MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

Digitally signed by Ceaicovschi Tudor
Date: 2020.10.23 16:44:16 EEST
Reason: MoldSign Signature
Location: Moldova

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/*Certificate no*	**Fecha de validez/*Date of validity***	**ON nº/*NB no***
2003 12 0391 ED	**Desde/*From* 26/11/2018 Hasta/*To* 18/11/2023**	**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*:
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
Fecha de la firma: 23/11/2018
Localizador: RP3FCJG870

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

CORREO ELECTRÓNICO
on0318@aemps.es

C/ CAMPEZO, 1 - EDIFICIO 8
28022 MADRID
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/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0391 ED	**Desde/*From* 26/11/2018 Hasta/*To* 18/11/2023**	**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:*
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 Ab ELISA cualitativo / *ELISA qualitative*

- BCAB.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. Mª Jesús Lamas Díaz

Firmado digitalmente por: Agencia Española de Medicamentos y Productos Sanitarios
Fecha de la firma: 23/11/2018
Localizador: RP3FCJG870

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

CORREO ELECTRÓNICO
on0318@aemps.es

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

ORGANISMO NOTIFICADO 0318

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

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/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0392 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**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*:
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
Fecha de la firma: 19/11/2018
Localizador: B86E8DZ586

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

CORREO ELECTRÓNICO
on0318@aemps.es

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*: **11/12/2003**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2003 12 0392 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**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:*
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 Ab ELISA cualitativo / *ELISA qualitative*

- CVAB.CE (192 tests)
- CVAB.CE.96 (96 tests)
- CVAB.CE.480 (480 tests)
- CVAB.CE.960 (960 tests)
- CVAB.CE.DB (192 tests - for Dia.Blood application)

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
Fecha de la firma: 19/11/2018
Localizador: B86E8DZ586

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

CORREO ELECTRÓNICO
on0318@aemps.es

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

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

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*: **04/12/2008**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2008 12 0588 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**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*:
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
Fecha de la firma: 19/11/2018
Localizador: P6LLDBAA94

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

CORREO ELECTRÓNICO
on0318@aemps.es

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*: **04/12/2008**
Fecha de última prórroga/ *Last extension date*: **27/11/2013**

Certificado nº/*Certificate no*	Fecha de validez/*Date of validity*	ON nº/*NB no*
2008 12 0588 ED	**Desde/*From* 19/11/2018 Hasta/*To* 18/11/2023**	**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*:
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 one Version ULTRA ELISA cualitativo / *ELISA qualitative*

- SAG1ULTRA.CE (192 tests)
- SAG1ULTRA.CE.96 (96 tests)
- SAG1ULTRA.CE.480 (480 tests)
- SAG1ULTRA.CE.960 (960 tests)
- SAG1ULTRA.CE.DB (192 tests - for Dia.Blood application)

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
Fecha de la firma: 19/11/2018
Localizador: P6LLDBAA94

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

CORREO ELECTRÓNICO
on0318@aemps.es

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

Ministero della Salute
DGFDM
0043588-P-26/10/2011

96082548

Ministero dell'Economia e delle Finanze MARCA DA BOLLO €14,62 QUATTORDICI/62
Agenzia Entrate
00011148 00008968 WDBATD01
00468407 29/06/2011 08:42:26
0001-00009 E3A3A5A456EF68C3
IDENTIFICATIVO : 01092857617099
0 1 09 285761 709 9

Ministero della Salute

DIPARTIMENTO DELLA PROGRAMMAZIONE E DELL'ORDINAMENTO DEL SERVIZIO SANITARIO NAZIONALE
DIREZIONE GENERALE DEI DISPOSITIVI MEDICI, DEL SERVIZIO FARMACEUTICO E DELLA SICUREZZA DELLE CURE
UFFICIO IV ex DGFDM – DIAGNOSTICI IN VITRO

