

**LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS**  
*THE AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS*

otorga el certificado número  
*grants the certificate no.*

**2013 11 0039 EN**

según la norma  
*in accordance with the standard*

**UNE-EN ISO 13485: 2018**

**(EN ISO 13485: 2016 & ISO 13485: 2016)**

**Productos Sanitarios: Sistemas de Gestión de Calidad – Requisitos para fines reglamentarios**  
*Medical devices – Quality management systems - Requirements for regulatory purposes*

a la empresa  
*to the company*

**Dia.Pro Diagnostic Bioprobes S.r.l.**

*Sede social y de fabricación/ Headquarters and manufacturing facility*  
Via G. Carducci, 27-20099-Sesto San Giovanni-Milano-Italy

**Para las siguientes actividades / For the following activities:**

**Diseño, desarrollo y producción de reactivos y productos reactivos, calibradores y materiales de control para inmunoquímica, microbiología, inmunología infecciosa y técnicas de biología molecular.**

**Diseño, desarrollo, producción y servicio técnico de instrumentos y software para diagnóstico *in vitro*.**

*Design, development and manufacturing of reagents, reagent products, calibrators and control materials for immunochemistry, microbiology, infectious immunology and molecular biology techniques.*

*Design and development, management of production and technical servicing of instruments and software for "in vitro" diagnostic.*

**Modificaciones de alcance/ Scope modifications: Ver Anexo I / see Annex I**

**Fecha de validez/ Date of validity: Desde/ From: 25-02-2021 Hasta/To: 18-11-2023**

**Certificación inicial/ Initial certification date: 27-11-2013**

**Renovaciones / Renewal of certification dates: 8-03-2019; 25-02-2021**

Madrid, 23 de febrero de 2021

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

  agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Fecha de la firma: 23/02/2021

Puede comprobar la autenticidad del documento en la sede de la AEMPS: <https://localizador.aemps.es>

CSV: 4TEYRF78EE



CORREO ELECTRÓNICO  
on0318@aemps.es

Página 1 de 2

CERTIFICACIÓN 13485

C/ CAMPEZO, 1 - EDIFICIO 8  
28022 MADRID  
Tel.: (+34) 902.101.322 / (+34) 91.822.59.97  
Fax: (+34) 91.822.52.89

**ANEXO I / ANNEX I**

**CERTIFICADO UNE-EN ISO 13485: 2018 / UNE-EN ISO 13485: 2018 CERTIFICATE**

**Modificaciones del alcance / Scope modifications:**

Fecha/Date	Descripción de la modificación/ Modification description
18-12-2018	<p>Cambio en la descripción del tipo de técnica en el ámbito tecnológico (inmunología infecciosa y técnicas de biología molecular). Cambio del nivel de detalle en la descripción del ámbito tecnológico</p> <p><i>Change in the description of the method of analysis in the technological scope (infectious immunology and molecular biology techniques). Change in the level of detail of the technological scope description.</i></p>
8-03-2019	<p>Ampliación del ámbito tecnológico para incluir: Inmunoquímica y microbiología Instrumentos y software para diagnóstico "in vitro". Modificación del alcance para incluir la actividad de asistencia técnica para Instrumentos y software para diagnóstico "in vitro".</p> <p><i>Extension of technological scope: Immunochemistry and Microbiology Instruments and software for "in vitro" diagnostic Modification of the scope to include the activity of technical servicing of instruments and software for "in vitro" diagnostic</i></p>

Madrid, 23 de febrero de 2021

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS



agencia española de medicamentos y productos sanitarios

Fdo. M<sup>a</sup> Jesús Lamas Díaz

Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)

Fecha de la firma: 23/02/2021

Puede comprobar la autenticidad del documento en la sede de la AEMPS: <https://localizador.aemps.es>

CSV: 4TEYRF78EE



CORREO ELECTRÓNICO  
on0318@aemps.es

Página 2 de 2

CERTIFICACIÓN 13485

C/ CAMPEZO, 1 - EDIFICIO 8  
28022 MADRID  
Tel.: (+34) 902.101.322 / (+34) 91.822.59.97  
Fax: (+34) 91.822.52.89



Dia.Pro  
**Diagnostic**  
Bio**Probes**

## EC DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
<b>PRODUCT</b>	<b>HCV Ab Confirmation</b> CODE: CCONF.CE (12 tests)
<b>CLASSIFICATION</b>	ANNEX II – LIST A
<b>CONFORMITY ASSESSMENT ROUTE</b>	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED  
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL  
DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

<b>NOTIFIED BODY</b>	AEMPS – n° 0318
<b>(EC) CERTIFICATE(S)</b>	<ul style="list-style-type: none"><li>• FULL QUALITY ASSURANCE SYSTEM N° 2003 12 0388 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• DESIGN CERTIFICATE N° 2005 09 0485 ED RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318</li></ul>

<b>PLACE &amp; DATE OF FIRST ISSUE</b>	MILANO – OCTOBER 2005
<b>PLACE &amp; DATE OF CURRENT EMISSION</b>	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
<b>SIGNATURE</b> Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA. PRO DIAGNOSTIC BIOPROBES srl

Rev: 12/2013





Dia.Pro  
**Diagnostic**  
Bio**Probes**

## EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	<b>Chlamydia Trachomatis IgA</b> CODE: CTA.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST B
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED  
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL  
DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

NOTIFIED BODY	AEMPS – n° 0318
(EC) CERTIFICATE(S)	<ul style="list-style-type: none"><li>• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318</li></ul>

PLACE & DATE OF FIRST ISSUE	MILANO – MAY 2009
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA. PRO. DIAGNOSTIC BIOPROBES srl

Rev: 12/2013



Dia.Pro  
**Diagnostic**  
Bio**Probes**

## EC DECLARATION OF CONFORMITY

<b>MANUFACTURER</b>	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
<b>PRODUCT</b>	<b>Chlamydia Trachomatis IgG</b> CODE: CTG.CE (96 tests)
<b>CLASSIFICATION</b>	ANNEX II – LIST B
<b>CONFORMITY ASSESSMENT ROUTE</b>	ANNEX IV

**WE HEREBY DECLARE THAT THE ABOVE MENTIONED  
PRODUCT MEETS THE PROVISIONS OF THE COUNCIL  
DIRECTIVE 98/79/EC  
FOR IN VITRO DIAGNOSTIC DEVICES.**

<b>NOTIFIED BODY</b>	AEMPS – n° 0318
<b>(EC) CERTIFICATE(S)</b>	<ul style="list-style-type: none"><li>• FULL QUALITY ASSURANCE SYSTEM N° 2004 05 0442 CT (in accordance with Annex IV – except Section IV) of the Directive 98/79/EC), RELEASED BY EC NOTIFIED BODY N° 0318</li><li>• UNI EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318</li></ul>

