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ORDIN DE PLATA NR.: 44                                TIP.DOC. 1 :
                                DATA EMITERII:6 februarie 2020 :
=====:
PLATITI: 1700-00                                LEI: Una Mie Sapte Sute lei 00 bani :
:
:
=====:
PLATITOR: (R) "BIOSISTEM                                CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L.                                MD95ML000000002251429243 :
                                CODUL FISCAL :1010600028048 / :
:
:
=====:
PRESTATORUL PLATITOR                                CODUL BANCII:
BC"Moldindconbank"S.A. suc."Invest" Chisinau                                :MOLDMD2X329:
=====:
BENEFICIAR (R) IMSP Spitalu                                CONTUL DE PLATI/CODUL IBAN :
1 Clinic Municipal Nr.1                                MD69VI000002251711136MDL :
                                CODUL FISCAL :1003600152673 / :
:
:
=====:
PRESTATORUL BENEFICIAR                                CODUL BANCII:
B.C."VICTORIABANK"S.A.                                :VICBMD2X :
=====:
DESTINATIA PLATII:plata pentru garantie : TIPUL TRANSFERULUI :
pentru oferta la licitatie Nr. ocde-b3w: NORMAL/URGENT :N:
dpl-MD-1577180329010 din 06.02.2020
:
:
:
:
:
:
=====:
                                CODUL TRANZACTIEI:001:
DATA PRIMIRII:06/02/2020                                : SEMNATURILE
DATA EXECUTARII:                                : EMITENTULUI
:-----:
CONDUCTATOR:Web Poiata Vitalie
MIIGQQYJKoZIhvcNAQcCoIIGMjCCBi4CAQExCzAJBgUrDgMCGGUAMAsGCSqGSIb3:
DQEHAaCCBEowggRGMIIDLqADAgECAhNHAABcVycdZVmKkP29AAAAAFxXMA0GCSq:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4:
DTE5MDEyODEwMTYyOFoXDTIxMDEyODEwMjYyOFowfjELMAkGA1UEBhMCTUQxGjA:
gNVBAoTEUJpb3Npc3RlbSBNTExwEAYDVQQLEwkwNjkyMDAzMTQxGjA :
:
(semnatura electronica)
CONTABIL-SEF:Web Nasedchin Alexandr
MIIGUgYJKoZIhvcNAQcCoIIGQzCCBj8CAQExCzAJBgUrDgMCGGUAMAsGCSqGSIb3:
DQEHAaCCBFswggRXMIIDP6ADAgECAhNHAABcVpWe/gMeSmneAAAAAFxWMA0GCSqG:
SIB3DQEBcWUAMCIXIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTE5MDEyODEwMTQwNFoXDTIxMDEyODEwMjYyOFowfjY4xCzAJBgNVBAYTAk1EMScw:
YDVQQKE5XZWR1Y29yIFNSTCwgQmlvc2lzdGVtIE1MRCBTUkwxEjAQBgNVBASt :
:
L.S. (semnatura electronica)
CONDUCTATOR: Digitally signed by Poiata Vitalie
Date: 2020.02.05 18:06:30 EET
Reason: MoldSign Signature
Location: Moldova
CONTABIL-SEF: (semnatura manuala)
SEMNATURA PRESTATORUL L.S.
:-----:
MOTIVUL REFUZULUI : L.S.
-----:

```







REPUBLICA MOLDOVA

# LICENȚĂ

Seria A MMII

Nr. 044322

Denumirea autorității de licențiere

Camera de Licențiere

Denumirea, forma juridică de organizare, sediul  
(adresa juridică) a titularului de licență

Societatea cu Răspundere Limitată  
"BIOSISTEM MLD"

mun. Chișinău, str. Albișoara, 16/1, ap. 7

Data și numărul certificatului de  
înregistrare de stat a titularului de licență

12.08.2010 MD 0101250

Numărul de înregistrare  
a întreprinderii sau IDNO

1010600028048

Codul fiscal

Genul de activitate, integral sau parțial,  
pentru a cărui desfășurare se eliberează licența

\* Importul, comercializarea, asistența tehnică  
și reparația dispozitivelor medicale \*

Data eliberării licenței

4 octombrie 2010

Reperfectată: 1) 19.10.2012; 2) 14.05.2014

Valabilă pînă la

4 octombrie 2015

Prelungită pînă la: 03.10.2020

Semnătura conducătorului  
autorității de licențiere

Director al Camerei de Licențiere

Valentin GUZNAC



Notă: Licența este valabilă numai cu anexa autenticată de autoritatea de licențiere,  
în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.





# BC "MOLDINDCONBANK" S.A.

## Filiala "Invest"

Republica Moldova, MD-2068  
mun. Chișinău, bd. Moscovei, 14/1  
Tel. : (373-22) 43-44-81, 43-46-24  
Fax : (373-22) 43-44-22  
cod: MOLDMD2X329

Data 14. IAN. 2016  
Nr. 03/2 - 19/23

Республика Молдова, MD-2068  
мун. Кишинэу, бул. Московской, 14/1  
Тел. : (373-22) 43-44-81, 43-46-24  
Факс : (373-22) 43-44-22  
код: MOLDMD2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent  
in moneda nationala al “BIOSISTEM MLD” S.R.L. (c/f 1010600028048), cu  
IBAN MD95ML000000002251429243.

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza  
Tel. 43-45-96

REPUBLICA



MOLDOVA

# CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"  
— ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT —

Numărul de identificare de stat - codul fiscal  
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei  
care a eliberat certificatul

*L. Svirepova*  
semnătura

MD 0101250







**„CAMERA ÎNREGISTRĂRII DE STAT” Î.S.**  
**Secția fonduri speciale și informații curente**

**EXTRAS**  
**din Registrul de stat al persoanelor juridice**

nr. 14419 din 11.07.2016

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**

Denumirea prescurtată: **«BIOSISTEM MLD» S.R.L.**

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

Sediul: **MD-2001, str. Albișoara, 16/1, ap.(of.) 7, mun. Chișinău, Republica Moldova.**

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

- 1 Activitatea farmaceutică;**
- 2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;**
- 4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;**
- 5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;**
- 6 Consultații în domeniul sistemelor de calcul.**

Capitalul social: **5400 lei.**

**Administrator: POIATA VITALIE, IDNP 0983103892591,**

Asociați:

- 1. POIATA VITALIE , IDNP 0983103892591**  
**cota 1803.60 lei, ce constituie 33,4 %**
- 2. NASEDCHIN ALEXANDR , IDNP 2002001070747**  
**cota 1798.20 lei, ce constituie 33,3 %**
- 3. KOJEVNIKOV DMITRII , IDNP 0972305012362**  
**cota 1798.20 lei, ce constituie 33,3 %.**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 11.07.2016.

Specialist principal  
tel. 022-266-252

  
**Lazari Aliona**





## **Lista fondatorilor Biosistem-mld SRL**

| <b>Nr.</b> | <b>Nume, Prenume</b>       | <b>IDNP</b>          |
|------------|----------------------------|----------------------|
| <b>1.</b>  | <b>Vitalie Poiata</b>      | <b>0983103892591</b> |
| <b>2.</b>  | <b>Alexandru Nasedchin</b> | <b>2002001070747</b> |
| <b>3.</b>  | <b>Dmitrii Kojevnikov</b>  | <b>0972305012362</b> |





Certificado ES10/81672

The management system of

**DELTA LAB, S.L.**

Pol. Ind. La Llana, Plaza De La Verneda, 1  
08191 Rubí (Barcelona)

has been assessed and certified as meeting the requirements of

**ISO 9001:2015**

For the following activities

**Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis.**  
**Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.**

**Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis de microbiología, biología molecular, hematología, bioquímica, histología, microscopía y coloración.**  
**Comercialización de equipos para el almacenamiento de muestras preparadas, almacenamiento de muestras para criogenización, material general de laboratorio y envases industriales.**

in/ from the following sites

**Pol. Ind. La Llana, Plaza De La Verneda 1 - 08191 Rubí (Barcelona)**

This certificate is valid from  
29 November 2017 until 11 October 2019.  
Issue 7. Certified since October 2010.

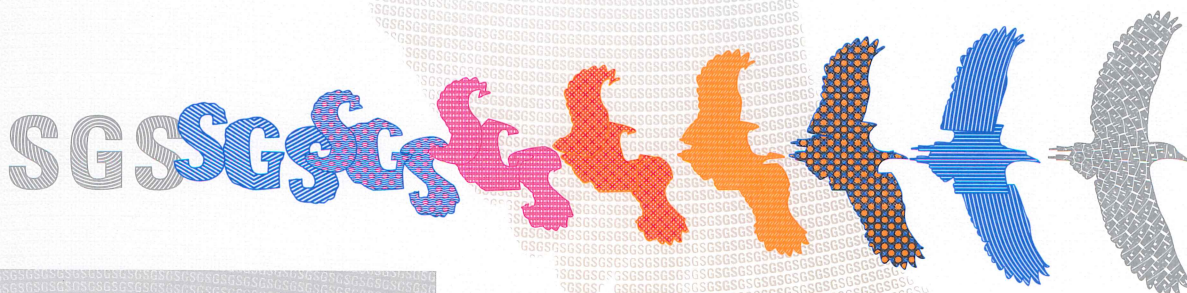
Este certificado es válido desde  
29 de noviembre de 2017 hasta 11 de octubre de 2019.  
Edición 7. Certificado desde octubre de 2010..

Authorized by

Dirección de Certificación

**SGS ICS Ibérica, S.A. (Unipersonal)**  
**C/Trespaderne, 29. 28042 Madrid, España.**  
**t 34 91 313 8115 f 34 91 313 8102 www.sgs.com**

Page 1 of 1



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Certificate ES10/81671

The management system of

**DELTALAB, S.L.**

Polígono Industrial La Llana, Plaza De La Veneda 1,  
08191 Rubí, Barcelona. Spain

has been assessed and certified as meeting the requirements of

**ISO 13485:2016**  
**EN ISO 13485:2016**



For the following activities

**Design, manufacture and sale of sterile and non sterile medical devices for the collection, transport and conservation of biological samples for clinical and IVD analysis.**

**Diseño, fabricación y comercialización de productos sanitarios estériles y no estériles para la toma, transporte y conservación de muestras biológicas para análisis clínicos y de IVD.**

This certificate is valid from 18 September 2017 until 11 October 2019  
and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 10 September 2019  
Issue 7. Certified since 12 October 2010

Authorised by



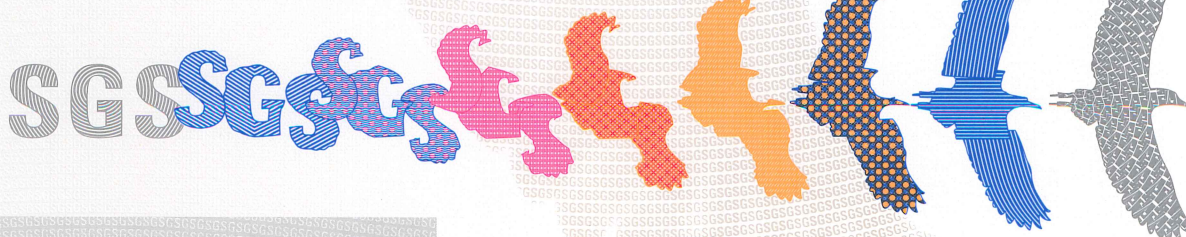
SGS United Kingdom Ltd  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 [www.sgs.com](http://www.sgs.com)

SGS 13485 2016 0417

Page 1 of 1



0005





S/REF  
N/REF: PS/DP/MST  
Date: 01/12/2015  
Subject: Information to the addressee

DELTALAB, S.L.  
