Digitally signed by Ceaicovschi Tudor
Date: 2024.12.17 17:38:30 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2002-10-25
Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14
Expiry Date: 2027-04-13

...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

Latest Revision Date: 2024-03-26

Effective Date: 2024-04-14

Expiry Date: 2027-04-13

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- 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

Declaration of Conformity

HL-7-0664DC DOI 2015/08 (1)

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
5267L	Thromboplastin L	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: 06 Aug 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

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

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- 0640DC DOI 2015/07 (1)

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
5504R	Calibration Plasma	55995

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: 30 Jul 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

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

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Awareness Technology, Inc.

Main Site: 1935 SW Martin Highway

Palm City, Florida 34990 USA

Additional site: 2325 SW Martin Highway, Palm City, Florida 34990 USA

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, distribution, installation and service of IVDD General Laboratory Instruments.

Main site: Management, QA, Design, Sales, Service

Additional site: Manufacturing, Quality Control, Distribution, Shipping, Installation and Service.

Certificate Number:
9362

Revision Level: 09

Initial Certification Date:
March 28, 2012

Date of Certification Decision:
December 19, 2023

Issuing Date:
December 19, 2023

Valid Until:
December 18, 2026

ISO 13485:2016 CERTIFICATION TM

SCC Accredited CB-MS OCSM Accrédité CCN TM

The SCC Accreditation Symbol is an official symbol of the Standards Council of Canada, used under licence.

intertek

Calin Moldovean
President

Intertek Testing Services NA Inc. dba Intertek,
900 Chelmsford Street,
Lowell, MA, USA

Certificate DE22/00000148

The management system of

ams-OSRAM AG

Tobelbader Strasse 30, Schloß Premstätten, AT 8141 Premstätten

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Research and development, design, production and sales of sensor solutions, ICs and related software, pre-materials, equipment, opto semiconductor and lighting products, services and components for sensing, illumination and visualization

This certificate is valid from 15 November 2023 until 06 March 2026 and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 20 July 2022

Organization certified since 28 September 2001 and first certified by SGS on 20 July 2022.

Certified activities performed by additional sites are listed on subsequent pages.

Authorised by

Jonathan Hall

Global Head - Certification Services

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

t +44 (0)151 350-6666 - www.sgs.com

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
de acuerdo con el Anexo IV (excepto punto 4) de la Directiva 98/79/CE
EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex IV (except Section 4) of Directive 98/79/EC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*			ON nº/*NB no*
2003 12 0388 CT	**Desde/*From***	**20-05-2022**	**Hasta/*To*** **26-05-2025**	**0318**

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*: 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 el Anexo de este Certificado/*Specified in Annex to this Certificate*

Elaborado en/*In the facilities*:

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

Fecha inicial/ *Initial date:* 11/12/2003
Fecha de prórroga anterior/ *Previous extension date:* 26/11/2018

Este certificado debe ir acompañado por certificado de examen de diseño: SI / *This certificate must be accompanied by design examination certificate*: *YES*

Este certificado es consecuencia de la auditoria del sistema completo de garantía de calidad y del examen de la documentación técnica contenida en el expediente nº 2003 05 0240, y garantiza que los productos descritos cumplen los requisitos de la Directiva./ *This certificate is issued on the full quality assurance system audit, and the examination of the technical documentation contained in dossier nº 2003 05 0240, and guarantees that the described products fulfils the requirements of the Directive.*

Madrid, 19 de mayo de 2022
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: 19/05/2022
Puede comprobar la autenticidad del documento en la sede de la AEMPS:https://localizador.aemps.es
CSV: N D A S R W L D 3 A

CORREO ELECTRÓNICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 91 822.57.87 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318

ANEXO Nº/*ANNEX NO:* I

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
de acuerdo con el Anexo IV (excepto punto 4) de la Directiva 98/79/CE

EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex IV (except Section 4) of Directive 98/79/EC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*			ON nº/*NB no*
2003 12 0388 CT	**Desde/*From***	**20-05-2022**	**Hasta/*To*** **26-05-2025**	**0318**

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*: **Idem**

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

Clasificación/ *Classification:* Lista A del Anexo II / *List A of Annex II*

1. **Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante técnicas de Inmunoabsorción enzimática (ELISA)/** *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Enzyme-linked immunosorbent assay (ELISA)* **[NANDO: IVD 0201; IVD 0202; IVD 0203]**