<b>PLACE &amp; DATE OF FIRST ISSUE</b>	MILANO – MAY 2009
<b>PLACE &amp; DATE OF CURRENT EMISSION</b>	SESTO SAN GIOVANNI (MI) – DECEMBER 2013
<b>SIGNATURE</b> Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA. PRO DIAGNOSTIC BIOPROBES srl

Rev: 12/2013



**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE  
**EC DESIGN-EXAMINATION CERTIFICATE**  
in accordance with Annex IV, Section 4, Directive 98/79/EC  
**PRÓRROGA/EXTENSION** — Fecha inicial/ Initial date: 15/03/2004  
Fecha de última prórroga/ Last extension date: 27/11/2013

<b>Certificado nº/Certificate no</b>	<b>Fecha de validez/Date of validity</b>	<b>ON nº/NB no</b>
<b>2004 03 0424 ED</b>	<b>Desde/From 26/11/2018 Hasta/To 18/11/2023</b>	<b>0318</b>

**A favor de /In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** DIA. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Para el producto/For the product:**

**Categoría/Category:** Productos Sanitarios para Diagnóstico “In Vitro” / In Vitro Diagnostic Medical Devices

**Grupo genérico/Generic group:** Diagnóstico de enfermedades infecciosas / Diagnostic of infectious diseases

**Tipo/Type:** Especificados en Anexos de este Certificado/Specified in Annexes to this Certificate.

**Elaborado en/In the facilities:**

**Dia. Pro Diagnostic Bioprobes S.r.l.**

**Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).**

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.

Madrid, 23 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: LVZBL763FF

Fecha de la firma: 23/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

Página 1 de 2

C/ CAMPEZO, 1 - EDIFICIO 8

28022 MADRID

on0318@aemps.es

Tel.: (+34) 902.101.322 / (+34) 91.822.59.97

Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318





**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*  
**PRÓRROGA/EXTENSION** — Fecha inicial/ Initial date: 15/03/2004  
Fecha de última prórroga/ Last extension date: 27/11/2013

Certificado nº/Certificate no	Fecha de validez/Date of validity	ON nº/NB no
<b>2004 03 0424 ED</b>	Desde/From <b>26/11/2018</b> Hasta/To <b>18/11/2023</b>	<b>0318</b>

**A favor de/In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** Dia. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Tipo de producto / Device type:** Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.

**Clasificación/Classification:** Lista A, Anexo II / List A, Annex II

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA) / Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA) [NANDO: IVD 0203]

**HBc IgM ELISA** cualitativo-cuantitativo / *ELISA qualitative-quantitative*

- BCM.CE (96 tests)

**Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad.** / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.*

Madrid, 23 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de medicamentos y productos sanitarios**

Fdo. M<sup>a</sup> Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: LVZBL763FF

Fecha de la firma: 23/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

on0318@aemps.es

Página 2 de 2

ORGANISMO NOTIFICADO 0318

C/ CAMPEZO, 1 - EDIFICIO 8

28022 MADRID

Tel.: (+34) 902.101.322 / (+34) 91.822.59.97

Fax: (+34) 91.822.52.89



**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*

**PRÓRROGA/EXTENSION** — Fecha inicial/ *Initial date*: 12/09/2007  
Fecha de última prórroga/ *Last extension date*: 27/11/2013

<b>Certificado nº/Certificate no</b>	<b>Fecha de validez/Date of validity</b>	<b>ON nº/NB no</b>
<b>2007 09 0532 ED</b>	<b>Desde/From 19/11/2018 Hasta/To 18/11/2023</b>	<b>0318</b>

**A favor de /In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** DIA. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Para el producto/For the product:**

**Categoría/Category:** Productos Sanitarios para Diagnóstico “In Vitro” / *In Vitro Diagnostic Medical Devices*

**Grupo genérico/Generic group:** Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*

**Tipo/Type:** Especificados en Anexos de este Certificado/ *Specified in Annexes to this Certificate.*

**Elaborado en/In the facilities:**

**Dia. Pro Diagnostic Bioprobes S.r.l.**

**Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).**

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: K2YCTJNABB

Fecha de la firma: 19/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

Página 1 de 2

C/ CAMPEZO, 1 - EDIFICIO 8

28022 MADRID

on0318@aemps.es

Tel.: (+34) 902.101.322 / (+34) 91.822.59.97

Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318





**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*  
**PRÓRROGA/EXTENSION** — Fecha inicial/ *Initial date*: 12/09/2007  
Fecha de última prórroga/ *Last extension date*: 27/11/2013

Certificado n°/Certificate no	Fecha de validez/Date of validity	ON n°/NB no
<b>2007 09 0532 ED</b>	Desde/From <b>19/11/2018</b> Hasta/To <b>18/11/2023</b>	<b>0318</b>

**A favor de/In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** Dia. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Tipo de producto / Device type:** Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

**Clasificación/Classification:** Lista A, Anexo II / *List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis C, mediante técnicas de Inmunoabsorción enzimática (ELISA) / *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis C infection, by Enzyme-linked immunosorbent assay (ELISA)* [NANDO: IVD 0203]

**HCV IgM ELISA** cualitativo-cuantitativo / *ELISA qualitative-quantitative*

- CVM.CE (96 tests)

**Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad.** / *This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.*

Madrid, 19 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de medicamentos y productos sanitarios**

Fdo. M<sup>a</sup> Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: K2YCTJNABB

Fecha de la firma: 19/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

Página 2 de 2

C/ CAMPEZO, 1 - EDIFICIO 8

28022 MADRID

on0318@aemps.es

Tel.: (+34) 902.101.322 / (+34) 91.822.59.97

Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318



**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*

**PRÓRROGA/EXTENSION** — Fecha inicial/ *Initial date*: 11/12/2003  
Fecha de última prórroga/ *Last extension date*: 27/11/2013

Certificado nº/ <i>Certificate no</i>	Fecha de validez/ <i>Date of validity</i>	ON nº/ <i>NB no</i>
<b>2003 12 0395 ED</b>	Desde/ <i>From</i> 19/11/2018 Hasta/ <i>To</i> 18/11/2023	<b>0318</b>

**A favor de /*In favour of*:**

**Fabricante/Manufacturer:**

**Nombre/Name:** DIA. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Para el producto/For the product:**

**Categoría/Category:** Productos Sanitarios para Diagnóstico “In Vitro” / *In Vitro Diagnostic Medical Devices*

**Grupo genérico/Generic group:** Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*

**Tipo/Type:** Especificados en Anexos de este Certificado/ *Specified in Annexes to this Certificate.*

**Elaborado en/In the facilities:**

**Dia. Pro Diagnostic Bioprobes S.r.l.**

**Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).**

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 19 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de  
medicamentos y  
productos sanitarios**