PLAZA DE LA VERNEDA, 1  
POLIGONO INDUSTRIAL LA LLANA  
081191 RUBÍ  
(BARCELONA)

In response to your email dated 24/11/2015 requesting information on the products detailed below, which are included as items for general laboratory use in your company's catalogue, and after having made the relevant inquiries, I can inform you that:

- Slides
- Uncoated cover slides
- Pasteur pipettes
- Tips for general purpose pipettes
- Sample cups and cuvettes
- Spreaders for extensions
- Calibrated loops
- Petri dishes
- Vials
- Caps
- Serological pipettes
- Cryovials
- Ritips
- Cassettes for biopsy
- Microtitre plates
- E.S.R. system stands
- Anticoagulants and preservatives in bulk
- Stains for microbiology.

[State seal]  
MINISTRY OF HEALTH, SOCIAL  
SERVICES AND EQUALITY  
SUPPORTING RECORD  
AGENCIA ESPAÑOLA DE  
MEDICAMENTOS Y PRODUCTOS  
SANITARIOS  
[SPANISH STATE AGENCY OF MEDICATION  
AND SANITARY PRODUCTS]  
EXIT  
Registration No: 26082/RG53761  
Date: 14/12/2015 09:24:32

These products do not fall under the scope of Royal Decrees 1591/2009 of 16 October and 1662/2000 of 29 September, which regulate medical devices and medical devices for in vitro diagnostics respectively. These decrees transpose Directive 93/42/EEC on medical devices and Directive 98/79/EC of the European Parliament and of the Council dated 27 October 1998 on in vitro diagnostic medical devices to Spanish legislation, therefore their marketing falls under commercial legislation, consumer and user protection legislation and any applicable specific legislation.

THE HEAD OF THE DEPARTMENT OF SANITARY PRODUCTS

[Illegible signature]  
M<sup>a</sup> del Carmen Abad Luna  
[Seal: Spanish State Agency of  
Medication and Sanitary Products]  
Page 1/1

EMAIL  
mpizarro@aemps.es

C/CAMPEZO, 1-EDIFICIO 8  
28022 MADRID  
TELEPHONE: 91 822 52 61  
FAX: 91 822 52 89

Dña Marta Casanova Hernández, Traductora e  
Intérprete jurada de inglés nombrada por el Ministerio  
de Asuntos Exteriores y Cooperación certifica que la  
que antecede es traducción fiel y completa al inglés de  
un documento redactado en español.  
En Salamanca, a 15 de diciembre de 2015

I, Marta Casanova, Sworn Translator and Interpreter of  
English named by the Ministry of Foreign Affairs and  
Cooperation, hereby certify that the foregoing is a true  
and complete translation into English of a document  
written in Spanish.  
In Madrid, 15 December 2015

MARTA CASANOVA HERNANDEZ  
Traductora-Intérprete Jurada de INGLÉS

Marta Casanova

## Declaración de Conformidad "CE" "CE" Declaration of conformity

Directiva Productos Sanitarios para el Diagnóstico In Vitro 98/79/CE  
In Vitro Diagnostic Medical Devices Directive 98/79/EC

Fabricante / Manufacturer: **AQUISEL, s.l.**  
Dirección / Address: Autovía A-2 Km 585,1 08630 ABRERA (BARCELONA) - SPAIN

Declaro bajo su responsabilidad que los productos listados debajo, han estado diseñados para la aplicación de diagnóstico In Vitro y cumplen todos los requisitos esenciales del anexo I del Real Decreto 1662/2000 transposición a la Legislación Española de la Directiva 98/79/CE sobre productos sanitarios para diagnóstico In Vitro.

Declares under their responsibility that the products listed below have been designed for In Vitro diagnostic application and that they comply with all essential requirements as laid out in Annex I of Real Decreto 1662/2000 transposition to the Spanish Legislation of the Directive 98/79/EC for In Vitro Diagnostic Medical Devices.

"Tubos AQUISEL"; contenedores para la recogida de muestras de sangre, variantes:

The "AQUISEL tube"; containers for blood sampling collection, kinds:

- |                                                                          |                                                                   |
|--------------------------------------------------------------------------|-------------------------------------------------------------------|
| • K3E/EDTA 3K (anticoagulante)                                           | • K3E/EDTA 3K (anticoagulant)                                     |
| • K2E/EDTA 2K (anticoagulante)                                           | • K2E/EDTA 2K (anticoagulant)                                     |
| • 4NC/Citrato 3Na (anticoagulante)                                       | • 4NC/Citrato 3Na (anticoagulant)                                 |
| • 9NC/Citrato 3Na (anticoagulante)                                       | • 9NC/Citrato 3Na (anticoagulant)                                 |
| • LH/Heparina Li (anticoagulante)                                        | • LH/Li Heparin (anticoagulant)                                   |
| • LH/Li Heparina Li - Gel (anticoagulante)                               | • LH/Li Heparin + Gel (anticoagulant)                             |
| • MonoiodoAcetato Li + Gránulos PS activador (antiglicolítico)           | • IodoAcetate Li + Granules activator (antiglycolitic)            |
| • LH/Heparina Li + MonoiodoAcetato Li (anticoagulante + antiglicolítico) | • LH/Li Heparin + IodoAcetate Li (anticoagulant + antiglycolitic) |
| • FX/Fluoruro Na + Oxalato K (antiglicolítico + anticoagulante)          | • FX/Na Fluoride + K Oxalate (antiglycolitic + anticoagulant)     |
| • Z/Vacio (sin aditivos)                                                 | • Z/Empty (non additive)                                          |
| • Z/ Tubo tratado (para suero)                                           | • Z/ Treatment Tube (for serum)                                   |
| • Z/ Tubo tratado con Gel separador (para suero)                         | • Z/ Treatment Tube with Separator Gel (for serum)                |
| • Z/ Tubo tratado con Gránulos PS (para suero)                           | • Z/ Treatment Tube with Granules PS (for serum)                  |
| • Z/ Tubo con activador de la coagulación (para suero)                   | • Z/ Tube with clotting activator (for serum)                     |
| • Z/ Tubo con activador + Gel separador (para suero)                     | • Z/ Tube with clotting activator + Separator Gel (for serum)     |
| • Z/ Tubo con activador + Gránulos PS (para suero)                       | • Z/ Tube with clotting activator + Granules PS (for serum)       |

**Accesorios**

- CAP-GALET (Embutido para muestras de sangre)

**Accesorios**

- CAP-GALET (Funnels for Blood Sampling)

Abre a 09 Octubre de 2014 , Abre a 09th October 2014

Firmado/Signed : Mabel Sotelo y Sotelo  
(Gerente / Manager)

AQUISEL, S.L. 08630 ABRERA ( Barcelona ) España Tl: (93) 770 39 00 Fax: (93) 770 39 15



## DECLARACIÓN DE CONFORMIDAD CE CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

DELTALAB S.L.  
Plaza de la Verneda, 1  
Pol. Ind. La Llana  
08191 RUBÍ (BARCELONA) - SPAIN

Declaro bajo su responsabilidad que el producto:  
Declares under its responsibility that the product:

SISTEMA INVASIVO ESTÉRIL DE TOMA DE MUESTRAS CON Y SIN MEDIO DE  
TRANSPORTE MARCA EUROTUBO  
INVASIVE STERILE EUROTUBO COLLECTION SWAB FOR SAMPLE COLLECTION WITH  
AND WITHOUT TRANSPORT MEDIUM  
(Códigos según Anexo 1 / Codes in Annex 1)

Tipo: Sistema invasivo estéril de recogida de muestras por contacto directo con el paciente  
Type: Invasive sterile collection system by direct contact with the patient

Finalidad Prevista: Recogida y transporte de muestras biológicas para posteriores análisis  
microbiológicos  
Intended Use: Collection and transport of biological samples for subsequent microbiological  
analysis

Código GMDN / GMDN Code: 33722

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:  
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

**ESCOBILLON - Swab**

Directiva 93/42/CEE Directiva Productos Sanitarios.  
Transposición a la legislación española en Real Decreto 1591/2009.  
Directive 93/42/ECC Medical Devices Directive.  
Transposition to Spanish legislation in Real Decreto 1591/2009.

Clasificación: Clase IIa  
Classification: Class IIa

**INFORMACIÓN ADICIONAL**

En referencia a los escobillones, este documento tiene su apoyo en el Certificado CE número 2005.06.0474 CP  
EpiGraph 1, de Garantía de Calidad de la Producción de acuerdo con los Anexos V y VII de la Directiva 93/42/CEE,  
emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Organismo Notificado número  
0318.

**OTHER INFORMATION:**

Regarding the swabs, this documentation is supported by the CE Certificate number 2005.06.0474 CP EpiGraph 1,  
Production Quality Assurance according to Annexes V and VII of Directive 93/42/EEC issued by the Agencia Española  
de Medicamentos y Productos Sanitarios (AEMPS), Notified Body number 0318.



## TUBO CON MEDIO DE TRANSPORTE - Tube with transport medium

Directiva 98/79/CE Directiva Productos Sanitarios para Diagnóstico In Vitro.  
Transposición a la legislación española en Real Decreto 1662/2000.  
Directive 98/79/EC In vitro Diagnostic Medical Devices Directive,  
Transposition to Spanish legislation in Real Decreto 1662/2000.