1.1. HBs Ab

- SAB.CE (96 tests)	Descrito en el certificado/ *Described in the certificate* 2003 12 0390 ED

1.2. HBc Ab

- BCAB.CE (96 tests)	Descrito en el certificado/ *Described in the certificate* 2003 12 0391 ED

1.3. HBc IgM

- BCM.CE (96 tests)	Descrito en el certificado/ *Described in the certificate* 2004 03 0424 ED

1.4. HBe Ag & Ab

- HBE.CE (96 tests)	Descrito en el certificado/ *Described in the certificate* 2004 03 0425 ED

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on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 91 822.57.87 /(+34) 91.822.59.97
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1.5. HBs Ag Confirmation

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

Descrito en el certificado/ *Described in the certificate* 2006 11 0511 ED

1.6. HBs Ag one Version ULTRA

- SAG1ULTRA.CE (192 tests)
- SAG1ULTRA.CE.96 (96 tests)
- SAG1ULTRA.CE.480 (480 tests)
- SAG1ULTRA.CE.960 (960 tests)
- SAG1ULTRA.CE.DB (192 tests)

Descrito en el certificado/ *Described in the certificate* 2008 12 0588 ED

1.7. HCV Ab

- CVAB.CE (192 tests)
- CVAB.CE.96 (96 tests)
- CVAB.CE.480 (480 tests)
- CVAB.CE.960 (960 tests)
- CVAB.CE.DB (192 tests)

Descrito en el certificado/ *Described in the certificate* 2003 12 0392 ED

1.8. HCV Ab Confirmation

- CCONF.CE (12 tests)

Descrito en el certificado/ *Described in the certificate* 2005 09 0485 ED

1.9. HCV IgM

- CVM.CE (96 tests)

Descrito en el certificado/ *Described in the certificate* 2007 09 0532 ED

1.10. HCV Ab (Format 20)

- CVAB.CE.EG (192 tests)
- CVAB.CE.EG.96 (96 tests)
- CVAB.CE.EG.480 (480 tests)
- CVAB.CE.EG.960 (960 tests)

Descrito en el certificado/ *Described in the certificate* 2015 10 0842 ED

1.11. HDV Ab

- DAB.CE (96 tests)

Descrito en el certificado/ *Described in the certificate* 2003 12 0393 ED

1.12. HDV Ag

- DAG.CE (96 tests)

Descrito en el certificado/ *Described in the certificate* 2003 12 0394 ED

1.13. HDV IgM

- DIM.CE (96 tests)

Descrito en el certificado/ *Described in the certificate* 2003 12 0395 ED

1.14. HTLV I & II Ab Version ULTRA

- HTLVABULTRA.CE (192 tests)
- HTLVABULTRA.CE.96 (96 tests)
- HTLVABULTRA.CE.480 (480 tests)
- HTLVABULTRA.CE.960 (960 tests)
- HTLVABULTRA.CE.DB (192 tests)

Descrito en el certificado/ *Described in the certificate* 2011 11 0775 ED

CORREO ELECTRÓNICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
Tel.: (+34) 91 822.57.87 /(+34) 91.822.59.97
Fax: (+34) 91.822.52.89

1.15. HIV Ab & Ag

- IVCOMB.CE (192 tests)
- IVCOMB.CE.96 (96 tests)
- IVCOMB.CE.480 (480 tests)
- IVCOMB.CE.960 (960 tests)
- IVCOMB.CE.DB (192 tests)

Descrito en el certificado/ *Described in the certificate* 2008 02 0539 ED

2. Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante técnicas de PCR en tiempo real/ *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Real-Time PCR* **[NANDO: IVD 0203]**

2.1 HBV DNA Quantitation (QT)

- HBVDNAQT.CE (50 tests)
- HBVDNAQT.CE.25 (25 tests)
- HBVDNAQT.CE.100 (100 tests)
- HBVDNAQT.CE.150 (150 tests)

Descrito en el certificado/ *Described in the certificate* 2012 09 0790 ED

2.2 HDV RNA Quantitation (QT)

- DRNA.CE (50 tests)
- DRNA.CE.25 (25 tests)
- DRNA.CE.100 (100 tests)
- DRNA.CE.150 (150 tests)