I.5.l.e.2/IV/2011/37

VISTA la direttiva 98/79/CE relativa ai dispositivi medico-diagnostici in vitro;
VISTO il D.lgs. n .332/2000 recante attuazione della direttiva 98/79/CE;
VISTA l'istanza del 29/09/2011 presentata dalla ditta Dia.Pro Diagnostic Bioprobes Srl con sede in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159;
CONSIDERATO che la ditta istante ha effettuato i versamenti richiesti dal D.M. 24 Maggio 2004;
VISTI gli atti d'ufficio;
HAVING REGARD *to 98/79/EC directive concerning the in vitro diagnostic medical-devices;*
HAVING REGARD *to legislative Decree (D.lgs.)n. 332/2000 reporting the accomplishment of 98/79/EC Directive;*
HAVING REGARD to *the request dated 29/09/2011 submitted by the company* Dia.Pro Diagnostic Bioprobes Srl con with legal site in Via Columella, 31 – 20128 Milano – C.F. and P.Iva 11924660159;
WHEREAS *this company paid the fees required by Ministerial Decree (D.M.) May 24, 2004;*
HAVING REGARD to *the official deeds;*

SI ATTESTA
IT IS ATTESTED

che la ditta, Dia.Pro Diagnostic Bioprobes Srl con sede in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159, ha prodotto e marcato CE, come dispositivo medico- diagnostico in vitro, secondo le procedure previste dalla direttiva 98/79/CE, il prodotto:
that the Company Dia.Pro Diagnostic Bioprobes Srl located in Via G.Carducci, 27 – 20099 Sesto San Giovanni (MI) – C.F./P.Iva 11924660159, manufactured and affixed CE marking as in vitro diagnostic medical device, according to the Directive 98/79/EC, the following product:

DP-9 DIA.BLOOD INSTRUMENT

Il suddetto prodotto, in base all'art. 4 della direttiva 98/79/CE, è di libera circolazione e può essere messo in commercio in Italia e in tutto il territorio dell'Unione Europea.

Si rilascia il presente attestato su richiesta dell'interessato per gli usi consentiti dalla legge e per l'esportazione nei paesi extra UE.

The above mentioned product, according to the art. 4 of 98/79/EC directive, can freely circulate and can be commercialized in Italy and in the whole of the European Union. This certificate is issued on the interested company's request according to the law and to export to non-European countries

IL DIRETTORE DELL'UFFICIO IV
(Dott.ssa Giovanna Nisticò)

IC/CM

MINISTERIO DE SANIDAD, CONSUMO Y BIENESTAR SOCIAL

agencia española de medicamentos y productos sanitarios

ENAC CERTIFICACIÓN Nº 39/C-SG055

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: Ver Anexo I / *see Annex I*

Fecha de validez/ *Date of validity:* **Desde/** *From:* **8-03-2019** **Hasta/***To:* **17-12-2021**

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

Renovación / *Renewal of certification date:* **8-03-2019**

Madrid, 08 de marzo de 2019

DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

agencia española de medicamentos y productos sanitarios

Fdo. Mª Jesús Lamas Díaz

13485 CERTIFICADO Revisión 17/12/2018

Agencia Española de Medicamentos y Productos Sanitarios

Fecha de la firma: 08/03/2019

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

Localizador: L P D T J L 5 2 D F

CORREO ELECTRÓNICO
on0318@aemps.es

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

ENAC
CERTIFICACIÓN
Nº 39/C-SG055

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	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 *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.*
8-03-2019	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". *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*

Madrid, 08 de marzo de 2019
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
Fecha de la firma: 08/03/2019
Puede comprobar la autenticidad del documento en la sede de la AEMPS: https://sede.aemps.gob.es
Localizador: L P D T J L 5 2 D F

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

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
ASO Latex kit	031100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

_____

Eddy Velthuis
Technical Director

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

DECLARATION OF CONFORMITY

PRODUCT IDENTIFICATION

Product name	Catalogue number
RPR Carbon kit	044150A 044500A

MANUFACTURER

Name	Lorne Laboratories
Address	Unit 1 Cutbush Park Industrial Estate Danehill Lower Earley Berks, RG6 4UT
Country	United Kingdom

MEANS OF CONFORMITY

I hereby declare that the products listed above comply with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

This declaration is valid from 17 May 2015.