José Saez  
Director General / Managing Director

Anna Mir  
Responsable Técnico / Technical Director



**ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS**  
**ANNEX 1 – ARTICLES DESCRIPTION**

| REF    | DESCRIPCIÓN                        | DESCRIPTION                    |
|--------|------------------------------------|--------------------------------|
| 300200 | ESCOBILLON MAD.+ALGODON PEEL/1     | SWAB I/W PEEL/1 WOOD+COTTON    |
| 300201 | ESCOBILLON PS+ALGODON PEEL/1       | SWAB I/W PEEL/1 PS+COTTON      |
| 300202 | ESCOBILLON PS+VISCOSA PEEL/1       | SWAB I/W PEEL/1 PS+VISCOS      |
| 300203 | ESCOBILLON ALU+ALGODON PEEL        | SWAB I/W PEEL ALUM+COTTON      |
| 300210 | ESCOBILLON MAD.+ALGOD. B/2 PEEL    | SWAB B/2 PEEL/2 WOOD+COTTON    |
| 300250 | ESCOBILLON MAD.+ALGODON TUBO       | SWAB IN TUBE WOOD+COTTON       |
| 300251 | ESCOBILLON ALU.+ALGODON TUBO       | SWAB IN TUBE ALUM+COTTON       |
| 300252 | ESCOBILLON PS+VISCOSA TUBO         | SWAB IN TUBE PS+VISCOS         |
| 300253 | ESCOBILLON ALU.+VISCOSA TUBO       | SWAB IN TUBE ALUM+VISCOS       |
| 300254 | ESC. ALUM. TRENZADO+VISCOSA TUBO   | SWAB TWISTED ALUM+VISCOS       |
| 300259 | ESCOBILLON MAD.+VISCOSA TUBO       | SWAB IN TUBE WOOD+VISCOS       |
| 300261 | ESCOBILLON PS+ALGODON TUBO         | SWAB IN TUBE PP+COTTON         |
| 300263 | ESCOBILLON 13X165MM PS C/POLIESTER | SWAB 13X165MM PS W/POLYESTER   |
| 300280 | CARY BLAIR MADERA+ALGODON          | CARY BLAIR SWAB WOOD+COTTON    |
| 300281 | AMIES ALUMINIO+VISCOSA             | AMIES SWAB ALUMINIUM+VISCOS    |
| 300284 | AMIES LIQUIDO PS+VISCOSA           | AMIES SWAB LIQUID PS+VISCOS    |
| 300285 | AMIES CARBON PS+VISCOSA            | AMIES+CHARCOAL SWAB PS+VISCOS  |
| 300287 | AMIES PS+VISCOSA                   | AMIES SWAB PS+VISCOS           |
| 300290 | STUART MADERA+ALGODON              | STUART SWAB WOOD+COTTON        |
| 300291 | STUART ALUMINIO+ALGODON            | STUART SWAB ALUM+COTTON        |
| 300292 | STUART ALUMIN. TRENZADO+VISCOSA    | STUART SWAB TWISTED ALU + VISC |
| 300294 | VIRUS ALUMINIO + POLIESTER         | VIRUS SWAB ALUMINIUM POLYESTER |
| 300295 | STUART 13X165MM PS C/VISCOSA       | STUART 13X165MM PS W/VISCOS    |
| 300296 | H. VIRUS ALUM. ALGODON             | SWAB FOR VIRUS WIRE+COTTON TIP |
| 300297 | VIRUS PS+POLIESTER                 | VIRUS SWAB PS POLYESTER        |
| 300299 | CHLAMYDIA PS+POLIESTER             | CHLAMYDIA SWAB PS+POLYESTER    |
| 310200 | ESCOBILLON MAD.+ALGODON FLOW       | WOOD+COTTON SWAB FLOW          |
| 310202 | ESCOBILLON PS+VISCOSA FLOW         | PS+VISCOS SWAB FLOW            |

Fecha / Date: 20/05/2016  
Pag. 3/4

CDCE-54 Rev.14

| REF       | DESCRIPCIÓN                       | DESCRIPTION                     |
|-----------|-----------------------------------|---------------------------------|
| 300211.1  | ESCOBILLON PS+ALG. PACK PEEL/2    | SWAB B/2 PS+COTTON PEEL/2       |
| 300212.1  | ESCOBILLON PS+VISCOSA PEEL/2      | SWAB PEEL/2 PS+VISCOS           |
| 300250.1  | ESCOBILLON MAD.+ALGOD. PURO TU    | SWAB IN TUBE WOOD+PURE COTTON   |
| 300250.M  | ESCOBILLON MAD.+ALGODON TUBO      | SWAB IN TUBE WOOD+COTTON        |
| 300261.M  | ESCOBILLON PS+ALGODON TUBO        | SWAB IN TUBE PS+COTTON          |
| 300268.B  | ESCOBILLON PS+POLIESTER PEEL PACK | SWAB PS+POLIESTER IND.WRAPPED   |
| 300280.2  | CARY BLAIR PS+VISCOSA             | CARY BLAIR SWAB PS+VISCOS       |
| 300281/1  | ESC. AMIES+CARBON ALUM.VISCOSA    | AMIES CHARCOAL SWAB WIRE+VISCOS |
| 300281T   | AMIES ALUMINIO TRENZADO+ VISCOS   | AMIES SWAB TWIST.WIRE+VISCOS    |
| 300281TC  | AMIES+CARBON ALU.TRENZADO+ VISC   | AMIES+CHARCOAL TWIS.WIRE+VISCOS |
| 300285.M  | AMIES CARBON PS VISCOSA 6x100     | AMIES CHARCOAL PS RAYON 6X100   |
| 300287.5  | AMIES PS VISCOSA CAJAS 6x100      | AMIES PS VISCOS CASES 6X100     |
| 300287.A  | ESCOB.AMIES PS+VISCOSA            | AMIES SWAB PS+VISCOS            |
| 300295C   | STUART CARBÓN PS + VISCOSA        | STUART+CHARCOAL SWAB PS+VISCOS  |
| 310253.1  | ESCOB. ALUM+VISCOSA FLOW          | ALUM+VISCOS SWAB FLOW           |
| 310211.1  | ESCOBILLON PS+ALGODON B/2 FLOW    | PS+COTTON SWAB B/2 FLOW         |
| 300250.MY | ESCOBILLON MAD.+ALGODON TUBO      | SWAB IN TUBE WOOD+COTTON        |
| 300211.10 | ESCOBILLON PS+ALG. PACK PEEL/10   | SWAB PS+COTTON PEEL/10          |
| 300261AV  | ESCOBILLON PS+ALGODON TUBO        | SWAB IN TUBE PS+COTTON          |

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**DECLARACIÓN DE CONFORMIDAD CE**  
**CE DECLARATION OF CONFORMITY**

El fabricante / The manufacturer:

**DELTALAB S.L.**  
Plaza de la Verneda, nº 1  
Pol. Ind. La Liana  
08191 Rubí (Barcelona) – España

Declara bajo su responsabilidad que el producto:  
Declares under its responsibility that the product:

**SISTEMA INVASIVO ESTÉRIL, CON PUNTA ABSORBENTE, PARA TOMA DE MUESTRAS CON Y SIN MEDIO DE TRANSPORTE.**  
**INVASIVE STERILE COLLECTION SWAB, WITH ABSORBENT TIPPED, FOR SAMPLE COLLECTION WITH AND WITHOUT TRANSPORT MEDIUM**  
(Códigos según Anexo 1 / Codes in Annex 1)

**Tipo:** Escobillón estéril con punta absorbente para la recogida de muestras.  
**Type:** Absorbent tipped sterile swab for samples collection.

**Finalidad Prevista:** Recogida y transporte de muestras biológicas para posteriores análisis microbiológicos  
**Intended Use:** Collection and transport of biological samples for subsequent microbiological analysis

Código GMDN / GMDN Code: 33722

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:  
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

**ESCOBILLON - Swab**

**Directiva 93/42/CEE** Directiva Productos Sanitarios.  
Transposición a la legislación española en **Real Decreto 1591/2009.**  
**Directive 93/42/EEC** Medical Devices Directive.  
Transposition to Spanish legislation in **Real Decreto 1591/2009.**

**Clasificación:** Clase I Estéril  
**Classification:** Class I Sterile

**INFORMACIÓN ADICIONAL**

En referencia a los escobillones, este documento tiene su apoyo en el Certificado CE número 2005.06.0475 CP Epigrafe 6, de Garantía de Calidad de la Producción de acuerdo con los Anexos VII punto 5 y V punto 3 de la Directiva 93/42/CEE, emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Organismo Notificado número 0318.

**OTHER INFORMATION:**

For the swabs, this documentation is supported by the CE Certificate number 2005.06.0475 CP Epigraph 6, according to Annexes VII section 5 and V section 3 of Directive 93/42/EEC issued by the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Notified Body number 0318.

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**TUBO CON MEDIO DE TRANSPORTE – Tube with transport medium**

**Directiva 98/79/CE** Directiva Productos Sanitarios para Diagnóstico In Vitro.  
Transposición a la legislación española en **Real Decreto 1662/2000.**  
**Directive 98/79/EC** In vitro Diagnostic Medical Devices Directive.  
Transposition to Spanish legislation in **Real Decreto 1662/2000.**

José Saez  
Director General / Managing Director

  
Anna Mir  
Responsable Técnico / Technical Director

  
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# ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS/ANNEX 1 – ARTICLES DESCRIPTION

| REF    | DESCRIPCIÓN                              | DESCRIPTION                                 |
|--------|------------------------------------------|---------------------------------------------|
| 300265 | ESCOBILLON PS+FLOCK EN TUBO              | SWAB / TUBE PS + FLOCK                      |
| 303806 | ESCOB.FLOCK ULTRA PEEL P.                | FLOCKED SWAB PS STAND.NO/BP ST.PEEL P.      |
| 304270 | VICUM 2ML ESC.FLOCK NASOFAR. 100MM       | VICUM 2ML FLOCKED SWAB NASOPH.100MM         |
| 304271 | VICUM 1ML ESC.FLOCK ESTANDARD 80MM       | VICUM 1ML FLOCKED SWAB STANDARD 80MM        |
| 304272 | VICUM 1ML ESC.FLOCK URETRAL 80MM         | VICUM 1ML FLOCKED SWAB URETRAL 80MM         |
| 304273 | VICUM 3ML ESC.FLOCK ESTANDARD 100MM      | VICUM 3ML FLOCKED SWAB STANDARD 100MM       |
| 304274 | VICUM 3ML ESC.FLOCK URETRAL 100MM        | VICUM 3ML FLOCKED SWAB URETRAL 100MM        |
| 304275 | VICUM 3ML ESC.FLOCK NASOFARINGEO 100MM   | VICUM 3ML FLOCKED SWAB NASOPH.100MM         |
| 304276 | VICUM 2ML ESC.FLOCK URETRAL 100MM        | VICUM 2ML FLOCKED SWAB URETRAL 100MM        |
| 304277 | VICUM 1ML ESC.FLOCK NASOFARINGEO 100MM   | VICUM 1ML FLOCKED SWAB NASOPH.100MM         |
| 304278 | VICUM 2ML ESC.FLOCK ESTANDARD 80MM       | VICUM 2ML FLOCKED SWAB STANDARD 80MM        |
| 304279 | VICUM 2ML ESC.FLOCK MINITIP 100MM        | VICUM 2ML FLOCKED SWAB MINITIP 100MM        |
| 304280 | CARY BLAIR 2ML ESC.FLOCK ESTANDARD 80MM  | CARY BLAIR 2ML FLOCKED SWAB STANDARD 80MM   |
| 304281 | AMIES 1ML ESC.FLOCK ESTANDARD 80MM       | AMIES 1ML FLOCKED SWAB STANDARD 80MM        |
| 304282 | AMIES 1ML ESC.FLOCK URETRAL 80MM         | AMIES 1ML FLOCKED SWAB URETRAL 80MM         |
| 304285 | AMIES 1ML ESC.FLOCK NASOFARINGEO 100MM   | AMIES 1ML FLOCKED SWAB NASOPH. 100MM        |
| 304286 | AMIES 1ML ESC.FLOCK MINITIP 100MM        | AMIES 1ML FLOCKED SWAB MINITIP 100MM        |
| 304287 | AMIES 2ML ESC.FLOCK ESTANDARD 80MM       | AMIES 2ML FLOCKED SWAB STANDARD 80MM        |
| 304291 | VIRUS 1ML ESC.FLOCK ESTANDARD 80MM       | VIRUS 1ML FLOCKED SWAB STAND. 80MM          |
| 304292 | VIRUS 1ML ESC.FLOCK URETRAL 80MM         | VIRUS 1ML FLOCKED SWAB URETRAL 80MM         |
| 304293 | VIRUS 3ML ESC.FLOCK ESTANDARD 100MM      | VIRUS 3ML FLOCKED SWAB STANDARD 100MM       |
| 304294 | VIRUS 3ML ESC.FLOCK URETRAL 100MM        | VIRUS 3ML FLOCKED SWAB URETRAL 100MM        |
| 304295 | VIRUS 3ML ESC.FLOCK NASOFARINGEO 100MM   | VIRUS 3ML FLOCK SWAB NASOPH.100MM           |
| 304297 | VIRUS 1ML ESC.FLOCK NASOFARINGEO 100MM   | VIRUS 1ML FLOCK SWAB NASOPH.100MM           |
| 304296 | VIRUS 2ML ESC.FLOCK NASOFARINGEO 2X100MM | VIRUS 2ML FLOCK SWAB NASOPH. 100MM          |
| 304298 | VIRUS 2ML ESC.FLOCK NASOF + ST. 100/80MM | VIRUS 2ML FLOCK SWAB NASOPH. + ST. 100/80MM |

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| REF    | DESCRIPCIÓN                            | DESCRIPTION                              |
|--------|----------------------------------------|------------------------------------------|
| 304288 | AMIES 1ML 3 ESC.FLOCK MRSA             | AMIES 1ML 3 FLOCKED SWABS MRSA           |
| 304212 | LIM BROTH 2ML ESC.FLOCK ESTANDARD 80MM | LIM BROTH 2ML FLOCKED SWAB STANDARD 80MM |

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## DECLARACIÓN DE CONFORMIDAD CE CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

**DELTALAB S.L.**  
Plaza de la Verneda, 1  
Pol. Ind. La Llana  
08191 RUBÍ (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:  
Declares under its responsibility that the product:

**CONTENEDORES PARA MUESTRAS NO ESTÉRILES**  
**GENERAL SPECIMEN CONTAINER NON-STERILE**  
(Códigos según Anexo 1 / Codes in Annex 1)

**Finalidad Prevista:** Recogida y conservación y/o transporte, de cualquier tipo de muestra para diagnóstico (por ejemplo, orina, heces, esputo, mucosa, tejido) para análisis y/u otra investigación.  