Descrito en el certificado/ *Described in the certificate* 2009 11 0660 ED

2.3 HDV ONESTEP Quantitation (QT)

- HDVONEQT.CE (50 tests)
- HDVONEQT.CE.25 (25 tests)
- HDVONEQT.CE.100 (100 tests)

Descrito en el certificado/ *Described in the certificate* 2022 04 0973 ED

3 Reactivos y productos reactivos para la determinación, confirmación y cuantificación de marcadores de infección en muestras humanas mediante ensayos de quimioluminiscencia (CLIA)/ *Reagents and reactive products for the determination, confirmation and quantification of infection markers in human samples by Chemiluminescence Immunoassay (CLIA)* **[NANDO: IVD 0201; IVD 0202; IVD 0203]**

3.1 DIA.CHEMILUX HCV Ab

- RACVAB.CE (100 tests)

Descrito en el certificado/ *Described in the certificate* 2015 01 0834 ED

3.2 DIA.CHEMILUX HBs Ag

- RASAG.CE (100 tests)

Descrito en el certificado/ *Described in the certificate* 2015 10 0841 ED

3.3 DIA.CHEMILUX HIV Ab & Ag

- RAIVCOMB.CE (100 tests)

Descrito en el certificado/ *Described in the certificate* 2016 02 0844 ED

3.4 DIA.CHEMILUX HBc Ab

- RABCAB.CE (100 tests)

Descrito en el certificado/ *Described in the certificate* 2017 07 0863 ED

ANEXO Nº/*ANNEX NO:* I

CERTIFICADO CE DE SISTEMA DE GARANTÍA DE CALIDAD TOTAL
de acuerdo con el Anexo IV (excepto punto 4) de la Directiva 98/79/CE

EC FULL QUALITY ASSURANCE SYSTEM CERTIFICATE
in accordance with Annex IV (except Section 4) of Directive 98/79/EC

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*			ON nº/*NB no*
2003 12 0388 CT	**Desde/*From***	**20-05-2022**	**Hasta/*To*** **26-05-2025**	**0318**

3.5 DIA.CHEMILUX HTLV I & II Ab

- RAHTLVAB.CE (100 tests)	Descrito en el certificado/ *Described in the certificate* 2018 11 0878 ED

3.6 DIA.CHEMILUX HDV Ab

- RADAB.CE (100 tests)	Descrito en el certificado/ *Described in the certificate* 2020 07 0932 ED

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 mayo de 2022
DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

CORREO ELECTRÓNICO
on0318@aemps.es

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28022 MADRID
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Fax: (+34) 91.822.52.89

ORGANISMO NOTIFICADO 0318

Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

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

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)	• 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 0392 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 srl

Rev:	0318

Dia.Pro
Diagnostic
BioProbes

EC DECLARATION OF CONFORMITY

MANUFACTURER	DIA.PRO DIAGNOSTIC BIOPROBES S.R.L. VIA G. CARDUCCI N° 27 – 20099 SESTO SAN GIOVANNI (MILANO) – ITALY
PRODUCT	**HBs Ag one Version ULTRA** CODES: **SAG1ULTRA.CE (192 tests)** SAG1ULTRA.CE.96 (96 tests) SAG1ULTRA.CE.480 (480 tests) SAG1ULTRA.CE.960 (960 tests) SAG1ULTRA.CE.DB (192 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)	• 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° 2008 12 0588 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 – DECEMBER 2008
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:	03/2018

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 120095 0001 Rev. 00

Holder of Certificate: **Hangzhou Tongzhou Biotechnology Co., Ltd.**
Room 102, Building 4, No. 191, Xintian Road, Yunhe Street
Linping District
311103 Hangzhou, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents, Control Material and Instruments for Clinical Chemistry, Immunochemistry (Immunology) and Infectious Diseases, including Professional Laboratory Use, Near Patient and Self Testing**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 120095 0001 Rev. 00

Report No.: SH23211001

Valid from: 2023-07-20
Valid until: 2026-07-19

Date, 2023-07-21

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 120095 0001 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Hangzhou Tongzhou Biotechnology Co., Ltd.
Room 102, Building 4, No. 191, Xintian Road, Yunhe Street, Linping District, 311103 Hangzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate

CE

DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer:	Hangzhou Tongzhou Biotechnology Co., Ltd.
Address:	Room 102, Building 4, No. 191, Xintian Road, Yunhe Street, Linping District, Hangzhou, China.
EC Representative:	CMC Medical Devices & Drugs S.L
Address:	C/Horacio Lengo № 18 CP 29006, Málaga-Spain
Product Name:	See attachments
Classification:	Others (IVDD)
Conformity Assessment Procedure:	Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO13485:2016, EN ISO14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO23640:2015, EN 13641:2002, EN ISO 15223-1:2016

Signature: 邵越水

Name/ Position: 邵越水/ Vice General Manager

Date: 2022.3.14

Place: Hangzhou / China

Attachment: Product List

No.	Product Description （产品名称）	CE Classification
1	Pregnancy (hCG) Rapid Test	Other
2	Pregnancy (hCG) Rapid Test (Urine)	Other
3	Pregnancy (hCG) Rapid Test Midstream	Other
4	Pregnancy (hCG) Rapid Test (Serum/Plasma/Urine)	Other
5	Pregnancy (hCG) Rapid Test (Whole Blood/Serum/Plasma)	Other
6	Ovulation (LH) Rapid Test	Other
7	Ovulation (LH) Rapid Test Midstream	Other
8	FSH Rapid Test	Other
9	AMH Rapid Test	Other
10	Fetal Fibronectin (fFN) Rapid Test	Other
11	Insulin-like Growth Factor-binding Protein 1 (iGFBP-1) Rapid Test	Other
12	HSV 1/2 IgM Rapid Test (Serum/Plasma)	Other
13	HSV 1/2 IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
14	HSV 1/2 IgG/IgM Rapid Test (Serum/Plasma)	Other
15	HSV 1/2 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
16	HSV 1/2 IgG/IgM Combo Rapid Test	Other
17	Candida albicans Rapid Test	Other
18	Gonorrhea Rapid Test	Other
19	Gonorrhea and Chlamydia Combo Rapid Test	Other
20	Strep B Rapid Test	Other
21	Adenovirus Rapid Test	Other
22	Rotavirus Rapid Test	Other
23	Norovirus Rapid Test	Other
24	Rotavirus and Adenovirus Combo Rapid Test	Other
25	Norovirus, Rotavirus and Adenovirus Combo Rapid Test	Other
26	Astrovirus Rapid Test	Other
27	Norovirus, Rotavirus, Adenovirus and Astrovirus Combo Rapid Test	Other
28	Entamoeba histolytica Rapid Test	Other
29	Giardia Lamblia Rapid Test	Other
30	Cryptosporidium Rapid Test	Other
31	Cryptosporidium and Giardia Lamblia Combo Rapid Test	Other
32	Entamoeba/Giardia/Crypto Rapid Test (1 Window)	Other
33	Entamoeba/Giardia/Crypto Combo Rapid Test (3 Windows)	Other
34	Campylobacter Rapid Test	Other
35	Clostridium difficile GDH Rapid Test	Other
36	Clostridium difficile Toxin A +Toxin B Combo Rapid Test	Other
37	Clostridium difficile GDH+ Toxin A +Toxin B Combo Rapid Test	Other
38	H. pylori Antibody Rapid Test (Serum/Plasma)	Other
39	H. pylori Antibody Rapid Test (Whole Blood/Serum/Plasma)	Other
40	H. pylori Antigen Rapid Test	Other
41	Vibrio cholerae O1 (VC O1) Rapid Test	Other
42	Vibrio cholerae O139 (VC O139) Rapid Test	Other
43	Vibrio cholerae O1/O139 Combo Rapid Test	Other
44	Chagas Rapid Test (Serum/Plasma)	Other
45	Chagas Rapid Test (Whole Blood/Serum/Plasma)	Other
46	Chikungunya IgG/IgM Rapid Test (Serum/Plasma)	Other
47	Chikungunya IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
48	Dengue IgG/IgM Rapid Test	Other
49	Dengue NS1 Rapid Test	Other
50	Dengue IgG/IgM and NS1 Combo Rapid Test	Other
51	Zika NS1 Rapid Test	Other
52	Zika IgG/IgM Rapid Test	Other
53	Zika IgG/IgM and NS1 Combo Rapid Test	Other