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: PVAN79R411

Fecha de la firma: 19/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

Página 1 de 2

C/ CAMPEZO, 1 - EDIFICIO 8

28022 MADRID

on0318@aemps.es

Tel.: (+34) 902.101.322 / (+34) 91.822.59.97

Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318



**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*  
**PRÓRROGA/EXTENSION** — Fecha inicial/ *Initial date*: 11/12/2003  
Fecha de última prórroga/ *Last extension date*: 27/11/2013

Certificado n°/Certificate no	Fecha de validez/Date of validity	ON n°/NB no
<b>2003 12 0395 ED</b>	Desde/From <b>19/11/2018</b> Hasta/To <b>18/11/2023</b>	<b>0318</b>

**A favor de/In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** Dia. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Tipo de producto / Device type:** Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / *Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.*

**Clasificación/Classification:** Lista A, Anexo II / *List A, Annex II*

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis D, mediante técnicas de Inmunoabsorción enzimática (ELISA) / *Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis D infection, by Enzyme-linked immunosorbent assay (ELISA)* [NANDO: IVD 0203]

**HDV IgM ELISA cualitativo / ELISA qualitative**

- DIM.CE (96 tests)

**Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.**

Madrid, 19 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de  
medicamentos y  
productos sanitarios**

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: PVAN79R411

Fecha de la firma: 19/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

Página 2 de 2

C/ CAMPEZO, 1 - EDIFICIO 8

28022 MADRID

on0318@aemps.es

Tel.: (+34) 902.101.322 / (+34) 91.822.59.97  
Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318



**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*

**PRÓRROGA/EXTENSION** — Fecha inicial/ *Initial date*: 17/11/2006  
Fecha de última prórroga/ *Last extension date*: 27/11/2013

<b>Certificado nº/Certificate no</b>	<b>Fecha de validez/Date of validity</b>	<b>ON nº/NB no</b>
<b>2006 11 0511 ED</b>	<b>Desde/From 26/11/2018 Hasta/To 18/11/2023</b>	<b>0318</b>

**A favor de /In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** DIA. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Para el producto/For the product:**

**Categoría/Category:** Productos Sanitarios para Diagnóstico “In Vitro” / *In Vitro Diagnostic Medical Devices*

**Grupo genérico/Generic group:** Diagnóstico de enfermedades infecciosas / *Diagnostic of infectious diseases*

**Tipo/Type:** Especificados en Anexos de este Certificado/ *Specified in Annexes to this Certificate.*

**Elaborado en/In the facilities:**

**Dia. Pro Diagnostic Bioprobes S.r.l.**

**Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).**

Este certificado debe ir acompañado por el certificado CE de Sistema de Garantía de Calidad Total Nº 2003 12 0388 CT/ *This certificate must be accompanied by the EC Full Quality Assurance System Certificate Nº 2003 12 0388 CT.*

Este certificado es consecuencia de la evaluación de la documentación técnica del diseño contenida en el expediente Nº 2003 05 0240, y garantiza que el diseño de los productos descritos cumple los requisitos de la Directiva/ *This certificate is issued on the assessment of the design documentation contained in dossier Nº 2003 05 0240, and guarantees that the design of the described products fulfil the requirements of the Directive.*

Madrid, 23 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de  
medicamentos y  
productos sanitarios**

Fdo. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: L3NQ3KL140

Fecha de la firma: 23/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

Página 1 de 2

C/ CAMPEZO, 1 - EDIFICIO 8

28022 MADRID

on0318@aemps.es

Tel.: (+34) 902.101.322 / (+34) 91.822.59.97

Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318





**CERTIFICADO DE EXAMEN CE DE DISEÑO**  
de acuerdo con el Anexo IV, punto 4, de la Directiva 98/79/CE

**EC DESIGN-EXAMINATION CERTIFICATE**  
*in accordance with Annex IV, Section 4, Directive 98/79/EC*  
**PRÓRROGA/EXTENSION** — Fecha inicial/ Initial date: 17/11/2006  
Fecha de última prórroga/ Last extension date: 27/11/2013

Certificado nº/Certificate no	Fecha de validez/Date of validity	ON nº/NB no
<b>2006 11 0511 ED</b>	Desde/From <b>26/11/2018</b> Hasta/To <b>18/11/2023</b>	<b>0318</b>

**A favor de/In favour of:**

**Fabricante/Manufacturer:**

**Nombre/Name:** Dia. Pro Diagnostic Bioprobes S.r.l.

**Dirección/Address:** Via G. Carducci, 27 -20099- Sesto San Giovanni – Milano (Italy).

**Representante autorizado ante la UE/Authorized EU representative:**

**Nombre/Name:** Idem **Dirección/Address:** Idem

**Tipo de producto / Device type:** Reactivos y productos reactivos, calibradores y materiales de control para el diagnóstico de enfermedades infecciosas / Reagents, and reagent products, calibrators and control materials for diagnostic of human infectious diseases.

**Clasificación/Classification:** Lista A, Anexo II / List A, Annex II

Reactivos y productos reactivos para la determinación, confirmación y cuantificación en muestras humanas de marcadores de infección por Hepatitis B, mediante técnicas de Inmunoabsorción enzimática (ELISA) / Reagents and reactive products for the determination, confirmation and quantification in human specimens of markers of Hepatitis B infection, by Enzyme-linked immunosorbent assay (ELISA) [NANDO: IVD 0203]

**HBs Ag Confirmation ELISA para confirmación / ELISA for confirmation**

- SCONF.CE (20 tests)
- SCONF.CE.40 (40 tests)

**Este certificado ampara todas las marcas de estos productos incluidas por el fabricante en su declaración de conformidad. / This certificate covers all trademarks of these products included by the manufacturer in his declaration of conformity.**

Madrid, 23 de noviembre de 2018

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

 **agencia española de medicamentos y productos sanitarios**

Fdo. M<sup>a</sup> Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios

Localizador: L3NQ3KL140

Fecha de la firma: 23/11/2018

Puede comprobar la autenticidad del documento en la aplicación Localizador de la Web de la AEMPS

CORREO ELECTRÓNICO

on0318@aemps.es

Página 2 de 2

ORGANISMO NOTIFICADO 0318

C/ CAMPEZO, 1 - EDIFICIO 8

28022 MADRID

Tel.: (+34) 902.101.322 / (+34) 91.822.59.97

Fax: (+34) 91.822.52.89



# 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)**

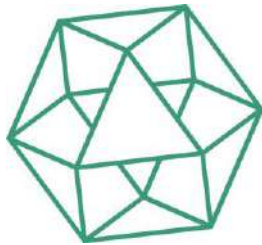
Approved by:  
Geraldine Larkin  
Chief Executive Officer