**Intended Use:** Collection and preservation and/or transport, of any type of diagnostic specimen (e.g. urine, faeces, sputum, mucous, tissue) for analysis and/or other investigation.

Código GMDN / GMDN Code: 47775

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:  
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

**Directiva 98/79/CE:** Directiva Productos Sanitarios para el Diagnóstico "in vitro".  
Transposición a la legislación española en Real Decreto 1662/2000.  
**Directive 98/79/EC:** "In-vitro" Diagnostics Medical Devices Directive.  
Transposition to Spanish legislation in Real Decreto 1662/2000.

**Clasificación:** Anexo 3, Clase: Otros  
**Classification:** Annex 3, Class: Other

  
José Saez  
Director General / Managing Director

  
Anna Mir  
Responsable Técnico / Technical Director

  
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## ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS ANNEX 1 – ARTICLES DESCRIPTION

| REF    | DESCRIPCIÓN                              | DESCRIPTION                            |
|--------|------------------------------------------|----------------------------------------|
| 202840 | FRASCO DE SEGURIDAD 20ML                 | SECURITY CONTAINER 20ML                |
| 202841 | FRASCO DE SEGURIDAD 40ML                 | SECURITY CONTAINER 40ML                |
| 202842 | FRASCO DE SEGURIDAD 60ML                 | SECURITY CONTAINER 60ML                |
| 202843 | FRASCO DE SEGURIDAD 90ML (Ø48-h75)       | SECURITY CONTAINER 90ML (Ø48-h75)      |
| 202844 | FRASCO DE SEGURIDAD 120ML                | SECURITY CONTAINER 120ML               |
| 202845 | FRASCO DE SEGURIDAD 250ML                | SECURITY CONTAINER 250ML               |
| 202846 | FRASCO DE SEGURIDAD 500ML                | SECURITY CONTAINER 500ML               |
| 202847 | FRASCO DE SEGURIDAD 1000ML               | SECURITY CONTAINER 1000ML              |
| 202848 | FRASCO DE SEGURIDAD 90ML(Ø53-h68)        | SECURITY CONTAINER 90ML(Ø53-h68)       |
| 300100 | TUBO 17 ML PS 16X150 MM                  | PS TUBE 16X150                         |
| 300101 | TUBO PS 8ML 16X75MM GRADUADO C/BORDE     | PS TUBE 8ML 16X75MM GRADUATED WITH RIM |
| 300300 | TUBO 4 ML PS 11X70 MM                    | TUBE 11X70 PS                          |
| 300400 | TUBO 6 ML PS 12X88 MM GRADUADO           | TUBE 12X88 PS GRADUATED                |
| 300500 | TUBO 3 ML PS 11X55 MM                    | TUBE 11X55 PS                          |
| 300700 | TUBO 13X75 PS                            | TUBE 13X75 PS                          |
| 300702 | TUBO 13X75 PS TAPADO                     | TUBE 13X75 PS CAPPED                   |
| 300704 | TUBO 13X75 PS TAPADO Y ETIQ              | TUBE 13X75 PS CAPPED&LABELLED          |
| 300705 | TUBO 10 ML PS 16X100 MM                  | TUBE 16X100 PS                         |
| 300800 | TUBO 5ML PS 12X75 MM GRADUADO            | TUBE 5ML PS 12X75MM GRADUATED          |
| 300802 | TUBO 12X75 PS + TAPON 305802             | PS TUBE 12X75 + CAP 305802             |
| 300804 | TUBO 12X75 PS TAPADO Y ETIQ              | TUBE 12X75 PS CAPPED LABELLED          |
| 300900 | TUBO 10ML PS 16X95MM GRADUADO            | TUBE 10ML PS 16X95MM GRADUATED         |
| 300903 | TUBO 16x95 PS TAPADO                     | TUBE 16x95 POLYSTYRENE CAPPED          |
| 300904 | TUBO 10 ML PS 16X95 MM TAPADO ETIQUETADO | TUBE 16X95 PS CAPPED LABELLED          |
| 300907 | TUBO 16X100 PS TAPADO                    | TUBE 16X100 PS CAPPED                  |
| 300908 | TUBO 16X100 PS TAPADO Y ETIQ             | TUBE 16X100 PS CAPPED LABELLED         |
| 300911 | TUBO 16X100 PS TAPADO C/308101           | TUBE 16x100 PS CAPPED W/308101         |
| 300912 | TUBO 16X95 PS TAPADO 305002              | 16X95 TUBE PS CAPPED 305002            |

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| REF    | DESCRIPCIÓN                          | DESCRIPTION                     |
|--------|--------------------------------------|---------------------------------|
| 300913 | TUBO 16X95 PS TAPADO                 | TUBE 16X95 PS CAPPED            |
| 300914 | TUBO 16x95 TAPADO 305002             | 16x95 TUBE CAPPED 305002        |
| 301200 | TUBO CONICO 16X102 PS                | CONICAL TUBE 16X102 PS          |
| 301201 | TUBO CONICO 12ML PS 16X100 MM        | CONICAL TUBE 16X100 PS          |
| 301202 | TUBO CONICO 16X102 PS                | CONICAL TUBE 16X102 PS          |
| 301205 | TUBO CONICO 301200 TAP/305502        | PS TUBE 12ML CONICAL CAPPED     |
| 301206 | TUBO CONICO 16X102+TAP.305502        | PS CON. TUBE 16X102 + CAP305502 |
| 301207 | TUBO CONICO 16x102 PS TAPADO         | CONICAL TUBE 16x102 PS CAPPED   |
| 301212 | TUBO CONICO 12 ML PS 17X105 MM       | CONICAL TUBE 17X105 PS          |
| 301213 | TUBO CÓNICO 12ML PS 16X105MM         | CONICAL TUBE 12ML PS 16X105MM   |
| 301403 | TUBO 12ML PS 15X102 MM TAPADO FALDON | TUBE 12ML PS CAPPED             |
| 301700 | TUBO 7 ML PS 13X100 MM               | TUBE 13X100 PS                  |
| 309201 | FRASCO 30ML PS ETIQUETADO            | 30ML UNIVERSAL LABELLED PS      |
| 309202 | FRASCO 30ML PS                       | 30ML CONTAINER PS               |
| 309206 | FRASCO 30ML PS TAPON ROJO            | 30ML PS CONTAINER RED CAP       |
| 309207 | FRASCO 30ML PS TAP.CU SEPARADA       | PS 30ML CONTAINER SEPARATED CAP |
| 309222 | FRASCO 30ML PS B/U                   | 30ML CONTAINER I/W PS           |
| 309402 | FRASCO 40ML PS                       | PS 40ML CONTAINER               |
| 309501 | FRASCO 60ML PS ETIQUETADO            | PS 60 ML CONTAINER PRINTED LBL  |
| 309502 | FRASCO 60ML PS                       | 60ML CONTAINER PS               |
| 309505 | FRASCO 60ML PS T/AZUL                | CONTAINER PS 60ML BLUE CAP      |
| 309552 | FRASCO 60ML PS ESPATULA              | 60ML CONTAINER WITH SPOON PS    |
| 400400 | TUBO 6 ML PP 12X88 MM GRADUADO       | TUBE 12X88 PP GRADUATED         |
| 400500 | TUBO 3 ML PP 11X55 MM                | TUBE 11X55 PP                   |
| 400700 | TUBO 5 ML PP 13X75 MM                | TUBE 13X75 PP                   |
| 400705 | TUBO 10 ML PP 16X100 MM              | TUBE 16X100 PP                  |
| 400800 | TUBO 5ML PP 12X75 MM GRADUADO        | TUBE 5ML PP 12X75MM GRADUATED   |
| 400806 | TUBO 75X12 PP TAPADO T/ROJO          | TUBE 12x75 PP CAPPED 305806     |
| 400900 | TUBO 16X95 PP                        | TUBE 16X95 PP                   |
| 400908 | TUBO 16x95 TAPADO 305007             | 16X95 PP TUBE CAPPED 305007     |
| 401100 | TUBO 5 ML PP 15X50 MM                | TUBE 15X50 PP                   |

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| REF    | DESCRIPCIÓN                          | DESCRIPTION                            |
|--------|--------------------------------------|----------------------------------------|
| 401200 | TUBO CONICO 12 ML PP 16X102 MM       | CONICAL TUBE 16X102 PP                 |
| 401201 | TUBO CONICO 12 ML PP 16X100 MM       | CONICAL TUBE 16X100 PP                 |
| 401202 | TUBO CONICO 16x102+TAPON 16MM        | CONICAL TUBE 16x102 + CAP 16MM         |
| 401204 | TUBO CÓNICO 12ML PP 16X100 MM        | CONICAL TUBE 12ML PP 16X100MM          |
| 401307 | TUBO CONICO 16X102 PP TAPADO         | CONICAL TUBE 16x102 PP CAPPED          |
| 401403 | TUBO 12ML PP 15X102 MM TAPADO FALDON | PP TUBE 13X100                         |
| 401700 | TUBO 7 ML PP 13X100 MM               | PP TUBE 13X100                         |
| 408702 | FRASCO 150 ML PP AL VACÍO            | CUP F/VACUUM COLLECTION 150ml          |
| 408726 | FRASCO 150 ML PP B/U AL VACÍO        | CUP F/VACUUM COLLEC.150ml I/B          |
| 409201 | FRASCO 30ML PP ETIQUETADO            | 30ML CONTAINER LABEL PP                |
| 409202 | FRASCO 30ML PP                       | 30ML CONTAINER PP                      |
| 409222 | FRASCO 30ML PP BOLSA UNITARIA        | 30ML CONTAINER I/W PP                  |
| 409402 | FRASCO 40ML PP GRADUADO              | 40ML CONTAINER PP GRADUATED            |