54	Filariasis IgG/IgM Rapid Test (Serum/Plasma)	Other
55	Filariasis IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
56	Typhoid IgG/IgM Rapid Test (Serum/Plasma)	Other
57	Typhoid IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	Other
58	Salmonella typhi Antigen Rapid Test	Other
59	Leishmania IgG/IgM Rapid Test	Other
60	Leptospira IgG/IgM Rapid Test	Other
61	Malaria P.f. Rapid Test	Other
62	Malaria P.f./ Pan Rapid Test	Other
63	Malaria P.f./P.v. Rapid Test	Other
64	Malaria P.f./P.v. /Pan Rapid Test	Other
65	HEV IgG/IgM Rapid Test	Other
66	Syphilis Rapid Test	Other
67	Strep A Rapid Test (Control Line in Red)	Other
68	Strep A Rapid Test (Control Line in Blue)	Other
69	Streptococcus pneumoniae Antigen Rapid Test	Other
70	Mycoplasma pneumoniae Antigen Rapid Test	Other
71	Mycoplasma Pneumoniae IgG/IgM Combo Rapid Test	Other
72	MONO Rapid Test	Other
73	Adenovirus pneumoniae Antigen Rapid Test	Other
74	Influenza A+B Rapid Test	Other
75	Influenza A Rapid Test	Other
76	RSV Rapid Test	Other
77	RSV&Influenza A+B Combo Rapid Test	Other
78	Adenovirus&RSV Combo Rapid Test	Other
79	Adenovirus, RSV and Influenza A+B Combo Rapid Test	Other
80	Brucella Abortus Antigen Rapid Test	Other
81	Lyme IgG/IgM Rapid Test	Other
82	Tetanus Rapid Test	Other
83	Tuberculosis (TB) Rapid Test	Other
84	7-Aminoclonazepam (7-ACL) Rapid Test	Other
85	Amphetamine (AMP) Rapid Test	Other
86	Barbiturate (BAR) Rapid Test	Other
87	Buprenorphine (BUP) Rapid Test	Other
88	Benzodiazepines (BZO) Rapid Test	Other
89	Cocaine (COC) Rapid Test	Other
90	Cotinine (COT) Rapid Test	Other
91	Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test	Other
92	Ethyl Glucuronide (ETG) Rapid Test	Other
93	Fentanyl (FYL) Rapid Test	Other
94	Ketamine (KET)Rapid Test	Other
95	Ecstasy (MDMA) Rapid Test	Other
96	Methamphetamine (MET) Rapid Test	Other
97	Morphine (MOP) Rapid Test	Other
98	Methylphenidate (MPD) Rapid Test	Other
99	Methadone (MTD) Rapid Test	Other
100	Opiates (OPI) Rapid Test	Other
101	Oxycodone (OXY) Rapid Test	Other
102	Phencyclidine (PCP) Rapid Test	Other
103	Synthetic Marijuana (K2) Rapid Test	Other
104	Tricyclic Antidepressants (TCA) Rapid Test	Other
105	Marijuana (THC) Rapid Test	Other
106	Zolpidem (ZOL) Rapid Test	Other
107	Zopiclone (ZOP) Rapid Test	Other
108	Multi-Drug Rapid Test	Other
109	Multi-Drug Rapid Test 1-Step Cup	Other
110	Multi-Drug Rapid Test Key Cup	Other
111	AFP Rapid Test	Other

112	CEA Rapid Test	Other
113	CA125 Rapid Test	Other
114	CA15-3 Rapid Test	Other
115	CA19-9 Rapid Test	Other
116	FOB Rapid Test	Other
117	Calprotectin and FOB Combo Rapid Test	Other
118	Transferrin and FOB Combo Rapid Test	Other
119	Hb+Hb-Hp Combo Rapid Test	Other
120	Cardiac Troponin I (cTnI) Rapid Test	Other
121	Cardiac Troponin T (cTnT) Rapid Test	Other
122	CK-MB Rapid Test	Other
123	Myoglobin Rapid Test	Other
124	H-FABP Rapid Test	Other
125	H-FABP and cTnI Combo Rapid Test	Other
126	Myoglobin/CK-MB/Troponin I Combo Rapid Test	Other
127	H-FABP and Myoglobin/CK-MB/Cardiac Troponin I Combo Rapid Test	Other
128	NT-proBNP Rapid Test	Other
129	D-dimer Rapid Test	Other
130	C-reactive protein Rapid Test	Other
131	C-reactive protein Semi-Quantitative Rapid Test	Other
132	Procalcitonin (PCT) Rapid Test (Serum/Plasma)	Other
133	Procalcitonin (PCT) Rapid Test (Whole Blood/Serum/Plasma)	Other
134	Ferritin Rapid Test	Other
135	Ferritin Semi-Quantitative Rapid Test	Other
136	SP-10 Male Fertility Rapid Test	Other
137	TSH Rapid Test	Other
138	Vitamin D Rapid Test	Other
139	HbA1c Rapid Test	Other
140	Blood Stain Rapid Test	Other
141	Human Semen Rapid Test	Other
142	Calprotectin Rapid Test	Other
143	Lactoferrin Rapid Test	Other
144	Calprotectin and Lactoferrin Combo Rapid Test	Other
145	IgE Rapid Test	Other
146	Rheumatoid Factor Rapid Test	Other
147	Micro-Albumin Semi-Quantitative Rapid Test	Other
148	Micro-Albumin Qualitative Rapid Test	Other
149	SAA Rapid Test	Other
150	SAA and CRP Combo Rapid Test	Other