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**

**DECLARATION OF CONFORMITY**

1) Manufacturer (Name, department): **Monobind Inc.**

Address: **100 North Pointe, LAKE FOREST, CA 92630. UNITED STATES**

and

2) European authorized representative: **CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**

(on product labels printed as:

CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. [www.cepartner4u.com](http://www.cepartner4u.com))

3) Product(s) (name, type or model/batch number, etc.):

Immunoassay products;

**AccuBind® ELISA,**

**AccuLite® CLIA,**

**QSure® Control,**

**Instruments**

*see appendix*

4) The product(s) described above is in conformity with:

<u>Document No.</u>	<u>Title</u>
98/79/EC	<i>In vitro</i> Diagnostic Medical Devices Directive

5) Additional information (Conformity procedure, Notified Body, CE certificate, Registration nr., etc.):

Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex III

Registration nr. : **NL- CA002-22758 and NL- CA002-22762**

Lake Forest, USA; 2021-09-20



(Place & date of issue (yyyy-mm-dd))

Tony Shatola; QA Director, Monobind Inc.  
(name, function and signature of manufacturer)



## Appendix

Date: 2021-09-20

### List of devices.

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
<b>Allergy &amp; Anemia</b>							
Ferritin Test System	2825-300A 2825-300B	2875-300A 2875-300B			12.07.01.02.00	Low	2005-11-11
Folate Test System	7525-300A 7525-300B	7575-300A 7575-300B			12.07.01.03.00	Low	2010-06-29
Immunoglobulin E (IgE) Test System	2525-300A 2525-300B	2575-300A 2575-300B			12.02.01.02.00	Low	2005-11-11
Transferrin Soluble Receptor (sTfR) Test System	8625-300A 8625-300B	8675-300A 8675-300B			12.07.01.06.00	Low	2010-06-29
Vitamin B-12 (Vit B12) Test System	7625-300A 7625-300B	7675-300A 7675-300B			12.07.02.04.00	Low	2011-09-26
Folate, Vitamin B-12 (Anemia Panel VAST) Test System	7825-300A 7825-300B	7875-300A 7875-300B			12.07.01.00.00	Low	2013-09-16
<b>Autoimmune</b>							
Anti-Cyclic Citrullinated Peptide IgG (Anti-CCP IgG) Test System	12725-300A 12725-300B	12775-300A 12775-300B			12.11.01.90.00	Low	2019-04-03
Anti-Thyroglobulin (Anti-Tg) Test System	1025-300A 1025-300B	1075-300A 1075-300B			12.10.03.04.00	Low	2005-11-11
Anti-Thyroperoxidase (Anti-TPO) Test System	1125-300A 1125-300B	1175-300A 1175-300B			12.10.03.01.00	Low	2005-11-11
<b>Bone Metabolism &amp; Growth</b>							
<b>Calcitonin Test System</b>	<b>9325-300A</b> 9325-300B	9375-300A 9375-300B			12.06.03.02.00	Low	2019-04-03
Growth Hormone (hGH) Test System	1725-300A 1725-300B	1775-300A 1775-300B			12.06.04.02.00	Low	2005-11-11
Parathyroid Hormone (PTH) Test System	9025-300A 9025-300B	9075-300A 9075-300B			12.06.03.13.00	Low	2011-09-26
Parathyroid Hormone (PTH) 3rd & 2nd Gen (VAST) Test System	10025-300A 10025-300B	10075-300A 10075-300B			12.06.03.13.00	Low	2019-04-03
25(OH) Vitamin D Total Direct (Vit D-Direct) Test System	7725-300A 7725-300B	7775-300A 7775-300B			12.06.03.10.00	Low	2017-07-05
<b>Cancer Markers</b>							
Alpha-Fetoprotein (AFP) Test System	1925-300A 1925-300B	1975-300A 1975-300B			12.03.90.01.00	Low	2005-11-11
CA-125 Test System	3025-300A 3025-300B	3075-300A 3075-300B			12.03.01.06.00	Low	2005-11-11
CA 15-3 Test System	5625-300A 5625-300B	5675-300A 5675-300B			12.03.01.02.00	Low	2010-06-29
CA 19-9 Test System	3925-300A 3925-300B	3975-300A 3975-300B			12.03.01.03.00	Low	2005-11-11
Carcinoembryonic Antigen (CEA) Test System	1825-300A 1825-300B	1875-300A 1875-300B			12.03.01.31.00	Low	2005-11-11
Next Generation Carcinoembryonic Antigen	4625-300A	4675-300A			12.03.01.31.00	Low	2010-06-29

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
(CEA-Next Gen) Test System	4625-300B	4675-300B					
Free β-Subunit Human Chorionic Gonadotropin (Free Beta hCG) Test System	2025-300A 2025-300B	2075-300A 2075-300B			12.03.01.90.00	Low	2005-11-11
<b>Cardiac Markers</b>							
CK-MB Test System	2925-300A 2925-300B	2975-300A 2975-300B			12.13.01.02.00	Low	2005-11-11
Digoxin (DIG) Test System	925-300A 925-300B	975-300A 975-300B			12.08.01.01.00	Low	2005-11-11
High Sensitivity CRP (hs-CRP) Test System	3125-300A 3125-300B	3175-300A 3175-300B			12.13.01.90.00	Low	2005-11-11
Myoglobin Test System	3225-300A 3225-300B	3275-300A 3275-300B			12.13.01.05.00	Low	2005-11-11
Troponin I (cTnI) Test System	3825-300A 3825-300B	3875-300A 3875-300B			12.13.01.07.00	Low	2005-11-11
<b>Diabetes</b>							
C-Peptide Test System	2725-300A 2725-300B	2775-300A 2775-300B			12.06.01.01.00	Low	2005-11-11
Insulin Test System	2425-300A 2425-300B	2475-300A 2475-300B			12.06.01.03.00	Low	2005-11-11
Rapid Insulin Test System	5825-300A 5825-300B				12.06.01.03.00	Low	2010-06-29
Insulin - C-Peptide (Diabetes Panel VAST)	7325-300A 7325-300B	7375-300A 7375-300B			12.06.01.03.00	Low	2005-11-11
<b>Endocrine</b>							
ACTH Test System	10625-300	10675-300			12.06.04.01.00	Low	2019-04-03
Aldosterone Test System	10125-300	10175-300			12.06.02.01.00	Low	2019-04-03
Leptin Test System	10925-300	10975-300			12.06.90.17.00	Low	2019-04-03
<b>Fertility &amp; Prenatal</b>							
Anti-Müllerian Hormone (AMH) Test System	9725-300A 9725-300B	9775-300A 9775-300B			12.05.02.16.00	Low	2019-04-03
Folicle Stimulating Hormone (FSH) Test System	425-300A 425-300B	475-300A 475-300B			12.05.01.04.00	Low	2005-11-11
B-Human Chorionic Gonadotropin (hCG) Test System	825-300A 825-300B	875-300A 875-300B			12.05.02.05.00	Low	2005-11-11
B-Human Chorionic Gonadotropin Extended Range (hCG-XR) Test System	8825-300A 8825-300B	8875-300A 8875-300B			12.05.02.05.00	Low	2013-09-16
Rapid B-Human Chorionic Gonadotropin (Rapid hCG) Test System	3325-300A 3325-300B				12.05.02.05.00	Low	2005-11-11
Inhibin A Test System	9525-300A 9525-300B	9575-300A 9575-300B			12.05.01.90.00	Low	2019-04-03
Inhibin B Test System	9625-300A 9625-300B	9675-300A 9675-300B			12.05.01.90.00	Low	2019-04-03
Luteinizing Hormone (LH) Test System	625-300A 625-300B	675-300A 675-300B			12.05.01.05.00	Low	2005-11-11
Pregnancy Associated Plasma Protein – A Mass Units (PAPP-A Mass Units) Test System	12625-300A 12625-300B	12675-300A 12675-300B			12.05.02.10.00	Low	2017-07-05
Prolactin Hormone (PRL) Test System	725-300A 725-300B	775-300A 775-300B			12.05.01.08.00	Low	2005-11-11

