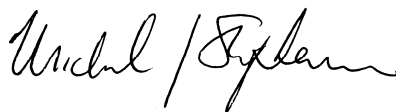
<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
5187	Routine Control A	30590

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

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

# 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

**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



# Declaration of Conformity

helena  
Biosciences Europe

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.

<b>Product Code</b>	<b>Description</b>	<b>GMDN Classification Code</b>
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

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



THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

**KIMA S.r.l.**

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - I-35028 Piove di Sacco (PD)

has implemented and maintains a

**Quality Management System**

for the following scope:

**Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.**

which fulfils the requirements of the following standard:

**ISO 9001:2015**

Issued on: **2019-01-18**  
 First issued on: **2007-01-18**  
 Expires on: **2022-01-17**

*This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.*

Registration Number: **IT-53168**



*Alex Stoichitoiu*  
 President of IQNET



*Ing. Claudio Provetti*  
 President of CISQ

**IQNet Partners\*:**

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy  
 CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil  
 FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica  
 IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
 NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
 SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia  
 IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)



THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

CISQ/ICIM SPA has issued an IQNet recognized certificate that the organization:

**KIMA S.r.l.**

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - I-35028 Piove di Sacco (PD)

has implemented and maintains a

**Quality Management System**

for the following scope:

**Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.**

which fulfils the requirements of the following standard:

**ISO 13485:2016**

Issued on: **2019-01-18**

First issued on: **2007-01-18**

Expires on: **2022-01-17**

*This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document.*

Registration Number: **IT-70247**



Alex Stoichitoiu  
President of IQNET



Ing. Claudio Provetti  
President of CISQ

**IQNet Partners\*:**

AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy  
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil  
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica  
IRAM Argentina JQA Japan KPQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia  
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.



# NSAI

## Certificate of Registration of Quality Management System to I.S. EN ISO 13485:2016

The National Standards Authority of Ireland certifies that:

**Monobind Inc.**  
**100 North Pointe Drive**  
**Lake Forest, CA 92630**  
**USA**

has been assessed and deemed to comply with the requirements of the above standard in respect of the scope of operations given below:

---

**The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents, Controls, and Semi-Manual and Automated Washers and Analyzers.**

**Additional sites covered under this multi-site certification are listed on the Annex (File No. MD19.4585)**

Approved by:  
Geraldine Larkin  
Chief Executive Officer

Approved by:  
Caroline Dore Geraghty  
Director of Medical Devices /  
Head of Notified Body

---

Registration Number: MD19.4585  
Certification Granted: May 18, 2010  
Effective Date: September 25, 2019  
Expiry Date: September 24, 2022





# NSAI

## **Annex to Certificate Number: MD19.4585**

### **Scope of Registration:**

**The Design, Manufacture and Distribution of In-Vitro Diagnostic Medical Device Immunoassays and Related Reagents, Controls, and Semi-Manual and Automated Washers and Analyzers.**

#### **Activity**

#### **Location**

Headquarters, Administration,  
Design, Manufacturing,  
Distribution

Monobind Inc.  
100 North Pointe Drive  
Lake Forest, CA 92630  
USA  
File No.: MD19.4585

Manufacturing, Distribution

Monobind Inc.  
103 North Pointe Drive  
Lake Forest, CA 92630  
USA  
File No.: MD19.4585/A

**Verified by:  
Operations 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:

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



Page: 1 of 2

...making excellence a habit.™

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

Expiry Date: 2021-04-13

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](http://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.

# CERTIFICATE OF REGISTRATION

This is to certify that the quality management system of:

## Medica Corporation

Main Site: 5 Oak Park Drive

Bedford, Massachusetts 01730 United States

has been assessed by Intertek as conforming to the requirements of:

## ISO 13485:2016

The quality management system is applicable to:

The Design, Development, Manufacture, Service, Distribution of in-vitro diagnostic medical devices, in-vitro diagnostic test kits, in-vitro diagnostic reagents, in-vitro diagnostic analyzers/software used in the diagnosis and management of cancer, immune status, disease status, autoimmune status, cardiac markers, protein metabolism, endocrine disorders, blood analytes, urinalysis, blood gases.

**Certificate Number:**

0082581-01

**Initial Certification Date:**

2009-04-17

**Certificate Issue Date:**

2019-01-01

**Certificate Expiry Date:**

2021-04-16



**Calin Moldovean**

President

Intertek Testing Services NA Ltd.,  
1829, 32nd avenue, Lachine, QC, H8T 3J1,  
Canada





# Instrument Training

Vital Scientific BV hereby declares that the participant has attended a four days seminar for service engineers and the participant is now a certified engineer for the declared instruments.

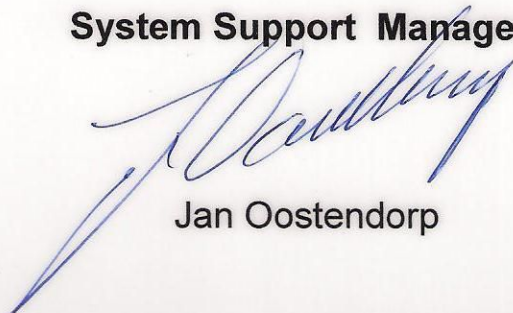
Participant: Mr. A. Legun

Company: Global Biomarketing Group-Moldova SRL  
Moldova

Instrument: Vitalab: XL Series  
E Series  
Junior Series  
Dry ISE  
Micro Series  
ProXS

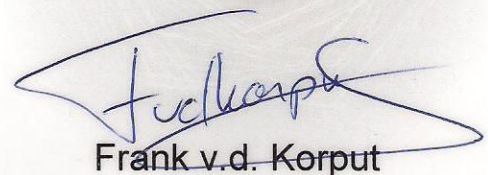
Date of training: April 20th – April 23rd, 2010

**System Support Manager:**



Jan Oostendorp

**System Support Engineer:**



Frank v.d. Kerput