_____

Eddy Velthuis
Technical Director

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
RF Latex kit	830100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

_____

Eddy Velthuis
Technical Director

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
CRP Latex kit	850100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

_____

Eddy Velthuis
Technical Director

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com
www.aptaca.com - www.vacucheck.com - www.vacuaptaca.it

P.IVA: 00862050960 - Cod.Fisc.: 07520900155 - R.E.A. MB 1167248

DECLARATION OF CONFORMITY FOR MATERIALS

Hereby we declare that Nuova Aptaca Srl In Vitro Medical Diagnostic Devices (Directive 98/79/CE) and Medical Device (93/42/CE):

1. During devices manufacturing no materials containing natural rubber, latex, synthetic rubber are used (except for Articles of latex). The statement is formulated on the basis of information and statements provided by the producers of the raw materials used.

2. Devices are produced with materials that do not contain substances submitted to restrictions provided by 10/2001/EU Regulation and respect the global and specific migration limits in accordance with the following conditions:
   - Simulant A (distilled water) -40°C for 10 days
   - Simulant B (acetic acid solution 3% p/v) – 40°C for 10 days
   - Simulant C (Ethyl alcohol solution 10% v/v) - 40°C for 10 days
   - Simulant D1 (ethyl alcohol solution at 50% v/v) - 40°C for 10 days
   - Simulant D2 (Vegetable oil - Try substitute made with 95% ethyl alcohol as indicated by the Italian Ministerial Decree 34 of 21.03.1973) - 40°C for 10 days

   The global migration limit, together with all other specific restrictions which monomers and/or additives present in the material can be exposed to, are respected in the use conditions here above. Notes and/or simulant used for migration tests allow to fix the food or the group of food, admitted to the contact with food.
   The statement is formulated on the basis of analytical tests made by our qualified Laboratory and information and statements provided by the producers of the raw materials used

3. Devices are produced with materials that satisfy the follow requirements:
   - Directive (UE) 2015/863 (substances use restriction – phthalates, sulphates) and following updates and changes
   - 1272/2008 Regulation (labeling and use of dangerous substances) and following updates and changes
   - 10/2011 Regulation (specific migration limits) and following updates and changes 1895/2005/CE Rule (substances use restriction for food contact) and following updates and changes
   - 2011/65/UE Directive (heavy metals, RoHS) and following updating and changes
   - 1895/2005/UE Regulation (objects intended to come in contact with food) and following updates and changes

   The use in an industrial or commercial venue of the material indicated in this statement does not exclude the determination of its compliance with applicable rules of competence as well as the technological suitability for the purpose which it is intended by the user.

Canelli, lì 21 May 2019

Buono Duilio
Quality and Regulatory Affairs Manager

APTACA
PLASTIC DISPOSABLE ITEMS FOR LABORATORIES OF ANALYSIS

NUOVA APTACA s.r.l.
Regione Monforte, 30 -14053 Canelli (Asti) ITALY
Tel: (+39) 0141 83.50.75 - Fax: (+39) 0141 83.52.92
e-mail: info@aptaca.com
www.aptaca.com - www.vacucheck.com - www.vacuaptaca.it

P.IVA: 00862050960 - Cod.Fisc.: 07520900155 - R.E.A. MB 1167248

DICHIARAZIONE DI CONFORMITA' DEI MATERIALI

Con la presente si dichiara che i Dispositivi Medico Diagnostici in Vitro (Direttiva 98/79/CE e s.m.i.) e i Dispositivi Medici (93/42/CE e s.m.i.) della Nuova Aptaca Srl:

1. sono stati prodotti utilizzando materiali che non contengono gomma naturale, latex, gomme sintetiche che contengono gomme naturali (ad esclusione degli articoli in lattice). L'affermazione è formulata sulla base delle informazioni e dichiarazioni fornite dai produttori delle materie prime utilizzate.