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CMC MEDICAL DEVICES & DRUGS S.L.

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Hangzhou Tongzhou Biotechnology Co., Ltd
Room 102, Building 4, No. 191, Xintian Road, Yunhe Street, Linping District, Hangzhou, China.

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive/regulation and standard mention in Annex I of this certificate, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all below mentioned models of the medical device.

CE

Authorized Signature

Issue date: 06/04/2022

Expiration date: 25/01/2027

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CMC MEDICAL DEVICES

ANNEX I

Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Zopiclone (ZOP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Zolpidem (ZOL) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Zika NS1 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Zika IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Zika IgG/IgM and NS1 Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Vitamin D Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Vibrio cholerae O139 (VC O139) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Vibrio cholerae O1 (VC O1) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Vibrio cholerae O1/O139 Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Typhoid IgG/IgM Rapid Test(Whole Blood/Serum/ Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Typhoid IgG/IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Tuberculosis (TB) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
TSH Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Tricyclic Antidepressants (TCA) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Transferrin and FOB Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Tetanus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Syphilis Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Synthetic Marijuana (K2) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Streptococcus pneumoniae Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Strep B Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Strep A Rapid Test(Control Line in Red)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

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Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Strep A Rapid Test(Control Line in Blue)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
SP-10 Male Fertility Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Salmonella typhi Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
SAA Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
SAA and CRP Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
RSV&Influenza A+B Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
RSV Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Rotavirus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Rotavirus and Adenovirus Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Rheumatoid Factor Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Procalcitonin (PCT) Rapid Test (Whole Blood/Serum/ Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Procalcitonin (PCT) Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test Midstream	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test (Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test (Urine)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test (Serum/Plasma/Urine)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Phencyclidine (PCP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Oxycodone (OXY) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ovulation (LH) Rapid Test Midstream	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ovulation (LH) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Opiates (OPI) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
NT-proBNP Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

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Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Norovirus, Rotavirus, Adenovirus and Astrovirus Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Norovirus, Rotavirus and Adenovirus Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Norovirus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Myoglobin/CK-MB/Troponin I Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Myoglobin Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Mycoplasma Pneumoniae IgG/ IgM Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Mycoplasma pneumoniae Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Multi-Drugs Rapid Test Key Cup	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Multi-Drugs Rapid Test 1-Step Cup	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Multi-Drugs Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Morphine (MOP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
MONO Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Micro-Albumin Semi-Quantitative Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Micro-Albumin Qualitative Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Methylphenidate(MPD) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Methamphetamine (MET) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Methadone (MTD) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Marijuana (THC) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Malaria P.f./P.v. Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Malaria P.f./P.v. /Pan Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Malaria P.f./ Pan Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Malaria P.f. Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Lyme IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Leptospira IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

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Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Leishmania IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Lactoferrin Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ketamine (KET)Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Insulin-like Growth Factor-binding Protein 1 (iGFBP-1) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Influenza A+B Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Influenza A Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
IgE Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Human Semen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgM Rapid Test (Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgG/IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgG/IgM Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HEV IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HbA1c Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Hb+Hb-Hp Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H. pylori Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H. pylori Antibody Rapid Test(Whole Blood/Serum/ Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H. pylori Antibody Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H-FABP Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H-FABP and cTnI Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Gonorrhea Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
~~Gonorrhea and Chlamydia Combo Rapid Test~~	~~CLASS IVD OTHERS~~	~~IVD - Directive 98/79~~	~~RPS/215/2022~~	~~Yes~~
Giardia Lamblia Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
FSH Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
FOB Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

