



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	HAV IgM CODE: AVM.CE (96 tests)
CLASSIFICATION	GENERAL IVD
CONFORMITY ASSESSMENT ROUTE	SELF CERTIFICATION

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

ISO CERTIFICATE	UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY AEMPS (AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS)
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PLACE & DATE OF FIRST ISSUE	MILANO – SEPTEMBER 2003
PLACE & DATE OF CURRENT ISSUE	SESTO SAN GIOVANNI (MI) – MARCH 2019
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	

Rev: 05/2018



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EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HBc Ab CODE: BCAB.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST A
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">• 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• DESIGN CERTIFICATE N° 2003 12 0391 ED RELEASED BY EC NOTIFIED BODY N° 0318• UNE EN ISO 13485 N° 2013 11 0039 EN, RELEASED BY EC NOTIFIED BODY N° 0318

PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MARCH 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.

Rev: 0318

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

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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



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MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	HCV Ab CODES: CVAB.CE (192 tests) CVAB.CE.96 (96 tests) CVAB.CE.480 (480 tests) CVAB.CE.960 (960 tests) CVAB.CE.DB (192 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

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NOTIFIED BODY	AEMPS – n° 0318
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PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
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Rev: 0318



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PRODUCT	HDV Ab CODE: DAB.CE (96 tests)
CLASSIFICATION	ANNEX II – LIST A
CONFORMITY ASSESSMENT ROUTE	ANNEX IV

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PLACE & DATE OF FIRST ISSUE	MILANO – JANUARY 2004
PLACE & DATE OF CURRENT EMISSION	SESTO SAN GIOVANNI (MI) – MAY 2018
SIGNATURE Legal Representative Dr.ssa Fiorenza Scozzesi	 DIA.PRO DIAGNOSTIC BIOPROBES S.R.L.

Rev: 05/2018