| 409426 | FRASCO 40ML PP B/U GRADUADO          | 40ML CONTAINER I/W PP                  |
| 409501 | FRASCO 60ML PP ETIQUETADO            | 60ML CONTAINER LABELLED PP             |
| 409502 | FRASCO 60ML PP                       | 60ML CONTAINER PP                      |
| 409507 | FRASCO 60ML PP ROSCADO T/VERDE       | 60ML SCREW CAP CONT PP C/GREEN         |
| 409511 | FRASCO 60ML PP ETIQUETADO T/AZUL     | 60ML BLUE CONTAINER LABEL PP           |
| 409552 | FRASCO 60ML PP C/ESPATULA            | 60ML CONTAINER W/SPOON                 |
| 409556 | FRASCO 60 ML. B/UNIT. CUCHARA        | 60 ML PP CONTAINER WITH SPOON UNIT BAG |
| 409602 | FRASCO 30ML PP C/CUCHARA             | 30ML CONTAINER WITH SPOON PP           |
| 409662 | FRASCO 30ML.T/AZUL CUC S/ROSC        | SCREW CAP CONT.30ml PP                 |
| 409701 | FRASCO 150ML PP ETIQUETADO           | 150ML CONTAINER LABELLED PP            |
| 409702 | FRASCO 150ML PP                      | 150ML CONTAINER PP                     |
| 409703 | FRASCO 150ML PP SIN ROSCAR           | 150ML CONT SEPARATED CAP PP            |
| 409707 | FRASCO 150ML PP T/VERDE              | PP 150 ML CONTAINER GREEN CAP          |
| 409711 | FRASCO 150ML AZUL ETIQUETADO         | 150ML BLUE CONTAINER LABEL PP          |
| 409752 | FRASCO 150ML PP C/CUCHARA            | 150ML CONTAINER WITH SPOON PP          |
| 409756 | FRASCO 150ML B/U ESPATULA PP         | 150ML CONTAINER I/W SPOON PP           |
| 409802 | FRASCO 50ML PP                       | 50ML CONTAINER PP                      |
| 409826 | FRASCO 50ML PP B/U                   | 50ML CONTAINER I/W PP                  |

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| REF       | DESCRIPCIÓN                         | DESCRIPTION                        |
|-----------|-------------------------------------|------------------------------------|
| 409852    | FRASCO 50ML PP CON ESPATULA         | 50ML CONTAINER WITH SPOON PP       |
| 409902    | FRASCO 200ML PP                     | 200ML CONTAINER PP                 |
| 409905    | FRASCO 200ML PP AZUL TRANS. ETI     | CONTAINER 200 ML PP BLUE-PLAIN LBL |
| 409915    | FRASCO 200ML PP AZUL TRANS S/E      | CONTAINER 200 ML PP BLUE           |
| 409926    | FRASCO 200ML PP B/U                 | 200ML CONTAINER PP I/W             |
| 410046    | FRASCO 50 ML PP T/PRECINTO          | TAMPER EVIDENT CONT.50ml H80mm     |
| 410047    | FRASCO T/BISAGRA 50ml H=80mm        | HINGED LID CONT.50ml H=80mm        |
| 410056    | FRASCO PRECINTO 50ml H80mm B/U      | HINGED LID CONT.50ml H80mm I/B     |
| 419802    | FRASCO 50ML PP T/PRECINTO           | 50ML CONT SEALED CAP PP            |
| 419805    | FRASCO 50ML PP T/PRECÍ AZUL         | PP 50 ML CONT. SEALED CAP BLUE     |
| 419825    | FRASCO 50ML PP T/PREC.AZUL B/U      | 50ML CONT SEAL.BLUE CAP I/W PP     |
| 419826    | FRASCO 50ML PP T/PRECINTO B/U       | 50ML CONT SEALED CAP I/W PP        |
| 429900    | TUBO CONICO 50 ML PP TAPADO         | 50ML CONICAL TUBE PP               |
| 429901    | TUBO CONICO 50ML PP FALDON TAPADO   | 50ML CONICAL TUBE SKIRT PP         |
| 429903    | TUBO 50ML PP CON.FALDON S/TAP       | 50ML CON.TUBE SKIRTE PP NO CAP     |
| 429910    | TUBO CONICO 15ML PP TAPADO          | 15ML CONICAL TUBE PP               |
| 444602801 | FRASCO DE SEG. 60ML T/AZUL          | CHILD PROOF CONT 60ML BLUE LID     |
| 444602802 | ANTI-CHILD. SIN TAPON               | CHILD PROOF CONT.60ML NO CAP       |
| 444602901 | FRASCO SEGURIDAD 60ML T/AZUL        | CHILDPROOF CONT 60ML BLUE LID      |
| 444602903 | ANTI-CHILD BLANCO T/BLANCO 60       | CHILD PROOF WHITE CONTAINER 60     |
| 444603202 | FRASCO DE SEG. 30ML T/BLAN PRECINTO | SECURITY CONT. 30ML WHITE CAP      |
| 444603204 | F.SEGURIDAD BLANCO 30ML T/BLANCO    | CHILDPROOF WH.CONT 30ML B/CAP      |
| 444603300 | FRASCO SEGURIDAD 60ML T/BLANCO      | CHILDPROOF CONT 60ML WHITE LID     |
| 444603305 | ANTI-CHILD.AZUL TAPON BLANCO        | CHILD PROOF BLUE CONT.WHIT CAP     |
| 444603306 | ANTI-CHILD. VERDE TAPON BLANCO      | CHILD PROOF GREEN CONT.WHIT CAP    |
| 444603308 | ANTI-CHILD.ROJO TAPON BLANCO        | CHILD PROOF RED CONT.WHIT CAP      |
| 444603402 | F. SEGURIDAD 125ML T/BLANCO         | CHILDPROOF CONT 125ML WHITE LID    |
| 202845N   | TARRO HISTOLOGIA 250ML. NEGRO       | HISTOLOGY CONTAINER 250ML BLACK    |
| 202846/T  | FRASCO DE SEGURIDAD 500ML TAPADO    | SECURITY CONTAINER 500ML CAPPED    |
| 202847/T  | FRASCO DE SEGURIDAD 1000ML TAPADO   | SECURITY CONTAINER 1000ML CAPPED   |

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| REF       | DESCRIPCIÓN                            | DESCRIPTION                        |
|-----------|----------------------------------------|------------------------------------|
| 300500.8  | TUBO 11X55 PS                          | TUBE 11X55 PS                      |
| 300800.1  | TUBO 5 ML PS 12X75 MM SIN ENRASES      | TUBE 12X75 PS                      |
| 300800.2  | TUBO 12X75 PS REFORZADO                | TUBE 12X75 PS                      |
| 300900M   | TUBO 16X95 PS GRAD.CAJA 5X100          | TUBE 16X95 PS GRAD.CASE 5X100      |
| 309202.4  | FRASCO 30ML PS                         | PS 30 ML. UNIVERSAL PLAIN LBL      |
| 309202.NR | FRASCO 30ML PS                         | 30ml CONTAINER PS NO SCREW         |
| 309202V   | FRASCO 30ML PS TAPÓN VERDE             | 30ML CONTAINER PS GREEN CAP        |
| 309202.WO | FRASCO 30ML PS SIN TAPÓN               | CONT.30ML PS NO CAP                |
| 309222.1  | FRASCO 30ML PS B/U ETIQUETADO          | CONTAINER 30 ML. UNIT BAG LABEL    |
| 309501BE  | FRASCO 60ML PS B/50 CÓD. BARRAS        | 60ML PS CONTAINER B/50 BAR COD     |
| 309502.10 | FP-60 S/ROSCAR C/600 T/ROJO            | CONT.60ML C/600 RED CAP            |
| 309502.6  | FRASCO 60 ML. PS ETIQUETA BLANC        | PS 60 ML. CONTAINER PLAIN LABEL    |
| 309602E   | FRASCO 30ML PS CON ESPATULA ETIQUETADO | 30ML CONTAINER WITH SPOON PS       |
| 309622.1  | FCO.30 CUCH. ETIQ. ESP. B/UNIT.        | PS 30ML SPOON+LABEL+UNIT BAG CONT. |
| 400004.1  | FRASCO 125ML PP 57X73                  | 125ML CONTAINER PP                 |
| 400500.B  | TUBO 11x55 PP B/400                    | TUBE 11x55 PP B/400                |
| 400706E   | TUBO 10ML C/A.BORICO TAP.ETIQ.B/U      | 100ML TUBE W/BORIC A. CAP.LAB. I/W |
| 400800.1  | TUBO 5 ML PP 12X75 MM SIN ENRASES      | TUBE 12X75 WITHOUT RINGS PP        |
| 400906BOR | TUBO 16X100 TAP- 308106 AC. BOR        | TUBE 16x100 PP CAP ACID BORIC      |
| 400906MD  | TUBO 16x100 PP TAPADO 308106           | 16x100 TUBE PP CAPPED 308106       |
| 409201.S  | FRASCO 30ML PP ETIQUETADO              | 30ML CONTAINER LABEL PP            |
| 409201.SE | FRASCO 30ML PP ETIQUETADO B100         | 30ML CONTAINER LABEL PP B/100      |
| 409202.8  | FRASCO 30 ML TAPADO TAPON AZUL         | 30ML CONTAINER PP BLUE CAP         |
| 409202.WO | FRASCO 30ML PP SIN TAPÓN               | CONT. 30ML PP NO CAP               |
| 409203.2  | FRASCO 30ML PP T/BLAN ENV. SEP         | PP 30 ML+ WHITE CAP SEPARAT.C/1800 |
| 409203.2A | FR.30ML PP T/BL.ENV.SEP.C/ANO          | PP 30ML WHITE CAP SEP.PLAIN BO     |
| 409502.2B | FR.60ML ETIQ.T/ROJO 10X50              | CONT.60ML LABEL RED C.10X50        |
| 409502.2C | FR. 60ML PP ETIQ.T/ROJO 16X50          | 60ML CONT. PP LABEL RED CAP 16X50  |
| 409502.4  | FRASCO 60ML S/ROSCAR 38X65 PP          | 60ML CONT. UNCAPPED 38X65MM PP     |
| 409502.4Y | FRASCO 60ml S/ROSCAR PP T/AMA          | 60ml CONT.UNCAPPED PP YEL/LID      |
| 409502G   | FRASCO 60ML GRADUADO                   | 60ML CONTAINER GRADUATED PP        |

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| REF       | DESCRIPCIÓN                         | DESCRIPTION                          |
|-----------|-------------------------------------|--------------------------------------|
| 409502G.4 | FR.60 GRAD.S/ROSCAR TAP.SEPARA      | CONT.60 GRAD.UNCAPPED SEP.CAP        |
| 409507G   | FRASCO 60ml PP GRAD.T/VERDE         | 60ml CONT.PP GRAD.GREEN CAP          |