2. sono realizzati con materiali che non contengono sostanze sottoposte a restrizioni secondo il Regolamento 10/2011 (limiti di migrazione) e s.m.i. e rispettano i limiti di migrazione globale e specifica (ove applicabile) alle seguenti condizioni:
   - simulante **A** (acqua distillata) - 40°C per 10 giorni
   - simulante **B** (soluzione di acido acetico al 3% p/v) - 40°C per 10 giorni
   - simulante **C** (soluzione di alcool etilico al 10% v/v) - 40°C per 10 giorni
   - simulante **D1** (soluzione di alcool etilico al 50% v/v) - 40°C per 10 giorni
   - simulante **D2** (Olio vegetale - Prova sostitutiva effettuata con alcool etilico al 95% secondo quanto indicato dal DM 34 del 21.03.1973) - 40°C per 10 giorni

   Il limite di migrazione globale, unitamente alle altre restrizioni specifiche alle quali possono essere sottoposti i monomeri e/o gli additivi presenti nel materiale, sono rispettati nelle condizioni d'uso sopra menzionate. Le note e/o i simulanti impiegati per le prove di migrazione consentono di determinare il prodotto alimentare o il gruppo di prodotti alimentari, ammessi al contatto con alimenti.
   L'affermazione è supportata da prove analitiche da noi condotte presso Laboratori qualificati in accordo con il Regolamento citato e sulla base delle informazioni e dichiarazioni fornite dai produttori delle materie prime utilizzate.

3. sono realizzati con materiali che soddisfano i seguenti dettati legislativi:
   - Direttiva Delegata (UE) 2015/863 (restrizione d'uso sostanze - ftalati, sulfati,) e s.m.i.
   - Regolamento 1272/2008 (etichettatura e uso sostanze pericolose) e s.m.i.
   - Direttiva 2011/65/UE (metalli pesanti, RoHS) e s.m.i.
   - Regolamento 1895/2005/CE (restrizione d'uso sostanze per contatto con alimenti) e s.m.i.
   - Regolamento 10/2011 (limiti di migrazione) e s.m.i.

   L'utilizzazione in sede industriale o commerciale del materiale indicato nella presente dichiarazione non esclude l'accertamento della sua conformità alle norme vigenti di competenza nonché della idoneità tecnologica allo scopo cui è destinato da parte dell'utilizzatore.

Canelli, lì 21.05.2019

Buono Duilio
Quality and Regulatory Manager

Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO

DGDMF/III/P/I.5.1.e.1/2020/78

VISTA la direttiva 93/42/CEE concernente i dispositivi medici;

HAVING REGARD *to the 93/42/EEC Directive concerning medical devices;*

VISTO il Decreto Legislativo n. 46/97 e successive modifiche recante l'attuazione della direttiva 93/42/CEE;

HAVING REGARD *to the Legislative Decree n. 46/97 and its following amendments implementing Directive 93/42 EEC;*

VISTA la richiesta con prot. 2843 – A-17/01/2020, presentata dalla Ditta **APTACA S.p.A.**, con sede in Via Monte Bianco 4, 20900 Monza (MB), Italia, P. Iva 00862050960;

HAVING REGARD *to the request with ref. 2843 – A-17/01/2020, submitted by the Company* ***APTACA S.p.A.****, located in Via Monte Bianco 4, 20900 Monza (MB), Italy, VAT number 00862050960;*

CONSIDERATO che la ditta richiedente ha effettuato i versamenti richiesti dal D.M. 16 Gennaio 2019;

WHEREAS *this Company paid the fees required by Ministerial Decree (D.M.) January 16, 2019;*

VISTI gli atti d'ufficio;