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
Prolactin Hormone Sequential (PRLs) Test System	4425-300A 4425-300B	4475-300A 4475-300B			12.05.01.08.00	Low	2005-11-11
Human Chorionic Gonadotropin (hCG) , Human Prolactin (hPRL), Human Luteinizing Hormone (hLH), Follicle Stimulating Hormone (FSH) (Fertility Panel VAST) Test System	8325-300B 8325-300D 8325-300E	8375-300B 8375-300D 8375-300E			12.05.01.90.00	Low	2006-08-24
Alpha-Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG), Unconjugated Estriol (u-E3) Triple Screen (Triple Screen Panel VAST) Test System	8525-300A 8525-300B	8575-300A 8575-300B			12.05.01.90.00	Low	2010-06-29
<b>Infectious Diseases</b>							
Anti-H. Pylori IgG (H. Pylori Ab IgG) Test System	1425-300A 1425-300B	1475-300A 1475-300B			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgM (H. Pylori Ab IgM) Test System	1525-300A 1525-300B	1575-300A 1575-300B			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgA (H. Pylori Ab IgA) Test System	1625-300A 1625-300B	1675-300A 1675-300B			15.01.04.03.00	Low	2005-11-11
Anti-SARS-CoV-2 (COVID-19) IgG Test System	11925-300A 11925-300B	11975-300A 11975-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) IgM Test System	11725-300A 11725-300B	11775-300A 11775-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) IgA Test System	11825-300A 11825-300B	11875-300A 11875-300B			15.04.80.90.00	Low	2020-08-25
Anti-SARS-CoV-2 (COVID-19) S1-RBD IgG Test System	12025-300A 12025-300B	12075-300A 12075-300B			15.04.80.90.00	Low	2021-09-20
D-Dimer Test System	9225-300A 9225-300B	9275-300A 9275-300B			13.02.05.03.00	Low	2020-08-25
Procalcitonin (PCT) Test System	1425-300A 1425-300B	1475-300A 1475-300B			12.06.90.16.00	Low	2017-07-05
<b>Neonatal</b>							
Neonatal 17OHP (N-17OHP) Test System	5525-300A 5525-300B				12.05.01.07.00	Low	2008-02-01
Neonatal (N-T4) Thyroxine Test System	2625-300A 2625-300B				12.04.01.12.00	Low	2005-11-11
Neonatal TBG (N-TBG) Test System	8925-300A 8925-300B				12.04.01.09.00	Low	2013-09-16
Neonatal TSH (N-TSH) Test System	3425-300A 3425-300B 3425-300D 3425-300E				12.04.01.90.00	Low	2005-11-11
<b>Steroid</b>							
Androstenedione (ANST) Test System	12425-300A 12425-300B	12475-300A 12475-300B			12.05.01.01.00	Low	2021-09-20
Cortisol Test System	3625-300A 3625-300B	3675-300A 3675-300B			12.06.02.04.00	Low	2005-11-11
Dehydroepiandrosterone (DHEA) Test System	7425-300A 7425-300B	7475-300A 7475-300B			12.05.01.02.00	Low	2011-09-26
Dehydroepiandrosterone Sulfate (DHEA-S) Test System	5125-300A 5125-300B	5175-300A 5175-300B			12.05.01.02.00	Low	2010-06-29
Estrone (E1) Test System	10325-300A 10325-300B	10375-300A 10375-300B			12.05.02.04.00	Low	2019-04-03

<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
Estradiol (E2) Test System	4925-300A 4925-300B	4975-300A 4975-300B			12.05.01.03.00	Low	2010-06-29
Unconjugated Estiol (u-E3) Test System	5025-300A 5025-300B	5075-300A 5075-300B			12.05.02.02.00	Low	2010-06-29
Progesterone Test System	4825-300A 4825-300B	4875-300A 4875-300B			12.05.01.06.00	Low	2010-06-29
17-OH Progesterone (17-OHP) Test System	5225-300A 5225-300B	5275-300A 5275-300B			12.05.01.07.00	Low	2010-06-29
17-OH Progesterone SI (17-OHP-SI) Test System	9925-300A 9925-300B	9975-300A 9975-300B			12.05.01.07.00	Low	2010-10-18
Sex Hormone Binding Globulin (SHBG) Test System	9125-300A 9125-300B	9175-300A 9175-300B			12.05.01.09.00	Low	2013-09-16
Testosterone Test System	3725-300A 3725-300B	3775-300A 3775-300B			12.05.01.10.00	Low	2007-11-01
Free Testosterone Test System	5325-300A 5325-300B	5375-300A 5375-300B			12.05.01.10.00	Low	2010-06-29
<b>Thyroid</b>							
Total Triiodothyronine (tT3) Test System	125-300A 125-300B 125-300D 125-300E	175-300A 175-300B 175-300D 175-300E			12.04.01.05.00	Low	2005-11-11
Free Triiodothyronine (fT3) Test System	1325-300A 1325-300B 1325-300A 1325-300B	1375-300A 1375-300B 1375-300D 1375-300E			12.04.01.01.00	Low	2005-11-11
Total Triiodothyronine (tT3 SBS) Test System	8125-300A 8125-300B	8175-300A 8175-300B			12.04.01.01.00	Low	2010-06-29
Rapid Total Triiodothyronine (Rapid -tT3) Test System	11225-300A 11225-300B				12.04.01.01.00	Low	2017-07-05
T3-Uptake (T3U) Test System	525-300A 525-300B	575-300A 575-300B			12.04.01.06.00	Low	2005-11-11
Thyroxine (tT4) Test System	225-300A 225-300B 225-300D 225-300E	275-300A 275-300B 275-300D 275-300E			12.04.01.07.00	Low	2005-11-11
Free Thyroxine (fT4) Test System	1225-300A 1225-300B 1225-300D 1225-300E	1275-300A 1275-300B 1275-300D 1275-300E			12.04.01.02.00	Low	2005-11-11
Total Thyroxine (tT4 SBS) Test System	8225-300A 8225-300B	8275-300A 8275-300B			12.04.01.01.00	Low	2010-06-29
Rapid Total Thyroxine (Rapid -tT4) Test System	11125-300A 11125-300B				12.04.01.01.00	Low	2017-07-05
Thyrotropin (TSH) Test System	325-300A 325-300B 325-300D 325-300E	375-300A 375-300B 375-300D 375-300E			12.04.01.11.00	Low	2005-11-11
Rapid TSH Test System	6025-300A 6025-300B	6075-300A 6075-300B			12.04.01.11.00	Low	2010-06-29
Thyroxine-Binding Globulin (TBG) Test System	3525-300A 3525-300B	3575-300A 3575-300B			12.04.01.09.00	Low	2005-11-11
Thyroglobulin (Tg) Test System	2225-300A	2275-300A			12.04.01.08.00	Low	2005-11-11