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Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Filariasis IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Filariasis IgG/IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Fetal Fibronectin (fFN) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ferritin Semi-Quantitative Rapid test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ferritin Rapid test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Fentanyl (FYL) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ethylenediamine-dimethylphosphinic acid (EDDP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ethyl Glucuronide (ETG) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Entamoeba/Giardia/Crypto Rapid Test (1 Window)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Entamoeba/Giardia/Crypto Combo Rapid Test (3 Windows)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Entamoeba histolytica Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ecstasy (MDMA) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Dengue NS1 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Dengue IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Dengue IgG/IgM and NS1 Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
D-dimer Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cryptosporidium Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cryptosporidium and Giardia Lamblia Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cotinine (COT) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cocaine (COC) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Clostridium difficile Toxin A +Toxin B Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Clostridium difficile GDH+ Toxin A +Toxin B Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Clostridium difficile GDH Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

Issue date: 06/04/2022

Expiration date: 25/01/2027

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

Verification Code

EC REP

CERTIFICATE

ECREP20220406.5

Ver: CERT-202110.V1

CERTIFICATE CERTIFICADO CERTIFIKAT CERTIFICAT 证书 자격증

Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
CK-MB Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Chikungunya IgG/IgM Rapid Test (Whole Blood/Serum/ Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Chikungunya IgG/IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Chagas Rapid Test(Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Chagas Rapid Test (Serum/ Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
CEA Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cardiac Troponin T (cTnT) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cardiac Troponin I (cTnI) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Candida albicans Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Campylobacter Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Calprotectin Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Calprotectin and Lactoferrin Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Calprotectin and FOB Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
CA19-9 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
CA15-3 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
CA125 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
C-reactive protein Semi-Quantitative Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
C-reactive protein Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Buprenorphine (BUP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Brucella Abortus Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Blood Stain Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Benzodiazepines (BZO) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Barbiturate (BAR) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Astrovirus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Amphetamine (AMP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

Issue date: 06/04/2022

Expiration date: 25/01/2027

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

Verification Code

EC REP

CERTIFICATE

ECREP20220406.5

Ver: CERT-202110.V1

Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
AMH Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
AFP Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Adenovirus&RSV Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Adenovirus, RSV and Influenza A+B Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Adenovirus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Adenovirus pneumoniae Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
7-Aminoclonazepam (7-ACL) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H-FABP and Myoglobin/CK-MB/Cardiac Troponin I Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

Issue date: 06/04/2022

Expiration date: 25/01/2027

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

Verification Code

CERTIFICATE CERTIFICADO CERTIFIKAT CERTIFICAT 证书 자격증

ITALCERT

CERTIFICATO N° 505SGQ06

CERTIFICATE N° 505SGQ06

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile. Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro. Commercializzazione di articoli da laboratorio.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices. Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics. Marketing of laboratory items.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2023-10-24	2026-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

ITALCERT

CERTIFICATO N° 505DM09

CERTIFICATE N° 505DM09

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2021 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile.
Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field.
Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices.
Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
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In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

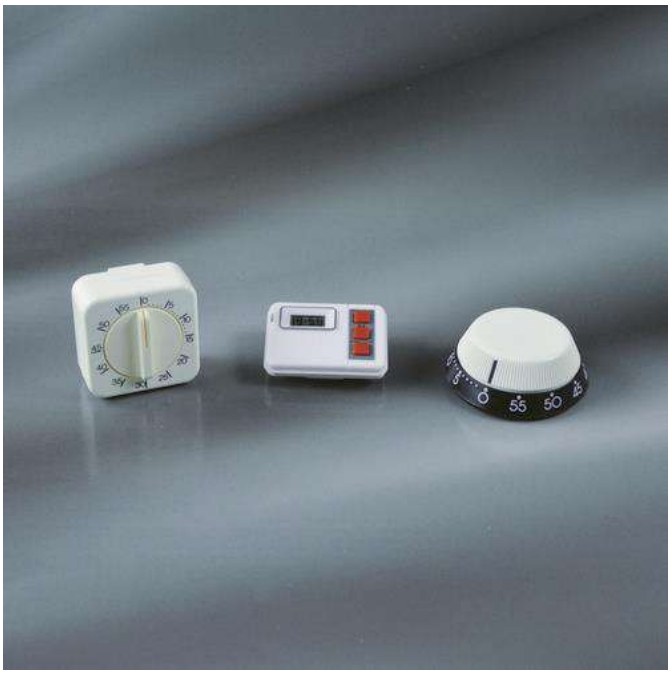
Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
2007-10-30	2011-10-30	2023-10-24	2026-10-29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

TECHNICAL DATA SHEET



TIMERS

“Clip” and “Onehand” models have mechanical movement, with timing up to 60 min.
“Electronic” model is battery operated, has a 4-digit display up to 19 hours 59 minutes, an electronic alarm and a free-standing clip and magnetic support. Material: ABS case.

