EasyLyte EasyBloodGas EasyStat

Training Certificate

This is to certify that

Semeonic Sergiu

Of Global Biomedical Group

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

November 25, 2004

Date

MEDICA

Randall Rollins

Signed: Randall Rollins
Technical Service Manager

Digitally signed by Ceaicovschi Tudor
Date: 2021.01.27 11:11:42 EET
Reason: MoldSign Signature
Location: Moldova

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

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800

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

CERTIFICACIÓN
Nº 05 / C - SC001

Dirección de Certificación

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.
C/Trespaderne, 29 28042 Madrid España
t 3491 313 8115 f 34 91 313 8102 www.sgs.com

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, microscopia 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, microscopia 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

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

Nº 05 / C - SC001

Direcció de Certificació

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.
C/Trespaderne, 29 28042 Madrid España
t 3491 313 8115 f 34 91 313 8102 www.sgs.com

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, Plaza 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 Navafría, 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 Verneda, 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).

Authorised by

Certification Management

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.
C/Trespaderne, 29 28042 Madrid España
t 3491 313 8115 f 34 91 313 8102 www.sgs.com

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 Navafría, 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.

N° 05 / C - SC001

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, microscopia 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

Dirección de Certificación

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.
C/Trespaderne, 29. 28042 Madrid. España.
t 34 91 313 8115□f 34 91 313 8102 □www.sgs.com

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 Rubi (Barcelona)

Vàlid des del
11 d'octubre de 2019 fins 11 d'octubre de 2022.
Edició 1.

El present document és part del certificat nº ES16/20725.
La vigència d'aquest document queda supeditada a la d'aquest certificat.

Nº 05 / C - SC001

Autoritzat per

Direcció de Certificació

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.
C/Trespaderne, 29. 28042 Madrid. España.
t 34 91 313 8115 f 34 91 313 8102 www.sgs.com

Certificate ES16/20725.01

DELTALAB, S.L.

Pol. Ind. La Llana
Plaza de la Verneda, 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 Verneda, 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.

Nº 05 / C - SC001

Authorized by

Certification Management

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.
C/Trespaderne, 29. 28042 Madrid. España.
t 34 91 313 8115 f 34 91 313 8102 www.sgs.com

Declaration of Conformity

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.

Product Code	Description	GMDN Classification Code
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: 31st 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

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
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

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

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

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.

Product Code	Description	GMDN Classification Code
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

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

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

0774CIM_03_EN

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 Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
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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

0774CM_03_EN

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

National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland T +353 1 807 3800

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

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:

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

...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: 2018-04-14

Latest Revision Date: 2018-11-28

Expiry Date: 2021-04-13

intertek
Total Quality. Assured.

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

SCC Accredited CB-MS
OCSM
Accrédité CCN

Calin Moldovean
President

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

ELITechGroup
VITAL
SCIENTIFIC

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. Korput