<i>Device types</i>	<i>Item# AccuBind® ELISA Microwells</i>	<i>Item# AccuLite® CLIA Microwells</i>	<i>Item# QSure® Control</i>	<i>Item# Instru- ment</i>	<i>EDMS code</i>	<i>Risk Class</i>	<i>First date of CE-marking</i>
	2225-300B	2275-300B					
Total Thyroxine (tT4), Total Triiodothyronine (tT3) & Thyroid Stimulating Hormone (TSH) (Thyroid Panel VAST) Test System	8025-300B 8025-300D 8025-300E	8075-300B 8075-300D 8075-300E			12.04.01.01.00	Low	2005-11-11
Free Thyroxine (fT4), Free Triiodothyronine (fT3) & Thyroid Stimulating Hormone (TSH) (Free Thyroid Panel VAST) Test System	7025-300B 7025-300D 7025-300E	7075-300B 7075-300D 7075-300E			12.04.01.01.00	Low	2010-06-29

<b>Miscellaneous Controls</b>							
Anti-H. Pylori Control (IgA, IgG, IgM) – Positive & Negative			HPC-300		12.50.01.16.00	Low	2013-09-16
Anti-Tg & Anti-TPO Control – Positive & Negative			AIT-101		12.50.01.16.00	Low	2010-06-29
Maternal Control – (AFP, uE3, hCG, Free beta hCG) Tri Level			MC-300		12.50.01.16.00	Low	2010-06-29
TBG Control – Tri-Level			TBG-300		12.50.01.16.00	Low	2013-09-16
Tg Control – Tri-Level			TG-300		12.50.01.16.00	Low	2010-06-29
Tumor Marker Control – (CA 125, CA 15-3, CA 19-9) Tri-Level			TMC-300		12.50.01.16.00	Low	2013-09-16

<b>Miscellaneous Instruments</b>							
Autoplex® ELISA & CLIA Analyzer				IN006	21.02.10.01	Low	2010-06-29
Autoplex® G2 ELISA & CLIA Analyzer				IN006-2	21.02.10.01	Low	2013-09-16
Autoplex® G3 ELISA & CLIA Analyzer				IN006-3	21.02.10.01	Low	2017-07-05
NeoEldex® ELISA Analyzer				IN009	21.02.10.01	Low	2011-09-26
Impulse® 3 CLIA Analyzer				IN007	21.02.10.01	Low	2010-06-29
NeoLumax® CLIA Analyzer				IN010	21.02.10.01	Low	2011-09-26
LuMatic® CLIA Analyzer				IN008	21.02.10.01	Low	2011-09-26
PrisMatic® ELISA Analyzer				IN013	21.02.10.01	Low	2013-09-16
PlateWash - Immunoassay Washer				IN002	21.02.10.01	Low	2010-06-29
TITIN® ELISA & CLIA Analyzer				IN015-EC	21.02.10.01	Low	2017-07-05
TITIN® ELISA Analyzer				IN015-E	21.02.10.01	Low	2017-07-05
TITIN-s® ELISA & CLIA Analyzer				IN016-EC	21.02.10.01	Low	2017-07-05
TITIN-s® ELISA Analyzer				IN016-E	21.02.10.01	Low	2017-07-05

**EC DECLARATION OF CONFORMITY**

ZAO "Vector-Best" hereby ensures under own responsibility and declares that the products listed on pages 2,4 are in conformity with applicable provisions and fulfill the essential requirements of Annex I Directive 98/79/EC of 27 October 1998 regarding in vitro diagnostic medical devices.

Classification of products: Other devices (all devices except Annex II and self-testing devices)

Conformity assessment procedure: Annex III (not including section G)

Manufacturer:  
ZAO "Vector-Best"  
Address: AHC, Koltsovo,  
Novosibirsk Region, 630559, Russia,  
Tel: +7 (383) 363 20 60,  
Fax: +7 (383) 363 35 55

European authorized representative:  
Bioron GmbH,  
Rheinhorststr. 18, D-67071  
Ludwigshafen, Germany.  
Tel: +49 (0) 621 5720 915,  
fax: +49 (0) 621 5720 916

Date: 2013/04/12



*Murat Khushainov*

Murat Khushainov  
General Director ZAO «Vector-Best»