| 409511.4  | FR.60ML AZUL CLARO S/ETIQUETA       | 60ML LIGHT BLUE CONTAINER            |
| 409511.5  | FR.60ML AZUL TRANS.L ETIQ. BLANC    | 60ML CONTAINER TRANS.BLUE LBL        |
| 409552.Y  | FRASCO 60ml PP C/ESPÁTULA T/AM      | 60ml CONTAINER W/SPOON YEL/LID       |
| 409552G   | FRASCO 60ML PP GRADUADO C/ESPA      | 60ML CONTAINER W/SPOON GRADUAT       |
| 409552.TA | FRASCO 60ML PP C/ESPATULA T.AZUL    | 60ML CONTAINER PP W/SPOON BLUE CAP   |
| 409702.3  | FRASCO 150ml PP TAPÓN BLANCO        | PP CONTAINER 150ml WHITE CAP         |
| 409702.P  | FRASCO 150ML PP ROSCADO             | 150ML PP CUPPED CONTAINER            |
| 409702.PB | FRASCO 150ML PP ROSCADO T.BLA       | 150ML PP CUPPED CONT.WHYTE C.        |
| 409703.5  | FRASCO 150 ML. T/AZUL S/ROSCAR      | 150ML CONT SEPARATED BLUE CAP        |
| 409703WC  | FRASCO 150ML PP SIN ROSCAR T/BLANCO | 150ML PP CONT.SEPAR.CAP WHITE        |
| 409711.4  | FR.150ML AZUL CLARO S/ETIQUETA      | 150ML LIGHT BLUE CONTAINER           |
| 409711.5  | FR.150ML AZUL TRANS. ETIQ. BLANC    | 150ML CONTAINER BLUE TRANS.LB        |
| 409805.6  | FRASCO 50ML PP T/ROJO SEPARADO      | 50ML PP CONTAINER SEP. RED CAP       |
| 410046.5  | FRASCO T/PREC.50ml H80mm C/500      | HINGED LID CONT.50ml H80 C/500       |
| 410046A.5 | FRASCO T/PREC.50ml 500UD AZUL       | HINGED LID CONT.500U BLUE            |
| 410046R.5 | FRASCO T/PREC.50ml 500UD ROSA       | HINGED LID CONT.500U PINK            |
| 420900E   | TUBO 12ML PP S/TAPON C/FALDON       | PP 12ML TUBE W/SKIRT W/OUT CAP       |
| 429900.25 | TUBO CONICO 50ml PP B/25            | 50ml CONICAL TUBE PP B/25            |
| 429900SP  | TUBO 50ML PP CONICO SIN ROSCAR      | 50ML CONICAL TUBE PP SEP.CAP         |
| 429901.25 | TUBO CON.50ml PP C/FALDON B/2       | 50ml CONICAL TUBE W/SKIRT B/25       |
| 429910SP  | TUBO 15ml PP CONICO SIN ROSCAR      | 15ml CONICAL TUBE PP SEP.CAP         |
| 429927S/E | TUBO CONICO 50ML C/FALDON B/U       | 50ML CONICAL TUBE SKIRT I/W PP       |
| 44462903M | ANTI-CHILD BLANCO T/BLANCO 60       | CHILDPROOF WHIE CONT.60ML WC         |
| 309202.O  | FRASCO 30ML PS ST. EO               | CONTAINER 30ML PS ST.EO              |
| 429930    | TUBO 50ML PP CONICO IMPRESO B/25    | 50ML TUBE PP CONICAL PRINT 25/B      |
| 429940    | TUBO 15 ML PP CONICO IMPRESO GRANEL | 15ML TUBE PP CONICAL PRINTED IN BULK |
| 429945    | TUBO 15 ML PP CONICO IMPRESO B/25   | 15ML TUBE PP CONICAL PRINT 25/B      |

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| REF        | DESCRIPCIÓN                           | DESCRIPTION                                |
|------------|---------------------------------------|--------------------------------------------|
| 429950     | TUBO 50 ML PP CONICO IMPRESO C/F B/25 | 50ML TUBE PP CONICAL PRINT SKIRTED 25/B    |
| 300500MI   | TUBO 11X55 PS                         | TUBE 11X55 PS                              |
| 175723     | TUBO 5ML PS 13X75 TAPADO ROJO         | TUBE 5ML PS 13X75 CAPPED RED               |
| 175724     | TUBO 10ML PS 16X95 TAPADO ROJO        | 10ML TUBE PS 16X95 CAPPED RED              |
| 400903     | TUBO 10ML PP 16X95 TAPADO ROJO        | 10ML TUBE PP 16X95 CAPPED RED              |
| 661035     | TUBO 10ML PS 16X95 TAPADO NATURAL     | 10ML TUBE PS 16X95 CAPPED NATURAL          |
| 408702C    | FRASCO VACÍO 120ml LOTE IMPRESO       | VACUUM CONT.120ML CML                      |
| 408726.A   | FRASCO P/VACÍO 120ml B/I C/AN.        | CUP F/VACUUM 120ml I/B PLAIN/C             |
| 400805     | TUBO 75X12 PP TAPADO T/AZUL           | TUBE 75X12 PP CAPPED C/BLUE                |
| 202844/T   | FRASCO DE SEGURIDAD 120ML TAPADO      | SECURITY CONTAINER 120ML CAPPED            |
| 409557     | FRASCO 60ML PP C/ESPATULA T/VERDE     | CONTAINER 60ML PP W/SPOON GREEN CAP        |
| 419802.T   | FRASCO 50ML PP T/PREC. DESTAPADO      | CONTAINER 50ML PP C/TAMPER EVID. UNCOVERED |
| 409502.4B  | FRASCO 60ML PP T/AZUL NO TAPADO       | 60ML CONTAINER PP BLUE CAP UNCOVERED       |
| 409702B    | FRASCO 150ML PP B/50                  | 150ML CONTAINER PP B/50                    |
| 309205     | FRASCO 30ML PS T/AZUL ETIQ.           | 30ML CONTAINER PS BLUE CAP LABEL           |
| 429906SP   | TUBO 50ML PP CONICO T/ROJO SIN ROSCAR | 50ML CONICAL TUBE PP SEP.CAP RED           |
| 429901SP   | TUBO CONICO 50ML PP FALDON SIN ROSCAR | TUBE 50ML PP SKIRTED SEP. CAP              |
| 175725     | TUBO 3ML PS 11X55 TAPADO ROJO         | TUBE 3ML PS 11X55 CAPPED RED               |
| 409511.4TA | FRASCO 60ML PP C/CUCHARA T/AZUL       | CONTAINER 60ML PP W/SPOON BLUE CAP         |
| 202842A    | FRASCO SEGURIDAD 60ML T/AZUL          | CONTAINER 60ML BLUE CAP                    |
| 202844A    | FRASCO DE SEGURIDAD 120ML T/AZUL      | SECURITY CONTAINER 120ML BLUE CAP          |
| 409512     | FRASCO 60ML PP T/ROJO C/GRIS          | CONT. 60ML PP RED C. GREY B.               |
| 301201CA   | TUBO CONICO 12ML PS 16X100 MM         | CONICAL TUBE 16X100 PS                     |

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## DECLARACIÓN DE CONFORMIDAD CE CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

**DELTALAB S.L.**  
Plaza de la Verneda, 1  
Pol. Ind. La Llana  
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:  
Declares under its responsibility that the product:

**TUBOS DE EXTRACCIÓN – CITRATO TAMPONADO**  
**BLOOD CONTAINERS – SODIUM CITRATE**  
(Códigos según Anexo 1 / Codes in Annex 1)

**Finalidad Prevista:** Recogida y conservación y/o transporte, de sangre para análisis y/u otra investigación (p.ej. para estudios de coagulación del plasma)  
**Intended Use:** Collection and preservation and/or transport, of blood for analysis and/or other (e.g. for plasma coagulation studies)

**Código GMDN / GMDN Code:** 58139

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:  
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

**Directiva 98/79/CE:** Directiva Productos Sanitarios para el Diagnostico "in vitro".  
Transposición a la legislación española en Real Decreto 1662/2000.  
**Directive 98/79/EC:** "In-vitro" Diagnostics Medical Devices Directive.  
Transposition to Spanish legislation in Real Decreto 1662/2000.

**Clasificación:** Anexo 3, Clase: Otros  
**Classification:** Annex 3, Class: Other

  
José Saez  
Director General / Managing Director

  
Anna Mir  
Responsable Técnico / Technical Director

Fecha / Date: 21/11/2013  
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CDCE-79 Rev.1

## ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS ANNEX 1 – ARTICLES DESCRIPTION

| REF      | DESCRIPCIÓN                    | DESCRIPTION                    |
|----------|--------------------------------|--------------------------------|
| 601102   | TUBO CITRATO PP 4 ML           | CITRATE TUBE 4ML PP            |
| 601103   | TUBO CITRATO PP 2,5ML          | CITRATE TUBE 2.5ML PP          |
| 601203   | TUBO CITRAT TAMP 3,2% PP 2,5ML | CITRATE TUBE 3.2% 2.5ML PP     |
| 621101   | TUBO CITRATO 1ML PERFORABLE    | CITRATE TUBE 1ML PIERCEABLE    |
| 621102   | TUBO CITRATO 2ML PERFORABLE    | CITRATE TUBE 1ML PIERCEABLE    |
| 601103.2 | TUBO CITRATO 2.5ML RETRACTIL   | CITRATE TUBE 2.5ML WRAPPEDRACK |
| 601203.1 | TUBO CITRATO 3.2% 2.5ML GRANEL | CITRATE TUBE 3.2% 2.5ML BULK   |

Fecha / Date: 21/11/2013  
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CDCE-79 Rev.1



# DECLARACIÓN DE CONFORMIDAD CE CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

**DELTALAB S.L.**  
Plaza de la Verneda, 1  
Pol. Ind. La Liana  
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:  
*Declares under its responsibility that the product:*

**TUBOS DE EXTRACCIÓN – K3EDTA**  
**BLOOD CONTAINERS – K3EDTA**  
(Códigos según Anexo 1 / Codes in Annex 1)

**Finalidad Prevista:** Recogida y conservación y/o transporte, de sangre para análisis y/u otra investigación (por ejemplo, hematología de sangre como conteo sanguíneo completo (SCS), y determinación cuantitativa de drogas.