Cod.	Dim. mm	Colour	Mod.
10851	56.5x56.5x28	White	Clip
10852	Ø 72.5x29.5	White-red	Onehand
10853	50x62x23	White	Electronic

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The International Certification Network

www.iqnet-certification.com

www.imq.it

CERTIFICATO N.
CERTIFICATE N. **9190.CRC3**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC) Italy

UNITA' OPERATIVE / *OPERATIVE UNITS*

Vedere gli Allegati per le Unità Operative (n. 2 pagine)
View the Annexes for the Operative Units (n. 2 pages)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL
REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	26-11-2002	04-10-2023	07-10-2026

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

CISQ

www.cisq.com

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CISQ is a member of

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The International Certification Network

www.iqnet-certification.com

www.imq.it

ALLEGATO N. **9190.CRC3-1**
ANNEX N.

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC) Italy

Attività:
Activities:

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori.

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	26-11-2002	04-10-2023	07-10-2026

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 07, 09, 19, 29, 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

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ALLEGATO N. **9190.CRC3-2**
ANNEX N.

CERACARTA SPA

VIA GRAMADORA 12/14 - 47122 FORLI' (FC) Italy

Attività:
Activities:

Produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi
Manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties

IL PRESENTE ALLEGATO HA LO SCOPO DI ESPLICITARE LE ATTIVITA' SVOLTE PRESSO IL SINGOLO SITO/UNITA' OPERATIVA NELL'AMBITO DELLA CERTIFICAZIONE DEL SISTEMA DI GESTIONE RILASCIATA A CERACARTA SPA

THE AIM OF PRESENT ANNEX IS TO EXPLAIN THE ACTIVITIES PERFORMED IN EACH SITE/OPERATIVE UNIT OF THE MANAGEMENT SYSTEM CERTIFICATION ISSUED TO CERACARTA SPA

PER LA VALIDITA' RIFERIRSI AL CERTIFICATO N. 9190.CRC3
FOR THE VALIDITY PLEASE REFER TO CERTIFICATE N. 9190.CRC3

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	26-11-2002	04-10-2023	07-10-2026

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

MS N° 0005MS

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Il presente documento integra il certificato n. 9190.CRC3
This document is a part of certificate n. 9190.CRC3

IAF: 12

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire management System within three years

CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale. CISQ is the Italian Federation of management system Certification Bodies.

IQNET

Building trust together.

Certificate

CISQ/IMQ has issued an IQNET recognized certificate that the organization:

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC) Italy

VIA GRAMADORA 12/14 - 47122 FORLI' (FC) Italy

has implemented and maintains a
Quality Management System

for the following scope:

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

which fulfils the requirements of the following standard:
ISO 9001:2015

Issued on: **2023/10/04**
Expires on: **2026/10/07**

Registration Number: **IT – 112265-9190.CRC3**

Alex Stoichitoiu
President of IQNET

Mario Romersi
President of CISQ

CISQ

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

IQNET Members*:
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 **EAGLE Certification Group** USA **FCAV** Brazil **FONDONORMA** Venezuela **ICONTEC** Colombia **ICS** Bosnia and Herzegovina **Inspecta Sertifiointi Oy** Finland **INTECO** Costa Rica **IRAM** Argentina **JQA** Japan **KFQ** Korea **LSQA** Uruguay **MIRTEC** Greece **MSZT** Hungary **Nemko AS** Norway **NSAI** Ireland **NYCE-SIGE** México **PCBC** Poland **Quality Austria** Austria **SII** Israel **SIQ** Slovenia **SIRIM QAS International** Malaysia **SQS** Switzerland **SRAC** Romania **TSE** Türkiye **YUQS** Serbia

* The list of IQNET Members is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com