HAVING REGARD *to the official deeds;*

SI ATTESTA
IT IS ATTESTED

che, la Ditta **APTACA S.p.A.,** con sede produttiva in Regione Monforte 30, 14053 Canelli (AT), Italia, è il fabbricante e ha marcato CE come dispositivi medici, secondo le procedure previste dalla direttiva 93/42 CEE, i prodotti:

that, according to Directive 93/42/EEC, the Company ***APTACA S.p.A.****, with manufacturing plant in Regione Monforte 30, 14053 Canelli (AT), Italy, is the manufacturer and has marked CE as medical devices the following products:*

ITEM CODE and DESCRIPTION
4002/SG/CS/L Tongue depressor in wood, 150 x 17 mm, sterile individually wrapped
4002/L Tongue depressor in wood 150 x 17 mm
4002/SG/CS Tongue depressor in PS, 150x20mm, sterile individually wrapped, box of 1000 pcs
4002 Plastic tongue depressor, non sterile
5601/SG/L Pap-Test cervical spatula in wood, lenght 175 mm, sterile individually wrapped
5601/L Pap-Test cervical spatula in wood, lenght 175 mm
5601/SG Pap-Test cervical spatula in high impact PS, lenght 175 mm, sterile individually wrapped

ITEM CODE and DESCRIPTION
5601 Pap-Test cervical spatula, in high impact PS, lenght 178 mm in bags of 500 pcs
5631/SG Cyto-Brush for endocervical cells collection, lenght 210mm sterile individually wrapped
5631 Cyto-Brush for endocervical cells collection, lenght 210mm not sterile
12790 Bed pan in PP with ergonomic handle, 2,500 ml
12791 Bed pan 2.500ml, in PP, autoclavable
12795 Bed pan lid in PP
12761 Male bed bottle 1,000ml, in PE , graduated
12762 Male bed bottle 1,000ml, in PP , graduated
12765 Male bed bottle cap in PE
12771 Female bed bottle in PE, 750 ml, graduated
12401 Irrigator in PP, graduated up to 1,000 ml
12402 Irrigator in PP, graduated up to 2,000 ml
5100 Cotton swabs with wooden stick lenght 150 mm, not sterile
6100 Rayon swabs with plastic stick lenght 150 mm, not sterile
7100 Swabs with alluminium stick, rayon tip, Ø0.9 x 145 mm, no sterile in bags of 100 pcs
301/SG Rayon swabs with clear Amies, plastic stick, in PP test tubes Ø12x150 mm, sterile
301/AL/SG Rayon swabs with clear Amies, metallic stick, in PP test tubes Ø12x150 mm, sterile
301/SG/XL Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with DOUBLE AMIES clear, with label, sterile individually wrapped
303/SG Rayon swabs with Amies with charcoal, plastic stick, test tubes Ø12x150 mm, sterile
303/AL/SG Rayon swabs with Amies with charcoal, metallic stick, test tubes Ø12x150 mm, sterile
303/SG/XL Rayon swabs with double Amies charcoal, plastic stick, test tubes Ø12x150 mm, sterile
305/SG Rayon swabs with clear Stuart, plastic stick, in PP test tubes Ø12x150 mm, sterile.
305/AL/SG Rayon swabs with clear Stuart, metallic stick, in PP test tubes Ø12x150 mm, sterile
307/SG Rayon swabs with Stuart with charcoal, plastic stick, test tubes Ø12x150 mm, sterile
307/AL/SG Rayon swabs with Stuart with charcoal, metallic stick, test tubes Ø12x150 mm, sterile
309/SG Rayon swabs with Cary Blair, plastic stick, in PP test tubes Ø12x150 mm, sterile
309/AL/SG Rayon swabs with Cary Blair, aluminium stick, in PP test tubes Ø12x150mm, sterile
311/SG VIRUS transport swabs plastic stick, rayon tip, in test tube Ø12x150, sterile .
313/SG VIRUS transport swabs, alluminium stick rayon tip in test tube Ø12x150, sterile
321/SG CHLAMYDIA transport swabs, plastic stick, rayon tip, in test tube Ø12x150, sterile