**Intended Use:** Collection and preservation and/or transport of blood for analysis and/or other investigation (e.g. whole blood hematology such as complete blood count (CBC) and quantitative drug assay determinations).

**Código GMDN / GMDN Code:** 58143

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:  
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

**Directiva 98/79/CE:** Directiva Productos Sanitarios para el Diagnostico "in vitro".  
Transposición a la legislación española en Real Decreto 1662/2000.  
**Directive 98/79/EC:** "In-vitro" Diagnostics Medical Devices Directive.  
Transposition to Spanish legislation in Real Decreto 1662/2000.

**Clasificación:** Anexo 3, Clase: Otros  
**Classification:** Annex 3, Class: Other



José Sáez  
Director General / Managing Director



Anna Mir  
Responsable Técnico / Technical Director

Fecha / Date: 22/11/2013  
Pag. 1/2

CDCE-77 Rev.2

# ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS ANNEX 1 – ARTICLES DESCRIPTION

| REF      | DESCRIPCIÓN                                  | DESCRIPTION                                   |
|----------|----------------------------------------------|-----------------------------------------------|
| 601603   | TUBO EDTA TRIPOTASICO 2,5ML PP 13X75MM       | EDTA TUBE TRI-K R/BOT 2.5ML PP                |
| 601612   | TUBO EDTA TRI-K PP 4ML                       | EDTA TUBE TRI-K 4ML PP                        |
| 601613   | TUBO EDTA TRI-K PP 2,5ML                     | EDTA TUBE TRI-K 2.5ML PP                      |
| 601702   | TUBO EDTA TRI-K PP 4ML                       | EDTA TUBE TRI-K 4ML PP                        |
| 611604   | TUBO EDTA TRI-K 3ML PP 13X80 T/GOMA PERF.    | EDTA TRI-K TUBE 3ML PP 13X80 RUBBER CAP PERF. |
| 621610   | TUBO EDTA TRI-1ML PP 12X55MM T/PRE PERF.     | EDTA TUBE TRI-K 1ML PP 12X55MM C/PRE-PERF.    |
| 621611   | TUBO EDTA TRI-K 2ML 16X55 FALDON T/PRE-PERF. | EDTA TUBE TRI-K 2ML 16X55 SKIRTED C/PRE-PERF. |
| 621613   | TUBO EDTA TRI 2,5ML PP 13X80MM T/PERFOR.     | EDTA TUBE TRI-K 2.5ML PP 13X80MM T/PRE-PERF.  |
| 601603.2 | TUBO EDTA TRI-K 2.5ML RETRACTILADO           | EDTA TRI-K TUBE 2.5ML WRAP/RAC                |
| 601702.2 | TUBO EDTA TRI-K 4ML RETRACTILADO             | EDTA TRI-K TUBE 4ML WRAPP/RACK                |
| 611603.1 | TUBO EDTA TRI-K PULV. 3ML 13X75 T/PERFO      | EDTA TUBE PUL.K3 3ML PIERC.CAP                |

Fecha / Date: 20/06/2016  
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CDCE-77 Rev.2.2

# DECLARACIÓN DE CONFORMIDAD CE CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

**DELTALAB S.L.**  
Plaza de la Verneda, 1  
Pol. Ind. La Liana  
08191 RUBI (BARCELONA) – SPAIN

Declara bajo su responsabilidad que el producto:  
*Declares under its responsibility that the product:*

**TUBOS DE EXTRACCIÓN – SEROTUB**  
**BLOOD CONTAINERS – SEROTUBE**  
(Códigos según Anexo 1 / Codes in Annex 1)

**Finalidad Prevista:** Recogida y conservación y/o transporte, de sangre para análisis y/u otra investigación (por ejemplo, determinación química del suero sanguíneo).

**Intended Use:** Collection and preservation and/or transport, of blood for analysis and/or other investigation (e.g. blood serum chemistry determinations)

**Código GMDN / GMDN Code:** 58138

CUMPLE LOS REQUISITOS DE LAS NORMAS Y DIRECTIVAS:  
CONFORMS TO THE REQUISITES OF THE STANDARDS AND DIRECTIVES:

**Directiva 98/79/CE:** Directiva Productos Sanitarios para el Diagnostico "in vitro".  
Transposición a la legislación española en Real Decreto 1662/2000.  
**Directive 98/79/EC:** "In-vitro" Diagnostics Medical Devices Directive.  
Transposition to Spanish legislation in Real Decreto 1662/2000.

**Clasificación:** Anexo 3, Clase: Otros  
**Classification:** Annex 3, Class: Other



José Sáez  
Director General / Managing Director



Anna Mir  
Responsable Técnico / Technical Director

Fecha / Date: 22/11/2013  
Pag. 1/2

CDCE-45 Rev.10

# ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS ANNEX 1 – ARTICLES DESCRIPTION

| REF    | DESCRIPCIÓN                   | DESCRIPTION                    |
|--------|-------------------------------|--------------------------------|
| 600300 | TUBO SUERO PP 9ML GRANULOS    | SEROTUBE W/GRANULES PP 9ML     |
| 600400 | TUBO SUERO PP 4ML GRANULOS    | SEROTUBE W/GRANULES PP 4ML     |
| 600602 | SEROTUB GLUCOSA PP 4ML        | SERUM GLUCOSE 4ML GRANULES PP  |
| 600610 | SEROTUB GLUCOSA PP 10ML       | PP SERUM GLUCOSE 10ML GRANULES |
| 600800 | TUBO SUERO PP 9ML GEL         | SERUM TUBE W/GEL 9ML PP        |
| 600801 | TUBO SUERO PP 4ML GEL         | SERUM TUBE W/GEL 4ML PP        |
| 620200 | TUBO SUERO 2ML PERF GRANULOS  | SERUM TUBE 2ML PIER W/GRANULES |
| 620300 | TUBO SUERO 10ML PERF GRANULOS | SERUM TUBE 10ML PIER W/GRANULE |
| 620400 | TUBO SUERO 4ML PERF GRANULOS  | SERUM TUBE 4ML PIER W/GRANULES |
| 620800 | TUBO SUERO 10ML PERF GEL      | SERUM TUBE 10ML PIERCEABLE GEL |

Fecha / Date: 22/11/2013  
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CDCE-45 Rev.10



# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Bioptik Technology, Inc.**  
**No. 188, Jhonghua South Road**  
**Gongguan Village**  
**Jhunan Township**  
**Miaoli County, 35057**  
**Taiwan**

has established and applies a quality management system  
for the following scope:

**Design and Development, Manufacture and Distribution**  
**of in vitro diagnostic for self-testing**  
**(see attachment for products included)**

Proof has been furnished that the requirements specified in

**EN ISO 9001:2008**

are fulfilled. The quality management system is subject to yearly surveillance.

Certificate Registration No.: SY 60089707 0001

An audit was performed. Report No.: 10042449 001

This Certificate is valid until: 17.09.2018

Certification Body

Date 14.01.2014



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 1

**Attachment to**  
**Registration No.:** SY 60089707 0001  
**Report No.:** 10042449 002

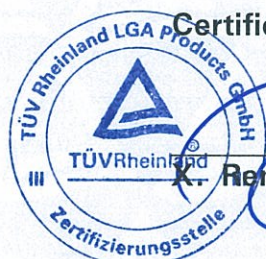
**Organization:** Bioptik Technology, Inc.  
No. 188, Jhonghua South Road  
Gongguan Village  
Jhunan Township  
Miaoli County, 35057  
Taiwan

**Scope:**

**Products:**

- Blood Glucose Monitoring Systems
- Blood Cholesterol Monitoring Systems
- Hemoglobin Monitoring Systems
- Blood Glucose/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol Monitoring Systems
- Blood Glucose/Hemoglobin Monitoring Systems
- Blood Glucose/Cholesterol/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol/Hemoglobin Monitoring Systems
- Blood Glucose/Cholesterol/Uric Acid/Hemoglobin Monitoring System
- Blood Pressure/Glucose/ Cholesterol Monitoring Systems (Monitoring System is including meter, strip and control solution)

**Date:** 2014-03-13



**Certification Body**

**Ren**



**EC Certificate**  
**Directive 98/79/EC Annex IV, excluding Sections 4 and 6**  
**Full Quality Assurance System**  
**In Vitro Diagnostic Medical Devices**

**Registration No.:** HL 60131743 0001

**Report No.:** 10042449 010

**Manufacturer:** Bioptik Technology, Inc.  
No. 188, Jhonghua South Road  
Gongguan Village  
Jhunan Township  
Miaoli County, 35057  
Taiwan

**Products:** In-vitro diagnostic Medical Devices for self-testing  
(see attachment for products included)  
Replaces Approval, Registration No.: HL 60088590 0001

**Expiry Date:** 2023-09-17

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

**Effective Date:** 2018-10-19

**Date:** 2018-10-19



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC  
concerning in vitro diagnostic medical devices with the identification number 0197.



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** HL 60131743 0001  
**Report No.:** 10042449 010

**Manufacturer:** Bioptik Technology, Inc.  
No. 188, Jhonghua South Road  
Gongguan Village  
Jhunan Township  
Miaoli County, 35057  
Taiwan

**Products:**

- Blood Glucose Monitoring Systems
- Blood Cholesterol Monitoring Systems
- Hemoglobin Monitoring Systems
- Blood Triglyceride Monitoring System
- Blood Glucose/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol Monitoring Systems
- Blood Glucose/Hemoglobin Monitoring System
- Blood Glucose/Cholesterol/Uric Acid Monitoring Systems
- Blood Glucose/Cholesterol/Hemoglobin Monitoring Systems
- Blood Glucose/Cholesterol/Triglyceride Monitoring Systems
- Blood Glucose/Cholesterol/Uric Acid/Hemoglobin Monitoring System
- Blood Glucose/Cholesterol/Uric Acid/Hemoglobin/Triglyceride Monitoring Systems
- Blood Pressure/Glucose/Cholesterol Monitoring Systems (assessment limited to Glucose/Cholesterol Monitoring)

**Date:** 2018-10-19

**Notified Body**



**Allen Chen**



# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Bioptik Technology, Inc.**  
**No. 188, Jhonghua South Road**  
**Gongguan Village**  
**Jhunan Township**  
**Miaoli County, 35057**  
**Taiwan**

has established and applies a quality management system for medical devices  
for the following scope:

**Design and development, manufacture and distribution of**  
**Medical devices**  
**(see attachment for products included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-10-19  
Certificate Registration No.: SX 60131746 0001  
An audit was performed. Report No.: 50145079 001  
This Certificate is valid until: 2021-09-17

Certification Body



Date 2018-10-19



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com <http://www.tuv.com/safety>

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60131746 0001  
**Report No.:** 50145079 001

**Organization:** Bioptik Technology, Inc.  
No. 188, Jhonghua South Road  
Gongguan Village  
Jhunan Township  
Miaoli County, 35057  
Taiwan

**Scope:**

**Products:**

- In vitro diagnostic medical devices used in blood analytes and blood glucose monitoring including meter, test strips and control solutions for self-testing, near patient/point of care.