No.	Product name	Identification data	REF
1.	Vectohep A-IgM	ELISA kit for determination of IgM to hepatitis A virus	D-0352
2.	Vectohep A-IgG	ELISA kit for quantitative and qualitative determination of IgG to hepatitis A virus	D-0362
3.	Vectohep ITV-IgG	ELISA kit for determination of IgG to TT virus	D-0802
4.	Vectohep E-IgG	ELISA kit for determination of IgG to hepatitis E virus	D-1096
5.	Vectohep E-IgM	ELISA kit for determination of IgM to hepatitis E virus	D-1098
6.	Vectohep G-IgG	ELISA kit for determination of IgG to hepatitis G virus	D-1252
7.	LymeBest-IgG	ELISA kit for determination of IgG to infectious borreliosis agents	D-1452
8.	LymeBest-IgM	ELISA kit for determination of IgM to infectious borreliosis agents	D-1454
9.	Recombibest antipallidum-IgG	ELISA kit for determination of IgG to Treponema pallidum	D-1852
10.	Recombibest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1856
11.	Recombibest antipallidum-IgM	ELISA kit for determination of IgM to Treponema pallidum	D-1858
12.	Recombibest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1857
13.	VectohSV-1,2 - IgG	ELISA kit for determination of IgG to herpes simplex virus types 1 and 2	D-2152
14.	VectohSV - IgM	ELISA kit for determination of IgM to herpes simplex virus types 1 and 2	D-2154
15.	VectohHV-8 - IgG	ELISA kit for determination of IgG to human herpes virus type 8	D-2160
16.	VectohHV-8 - IgG	ELISA kit for determination of IgG to human herpes virus type 8	D-2166
17.	Ureaplasma urealyticum - IgG-EIA-BEST	ELISA kit for determination of IgG to Ureaplasma urealyticum antigens	D-2254
18.	Ureaplasma urealyticum - IGA-EIA-BEST	ELISA kit for determination of IGA to Ureaplasma urealyticum antigens	D-2258
19.	VectoParotitis-IgG	ELISA kit for determination of IgG to parotitis virus	D-2602
20.	VectoParotitis-IgM	ELISA kit for determination of IgM to parotitis virus	D-2604
21.	Toxocara-IgG-EIA-BEST	ELISA kit for determination of IgG to toxocara antigens	D-2752
22.	Opisthorchiasis - IgG-EIA-BEST	ELISA kit for determination of IgG to opisthorchiasis antigens	D-2952
23.	Echinococcus-IgG-EIA-BEST	ELISA kit for determination of IgG to Echinococcus antigens	D-3356



24.	Ascend- IgG-EIA-BEST	antigens	ELISA kit for determination of IgG to Ascaris lumbricoides	D-3452
25.	Lamblija-antibodies-EIA-BEST		ELISA kit for determination of IgG, IgM and IgA to Lamblija antibodies	D-3552
26.	Lamblija-IgM-EIA-BEST		ELISA kit for determination of IgM to Lamblija antibodies	D-3554
27.	Lamblija-antigen-EIA-BEST		ELISA kit for determination of Lamblija antigen	D-3556
28.	Helicobacter pylori-Caga-antigen-EIA-BEST		ELISA kit for determination of total antibodies to Caga Helicobacter pylori	D-3752
29.	TSH-EIA-BEST		ELISA kit for determination of concentration of thyrotropin releasing hormone	X-3952
30.	T3 total-EIA-BEST		ELISA kit for determination of concentration of total triiodothyronine	X-3954
31.	T4 total-EIA-BEST		ELISA kit for determination of concentration of total thyroxine	X-3956
32.	Anti-TPO-EIA-BEST		ELISA kit for determination of antibody concentration to thyroperoxidase	X-3968
33.	PAPP-A-EIA-BEST		ELISA kit for determination of concentration of pregnancy-associated plasma protein A	D-4150
34.	Mycoplasma hominis-IgG-EIA-BEST		ELISA kit for determination of IgG to Mycoplasma hominis	D-4352
35.	Mycoplasma hominis-IgA-EIA-BEST		ELISA kit for determination of IgA to Mycoplasma hominis	D-4356
36.	Mycoplasma pneumoniae-IgG-EIA-BEST		ELISA kit for determination of IgG to Mycoplasma pneumoniae	D-4362
37.	Mycoplasma pneumoniae-IgM-EIA-BEST		ELISA kit for determination of IgM to Mycoplasma pneumoniae	D-4366
38.	Veddoctimean - CHF - IgG		ELISA kit for determination of IgG to Crinear-Congo hemorrhagic fever virus	D-5052
39.	Veddoctimean - CHF - IgM		ELISA kit for determination of IgM to Crinear-Congo hemorrhagic fever virus	D-5054
40.	CEA-EIA-BEST		ELISA kit for determination of concentration of carcinoembryonic antigen	T-8454
41.	AFP-EIA-BEST		ELISA kit for determination of concentration of Alpha-Fetal Protein	T-8456
42.	CA-125-EIA-BEST		ELISA kit for determination of concentration of oncomarker CA-125	T-8466
43.	CA 19-9-EIA-BEST		ELISA kit for determination of concentration of CA 19-9	T-8470
44.	CA 15-3-EIA-BEST		ELISA kit for determination of concentration of oncomarker CA 15-3	T-8472
45.	NSE-EIA-BEST		ELISA kit for determination of concentration of neuron specific enolase	T-8476

46.	Ferritin-EIA-BEST		ELISA kit for determination of concentration of ferritin	T-8552
47.	IgE total-EIA-BEST		ELISA kit for determination of concentration of total IgE	A-8660
48.	IgG total-EIA-BEST		ELISA kit for determination of concentration of total IgG	A-8662
49.	IgM total-EIA-BEST		ELISA kit for determination of concentration of total IgM	A-8664
50.	IgA total-EIA-BEST		ELISA kit for determination of concentration of total IgA	A-8666
51.	Gamma-Interferon-EIA-BEST		ELISA kit for determination of concentration of gamma-interferon	A-8752
52.	Interleukine-4-EIA-BEST		ELISA kit for determination of concentration of interleukine-4	A-8754
53.	Alpha-TNF-EIA-BEST		ELISA kit for determination of concentration of alpha-tumor necrosis factor	A-8756
54.	Alpha-Interferon-EIA-BEST		ELISA kit for determination of concentration of alpha-interferon	A-8758
55.	Interleukine-6-EIA-BEST		ELISA kit for determination of concentration of interleukine 6	A-8768
56.	Interleukine-2-EIA-BEST		ELISA kit for determination of concentration of interleukine-2	A-8772
57.	Procalcitonin-EIA-BEST		ELISA kit for determination of concentration of procalcitonin	A-9004
58.	NTproBNP-EIA-BEST		ELISA kit for determination of concentration of N-terminal prohomone of brain natriuretic peptide	A-9102
59.	Troponin I-EIA-BEST		ELISA kit for determination of concentration of troponin I	A-9106



	<b>AO Vector-Best</b>	Rev. 2
	EC Declaration of conformity ELISA	Page 1 of 3

## EC DECLARATION OF CONFORMITY

**AO Vector-Best hereby ensures under own responsibility and declares that the products listed on pages 2-3 are in conformity with relevant provisions of EC Council Directive 98/79/EC on in vitro diagnostic medical devices and fulfill the essential requirements of that directive.**

### Classification of products:

Other devices (all devices except Annex II and self-testing devices)

### Harmonized standards applied:

EN ISO 18113-1:2011; EN ISO 18113-2:2011 (In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements. In vitro diagnostic reagents for professional use); EN ISO 15223-1:2016 (Symbols to be used with medical device labels, labelling and information to be supplied); EN ISO 13485:2016+AC:2016 (Medical devices. Quality management systems. Requirements for regulatory purposes); EN 13612:2002 (Performance evaluation of in vitro diagnostic medical devices); EN 23640:2015 (In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents); EN 13641:2002 (Elimination or reduction of risk of infection related to in vitro diagnostic reagents); EN ISO 14971:2012 (Medical devices. Application of risk management to medical devices).