323/SG CHLAMYDIA transport swabs, alluminium stick rayon tip in test tube Ø12x150, sterile
430/SG/ST CliniswabLTS-Flocked standard swabs + Amies liquid medium in tubes screw cap, sterile
430/SG/FT CliniswabLTS-Flocked fine swabs + Amies liquid medium in tubes screw cap, sterile
430/SG/PT CliniswabLTS-Flocked paediat. swabs + Amies liquid medium in tubes screw cap, sterile
435/SG/ST CliniswabLTS-Flocked standard swabs+Stuart liquid medium in tubes screw cap, sterile
435/SG/FT CliniswabLTS - Flocked fine swabs+Stuart liquid medium in tubes screw cap, sterile
435/SG/PT CliniswabLTS-Flocked paediatr. swabs+Stuart liquid medium in tubes screw cap, sterile
440/SG/ST CliniswabLTS-Flocked standard swabs+Cary Blair liquid medium in tubes screw cap, sterile
440/SG/FT CliniswabLTS-Flocked fine swabs+Cary Blair liquid medium in tubes screw cap, sterile
440/SG/PT CliniswabLTS-Flocked paediatr. swabs+Cary Blair liquid medium in tubes screw cap, sterile
445/SG/ST CliniswabLTS-Flocked standard swabs+ Selenite liquid medium in tubes screw cap, sterile
445/SG/FT CliniswabLTS - Flocked fine swabs+ Selenite liquid medium in tubes screw cap, sterile
445/SG/PT CliniswabLTS-Flocked paediatr. swabs+ Selenite liquid medium in tubes screw cap, sterile
450/SG/ST CliniswabLTS-Flocked standard swabs+ Saline liquid solution in tubes screw cap, sterile
450/SG/FT CliniswabLTS-Flocked fine swabs+ Saline liquid solution in tubes screw cap, sterile
450/SG/PT CliniswabLTS-Flocked paediatr. swabs+ Saline liquid solution in tubes screw cap, sterile
430/SG/ST/F CliniswabLTS - Foam standard swabs + Amies liquid medium in tubes screw cap, sterile
430/SG/FT/F CliniswabLTS - Foam fine tip swabs + Amies liquid medium in tubes screw cap, sterile
435/SG/ST/F CliniswabLTS - Foam standard swabs +Stuart liquid medium in tubes screw cap, sterile
435/SG/FT/F CliniswabLTS - Foam fine tip swabs +Stuart liquid medium in tubes screw cap, sterile
440/SG/ST/F CliniswabLTS - Foam standard swab+Cary Blair liquid medium in tubes screw cap, sterile
440/SG/FT/F CliniswabLTS - Foam fine tip swab+Cary Blair liquid medium in tubes screw cap, sterile
445/SG/ST/F CliniswabLTS - Foam standard swab+ Selenite liquid medium in tubes screw cap, sterile
445/SG/FT/F CliniswabLTS - Foam fine tip swab+ Selenite liquid medium in tubes screw cap, sterile
450/SG/ST/F CliniswabLTS - Foam standard swab+ Saline liquid solution in tubes screw cap, sterile
450/SG/FT/F CliniswabLTS - Foam fine tip swab+ Saline liquid solution in tubes screw cap, sterile
430/SG/ST/D CliniswabLTS - Polyester std. swab + Amies liquid medium in tubes screw cap, sterile
430/SG/FT/D CliniswabLTS - Polyester fine swab + Amies liquid medium in tubes screw cap, sterile
435/SG/ST/D CliniswabLTS - Polyester std. swab + Stuart liquid medium in tubes screw cap, sterile
435/SG/FT/D CliniswabLTS - Polyester fine swab + Stuart liquid medium in tubes screw cap, sterile
440/SG/ST/D CliniswabLTS - Polyester std. swab+Cary Blair liquid medium in tubes screw cap, sterile
440/SG/FT/D CliniswabLTS - Polyester fine swab+Cary Blair liquid medium in tubes screw cap, sterile
445/SG/ST/D CliniswabLTS - Polyester std. swab+ Selenite liquid medium in tubes screw cap, sterile
445/SG/FT/D CliniswabLTS - Polyester fine swab+Selenite liquid medium in tubes screw cap, sterile
450/SG/ST/D CliniswabLTS - Polyester std. swab + Saline liquid solution tubes screw cap, sterile