### Conformity assessment procedure:

Annex III (not including section 6).

### Manufacturer:

AO Vector-Best

Address: 630559, Koltsovo, Novosibirsk Region, Research and Production area, building 36, office 211, Russian Federation, tel. +7 (383) 336-73-46, tel./fax +7 (383) 332-67-49.

### European authorized representative:

BIORON GmbH

Address: In den Rauhweiden 20, 67354 Roemerberg, Germany, tel.: +49 (0) 6232 298 450.


Date: 2020/12/09  
Place: Novosibirsk

Valid until: 2022/07/03




Murat Khusainov  
General Director AO Vector-Best



	<b>AO Vector-Best</b>	Rev. 2
	EC Declaration of conformity ELISA	Page 2 of 3

No.	Product name	Identification data	REF
1.	Vectohep A-IgG	Enzyme immunoassay kit for the detection and quantification of IgG to hepatitis A virus	D-0362
2.	VectoMeasles-IgG	Enzyme immunoassay kit for the detection and quantification of IgG to measles virus in blood serum (plasma)	D-1356
3.	VectoMeasles-IgM	Enzyme immunoassay kit for the detection of IgM to measles virus in blood serum (plasma)	D-1358
4.	Rotavirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human rotavirus antigen	D-1652
5.	Adenovirus-antigen-EIA-BEST	Enzyme immunoassay kit for the detection of human adenovirus antigen	D-1654
6.	VectoEBV-NA-IgG	Enzyme immunoassay kit for the detection of IgG to Epstein-Barr virus nuclear antigen in blood serum (plasma)	D-2170
7.	VectoEBV-EA-IgG	Enzyme immunoassay kit for the detection of IgG to Epstein-Barr virus early antigens in blood serum (plasma)	D-2172
8.	VectoEBV-VCA-IgM	Enzyme immunoassay kit for the detection of IgM to viral capsid antigen of Epstein-Barr virus in blood serum (plasma)	D-2176
9.	VectoMumps-IgG	Enzyme immunoassay kit for the detection of IgG to mumps virus in blood serum (plasma)	D-2602
10.	Toxocara-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Toxocara antigens in blood serum (plasma)	D-2752
11.	Trichinella-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Trichinella antigens in blood serum (plasma)	D-3152
12.	Yersinia-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to causative agents of yersiniosis	D-3202
13.	Yersinia-IgA-EIA-BEST	Enzyme immunoassay kit for the detection of IgA to causative agents of yersiniosis	D-3204
14.	Yersinia-IgM-EIA-BEST	Enzyme immunoassay kit for the detection of IgM to causative agents of yersiniosis	D-3206
15.	Echinococcus-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Echinococcus granulosus antigens in blood serum (plasma)	D-3356
16.	Ascaris-IgG-EIA-BEST	Enzyme immunoassay kit for the detection of IgG to Ascaris lumbricoides antigens in blood serum (plasma)	D-3452
17.	IgA-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantification of IgA to tissue transglutaminase in blood serum (plasma)	D-3758

	<b>AO Vector-Best</b>	Rev. 2
	EC Declaration of conformity ELISA	Page 3 of 3

18.	IgG-Transglutaminase-EIA-BEST	Enzyme immunoassay kit for the quantification of IgG to tissue transglutaminase in blood serum (plasma)	D-3760
19.	Pepsinogen 1-EIA-BEST	Enzyme immunoassay kit for the quantification of pepsinogen 1 in blood serum (plasma)	D-3762
20.	Pepsinogen 2-EIA-BEST	Enzyme immunoassay kit for the quantification of pepsinogen 2 in blood serum (plasma)	D-3764
21.	VectoHanta-IgG	Enzyme immunoassay kit for the detection of IgG to hantavirus in blood serum (plasma)	D-4902
22.	VectoHanta-IgM	Enzyme immunoassay kit for the detection of IgM to hantavirus in blood serum (plasma)	D-4904
23.	VectoNile-IgM	Enzyme immunoassay kit for the detection of IgM to West Nile virus in blood serum (plasma)	D-5150
24.	VectoNile-IgG	Enzyme immunoassay kit for the detection of IgG to West Nile virus in blood serum (plasma)	D-5152
25.	VectoNile-IgG-avidity	Enzyme immunoassay kit for the determination of avidity index of IgG to West Nile virus in blood serum (plasma)	D-5154
26.	VectoCrimean-CHF-IgG	Enzyme immunoassay kit for the detection of IgG to Crimean-Congo hemorrhagic fever virus in blood serum (plasma)	D-5052
27.	VectoCrimean-CHF-IgM	Enzyme immunoassay kit for the detection of IgM to Crimean-Congo hemorrhagic fever virus in blood serum (plasma)	D-5054
28.	VectoCrimean-CHF-antigen	Enzyme immunoassay kit for the detection of Crimean-Congo hemorrhagic fever virus antigen	D-5056



# Certificate

**mdc medical device certification GmbH**  
certifies that

VECTOR



**AO Vector-Best  
Research and Production Area  
Building 36, Office 211, Koltsovo  
630559 Novosibirsk region  
Russian Federation**

with the locations listed in the attachment  
for the scope

**Design and development, production and distribution of  
medical devices for in vitro diagnostics (PCR, ELISA, Biochemistry)**

has introduced and applies a

## Quality Management System

The mdc audit has proven that this quality management system  
meets all requirements of the following standard

### EN ISO 13485

Medical devices – Quality management systems –  
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2020-07-04
Valid until	2023-07-03
Registration no.	D1213100019
Report no.	P20-00568-173687
Stuttgart	2020-06-02

  
Head of Certification Body



**Attachment of the certificate**

**No. D1213100019**

date 2020-06-02

Page 1 of 1

<b>Location</b>	<b>Scope</b>
AO Vector-Best Arbuzova str. 1/1, 630117 Novosibirsk Russian Federation	design and development, production and distribution of medical devices for in vitro diagnostics
AO Vector-Best Research and Production area, building 36, Koltsovo, 630559 Novosibirsk region Russian Federation	design and development, production of medical devices for in vitro diagnostics
AO Vector-Best Pasechnaya str, 3, 630117 Novosibirsk Russian Federation	design and development, production of medical devices for in vitro diagnostics



  
\_\_\_\_\_  
Head of Certification Body