ITEM CODE and DESCRIPTION
450/SG/FT/D CliniswabLTS - Polyester fine swab + Saline liquid solution tubes screw cap, sterile
430/SG/ST/R CliniswabLTS - Rayon standard swabs + Amies liquid medium in tubes screw cap, sterile
430/SG/FT/R CliniswabLTS - Rayon fine tip swabs + Amies liquid medium in tubes screw cap, sterile
435/SG/ST/R CliniswabLTS - Rayon standard swabs+Stuart liquid medium in tubes screw cap, sterile
435/SG/FT/R CliniswabLTS - Rayon fine tip swabs+Stuart liquid medium in tubes screw cap, sterile
440/SG/ST/R CliniswabLTS - Rayon standard swabs+Cary Blair liquid medium in tubes screw cap, sterile
440/SG/FT/R CliniswabLTS - Rayon fine tip swabs+Cary Blair liquid medium in tubes screw cap, sterile
445/SG/ST/R CliniswabLTS - Rayon standard swabs+Selenite liquid medium in tubes screw cap, sterile
445/SG/FT/R CliniswabLTS - Rayon fine tip swabs+Selenite liquid medium in tubes screw cap, sterile
450/SG/ST/R CliniswabLTS - Rayon standard swabs+ Saline liquid solution in tubes screw cap, sterile
450/SG/FT/R CliniswabLTS - Rayon fine tip swabs+ Saline liquid solution in tubes screw cap, sterile
430/SG/AL CliniswabLTS - Aluminium std. swabs + Amies liquid medium in tubes screw cap, sterile
435/SG/AL CliniswabLTS - Aluminium std. swabs+Stuart liquid medium in tubes screw cap, sterile
440/SG/AL CliniswabLTS - Aluminium std. swabs+Cary Blair liquid medium in tubes screw cap, sterile
445/SG/AL CliniswabLTS - Aluminium std. swabs + Selenite liquid medium in tubes screw cap, sterile
450/SG/AL CliniswabLTS - Aluminium swabs+ Saline liquid solution in tubes screw cap, sterile
2150/SG Cotton swabs with wooden stick in PP test tubes Ø12 x 150 mm, sterile
2150/SG/CS Cotton swabs with wooden stick in PP test tubes Ø12 x 150 mm, sterile individually wrapped
2160/SG Rayon swabs with plastic stick in PP test tubes Ø12 x 150 mm, sterile
2160/SG/CS Rayon swabs with plastic stick in PP test tubes Ø12 x 150 mm, sterile individually wrapped
2170/SG Rayon swab with metallic stick in PP test tubes Ø12 x 150 mm, sterile
2170/SG/CS Rayon swab with metallic stick in PP test tubes Ø12 x 150 mm, sterile individually wrapped
2190/SG FOAM swabs with plastic stick in PP test tubes Ø12 x 150 mm, sterile
2190/SG/CS FOAM swabs with plastic stick in PP test tubes Ø12 x 150 mm, sterile individually wrapped
2191/SG Swabs Plastic stick and Fine FOAM tip, in PP test tubes Ø12x150 mm, with label, sterile
2191/SG/CS Swabs Plastic stick and Fine FOAM tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
2195/SG Swabs Plastic stick and Standard FLOCKED tip, in PP test tubes Ø12x150 mm, with label, sterile
2195/SG/CS Swabs Plastic stick and Standard FLOCKED tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
2196/SG Swabs Plastic stick and Fine FLOCKED tip, in PP test tubes Ø12x150 mm, with label, sterile
2196/SG/CS Swabs Plastic stick and Fine FLOCKED tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
2197/SG Swabs Plastic stick and Paediatric FLOCKED tip, in PP test tubes Ø12x150 mm, with label, sterile
2197/SG/CS Swabs Plastic stick and Paediatric FLOCKED tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
5100/SG/CS Cotton swabs with wooden stick lenght 150 mm, sterile individually wrapped
5100/SG/2 Cotton swabs with wooden stick lenght 150 mm, sterile, pack of 2pcs
5100/SG/10 Cotton swabs with wooden stick lenght 150 mm, sterile, pack of 10pcs
6100/SG/CS Rayon swabs with plastic stick lenght 150 mm, sterile individually wrapped
7100/SG/CS Swabs with alluminium stick, rayon tip, Ø0.9 x 145 mm, sterile in individual peelpack
6200/SG/CS FOAM swabs with plastic stick and standard tip, sterile, individually wrapped.
6300/SG/CS FOAM swabs with plastic stick and fine tip, sterile, individually wrapped.
6510/SG/CS Plastic stick, flocked standard tip, sterile individually wrapped in blister
6520/SG/CS Plastic stick, flocked fine tip, sterile individually wrapped in blister
6530/SG/CS Plastic stick, flocked paediatric tip, sterile individually wrapped in blister
Swabs Plastic stick and POLYESTER tip, sterile individually wrapped
201/SG Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES Clear, with label, sterile
201/SG/CS Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES Clear, with label, sterile individually wrapped
203/SG Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES with Charcoal, with label, sterile
203/SG/CS Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES Charcoal, with label, sterile individually wrapped
205/SG Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART Clear, with label, sterile
205/SG/CS Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART Clear, with label, sterile individually wrapped
207/SG Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART with Charcoal, with label, sterile
207/SG/CS Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART Charcoal, with label, sterile individually wrapped
209/SG Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with CARY BLAIR, with label, sterile
209/SG/CS Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with CARY BLAIR, with label, sterile individually wrapped
31300 Holder in PP, disposable
020 44020 000 600 Holder in PP, disposable

The above mentioned products, according to the art. 4 of Directive 93/42/EEC, can freely circulate and can be placed on the market in Italy and all over the European Union.

Questo documento è rilasciato in unico originale a richiesta del fabbricante ai fini di esportazione di dispositivi medici **al di fuori della Unione Europea**.

This document has been issued in a unique original version upon request of the manufacturer in order to export medical devices to ***Countries outside European Union.***

Non è consentita la sua riproduzione o pubblicazione su carta, stampa, supporti elettronici o siti internet.

It is not allowed any reproduction or publication of this document by paper, press, electronic base or websites.

Ne è consentita la sola esibizione o consegna alle autorità doganali o sanitarie del paese di importazione.

It is only allowed to show or to delivery it, upon request of the customs or Health Competent Authorities of the importing country.

MINISTERO DELLA SALUTE
Dispositivi Medici e Servizio Farmaceutico
DGDMF 03

Il Dirigente
The Executive Manager
Dott. Marco Musella

DP

MODULARIO
Salute - 2

MOD. 2 - U.G.

MINISTERO DELLA SALUTE

APTACA S.p.A.
Regione Monforte 30
14053 Canelli (AT)

ITALCERT

CERTIFICATO N° 505SGQ04

CERTIFICATE N° 505SGQ04

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 ed 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. Commercializzazione di dispositivi medici 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. Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

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 Modifica *Modified Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2019-11-06	2020-10-29

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

intertek
Total Quality. Assured.

CERTIFICATE OF REGISTRATION

This is to certify that the quality 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 and service of IVDD General Laboratory Instruments.

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

Certificate Number:
9362-7

Initial Certification Date:
March 28, 2012

Certificate Issue Date:
March 27, 2018

Certificate Expiry Date:
March 27, 2021

SCC Accredited CB-MS
OCSM
Accrédité CCN
TM

Calin Moldovean
President

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