- Blood Pressure/Glucose/Cholesterol Monitoring System (assessment limited to Blood Pressure Monitoring)

**Certification Body**



**Date:** 2018-10-19





Gessate, 7 February 2012

## CONFORMITY OF GIMA PRODUCTS

According to the annex VII of the Council Directive 93/42/EEC  
as amended by the European Directive 2007/47/EEC concerning medical devices

GIMA declares that all medical devices illustrated on

### GIMA INTERNATIONAL CATALOGUE

meet the provisions of the following Council Directive (when applicable)

### 93/42/EEC AS AMENDED BY THE EUROPEAN DIRECTIVE 2007/47/EEC

as below:

- A) For all products classified in **CLASS I**, we have in our company a technical file as required from annex VII, and it is available a certificate of conformity signed by the responsible inside the EU (generally GIMA).
- B) For all products in CLASS IIa and IIb it is available, or it will be available in one month, a declaration of conformity signed by an official European Notified Body or the ISO 9002 certificate of the manufacturer.

**GIMA S.p.A.**  
Q.A. Department  
Nicola Manzoni

A handwritten signature in black ink, appearing to read 'N. Manzoni', with a stylized flourish at the end.



|                  |            |                  |            |
|------------------|------------|------------------|------------|
| Reg. Number      | 10164 - A  | Valid From       | 2018-10-01 |
| First issue date | 2012-10-15 | Last change date | 2018-10-01 |
| Valid Until      | 2021-10-14 | IAF Sector       | 29         |

## Quality Management System Certificate ISO 9001:2015

We certify that the Quality Management System of the Organization:

### **GIMA S.p.A.**

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Trade, packaging and service of medical devices (MD), in vitro diagnostic products (IVD), personal protective equipments (PPE), biocides, veterinary items, medical accessories furniture and aids

Chief Operating Officer  
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.  
Società con socio unico,  
soggetta all'attività di  
direzione e coordinamento di  
Kiwa Italia Holding Srl  
Via Cadriano, 23  
40057 Granarolo dell'Emilia  
(BO)  
Tel +39.051.459.3.111  
Fax +39.051.763.382  
E-mail: info@kiwacermet.it  
www.kiwacermet.it

### **GIMA S.p.A.**

#### **Registered Headquarters**

- Via Grossi, 2 20121 Milano Italia

#### **Certified Sites**

- Via Marconi, 1 20060 Gessate ( MI ) Italia



SGQ N° 007A  
SGA N° 010D  
PRD N° 069B  
FSM N° 004I  
PRS N° 089C





|                  |            |                  |            |
|------------------|------------|------------------|------------|
| Reg. Number      | 10164 - M  | Valid From       | 2018-10-01 |
| First issue date | 2012-10-15 | Last change date | 2018-10-01 |
| Valid until      | 2021-10-14 |                  |            |

## Quality Management System Certificate **ISO 13485:2016**

We certify that the Quality Management System of the Organization:

### **GIMA S.p.A.**

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Trade, packaging and service of: medical devices (MD), in vitro diagnostic products (IVD), medical accessories, furniture and aids,

Chief Operating Officer  
Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.  
Società con socio unico,  
soggetta all'attività di  
direzione e coordinamento di  
Kiwa Italia Holding Srl  
Via Cadriano, 23  
40057 Granarolo dell'Emilia  
(BO)  
Tel +39.051.459.3.111  
Fax +39.051.763.382  
E-mail: [info@kiwacermet.it](mailto:info@kiwacermet.it)  
[www.kiwacermet.it](http://www.kiwacermet.it)

### **GIMA S.p.A.**

#### **Registered Headquarters**

- Via Grossi, 2 20121 Milano Italia

#### **Certified Sites**

- Via Marconi, 1 20060 Gessate ( MI ) Italia



SGQ N° 007A  
SGA N° 010D  
PRD N° 069B  
FSM N° 0041  
PRS N° 089C

**EC Certificate**  
**Directive 93/42/EEC Annex V**  
**Production Quality Assurance**  
**Medical Devices**

**Registration No.:** DD 60100980 0001

**Report No.:** 26300270 002

**Manufacturer:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

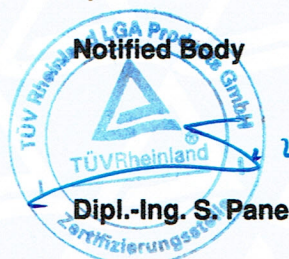
**Products:** (see attachments for products and site included)  
Replaces approval, registration no.: DD 60040589 0001

**Expiry Date:** 2020-04-13

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

**Effective Date:** 2015-04-30

**Date:** 2015-04-30



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

**TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** DD 60100980 0001  
**Report No.:** 26300270 002

**Manufacturer:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

**Products included:**

- Disposable trocars
- Infusion sets
- Retrieval bags
- Disposable skin staplers
- Suction cannulas and suction sets
- Thoracentesis/Paracentesis sets
- Transfusion sets
- Veress needles
- Thoracic catheters
- Suction-irrigation sets
- Silicone slings

For the following medical devices the scope covers  
only the aspects of manufacture concerned with securing  
and maintaining sterile conditions:

- Disposable skin staples removers
- Chest drainage systems
- Connecting tubes
- Absorbing pads

**Date: 2015-04-30**





**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

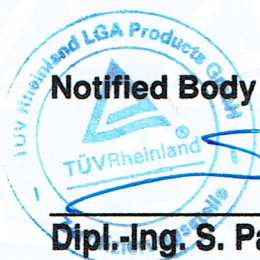
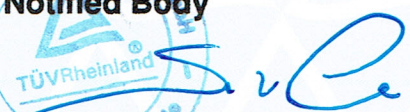
**Registration No.:** DD 60100980 0001  
**Report No.:** 26300270 002

**Manufacturer:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

**Site included:**

Grena Limited  
Chelsea House, Chelsea Street,  
Nottingham, NG7 7HP,  
United Kingdom

**Date: 2015-04-30**

  
**Notified Body**  
  
**Dipl.-Ing. S. Pane**



**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60100981 0001

**Report No.:** 26300270 002

**Manufacturer:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

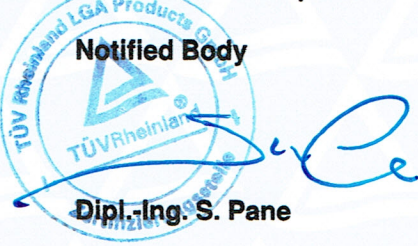
**Products:** (see attachments for products and site included)  
Replaces approval, registration no.: HD 60040590 0001

**Expiry Date:** 2020-04-13

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2015-04-30

**Date:** 2015-04-30

**Notified Body**  
  
**Dipl.-Ing. S. Pane**

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

**TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.**



**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60100981 0001  
**Report No.:** 26300270 002

**Manufacturer:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

**Products included:**

- Reusable endoscopic surgical instruments
- Disposable endoscopic surgical instruments
- Disposable linear cutting staplers with cartridges
- Disposable linear staplers with cartridges
- Disposable circular staplers with related surgical instruments
- Staples cartridges for reusable circular staplers
- Staples cartridges for reusable linear staplers
- Ligating clips
- Surgical meshes
- Cartridges for disposable endoscopic linear cutting staplers
- Disposable endoscopic linear cutting staplers

**Date: 2015-04-30**





**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60100981 0001  
**Report No.:** 26300270 002

**Manufacturer:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

**Site included:**

Grena Limited  
Chelsea House, Chelsea Street,  
Nottingham, NG7 7HP,  
United Kingdom

**Date: 2015-04-30**



**Dipl.-Ing. S. Pane**



# Certificate

The Certification Body of  
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

**Grena Ltd.**  
**1000 Great West Road**  
**Brentford, Middlesex**  
**TW8 9HH**  
**United Kingdom**

has established and applies a quality management system for medical devices  
for the following scope:

**Design and development, production and distribution  
of disposable and reusable medical devices for surgical and  
patient care procedures  
(See attachment for site included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2012**  
**EN ISO 13485:2012/AC:2012**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2015-04-30  
Certificate Registration No.: SX 60100982 0001  
An audit was performed. Report No.: 26300270 002  
This Certificate is valid until: 2018-04-13

Certification Body



Date 2015-04-30



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to**  
**Registration No.:** SX 60100982 0001  
**Report No.:** 26300270 002

**Organization:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

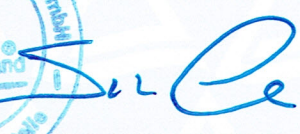
**Scope:** Site included:  
  
Grena Limited  
Chelsea House, Chelsea Street,  
Nottingham, NG7 7HP,  
United Kingdom  
  
Distribution

**Certification Body**



**Date: 2015-04-30**



  
**Dipl.-Ing. S. Pane**



# Certificate

The Certification Body of  
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

**Grena Ltd.**  
**1000 Great West Road**  
**Brentford, Middlesex**  
**TW8 9HH**  
**United Kingdom**

has established and applies a quality management system  
for the following scope:

**Design and development, production and distribution  
of disposable and reusable medical devices for surgical and  
patient care procedures  
(see attachment for site included)**

Proof has been furnished that the requirements specified in

**EN ISO 9001:2008**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2015-04-30  
Certificate Registration No.: SY 60100983 0001  
An audit was performed. Report No.: 26300270 002  
This Certificate is valid until: 2018-04-13

Certification Body

Date 2015-04-30



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to**  
**Registration No.:** SY 60100983 0001  
**Report No.:** 26300270 002

**Organization:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

**Scope:** Site included:  
  
Grena Limited  
Chelsea House, Chelsea Street,  
Nottingham, NG7 7HP,  
United Kingdom  
  
Distribution

**Date: 2015-04-30**

**Certification Body**  
  
**Dipl.-Ing. S. Pane**



## DECLARATION OF CONFORMITY

### Manufacturer

Grena Limited  
1000 Great West Road  
Brentford, Middlesex, TW8 9HH  
United Kingdom

### Product(s)

Disposable circular staplers with related surgical instruments (class IIb, rule 8)  
Disposable linear staplers and cartridges for linear staplers (class IIb, rule 8)  
Disposable bone marrow aspiration needles (class IIa, rule 6)  
Disposable bone marrow biopsy needles (class IIa, rule 6)  
Disposable staples cartridges for reusable linear staplers (class IIb, rule 8)  
Disposable staples cartridges for reusable circular staplers (class IIb, rule 8)  
Disposable endoscopic linear cutting staplers (class IIa, rule 6)  
Cartridges for disposable endoscopic linear cutting staplers (class IIb, rule 8)  
Surgical meshes (class IIb, rule 8)  
Disposable automatic clip appliers with clips (class IIb, rule 8)  
LigaV® – Titanium ligating clips (class IIb, rule 8)  
VClip® – Titanium ligating clips (class IIb, rule 8)  
Click'a-V® – Polymer ligating clips (class IIb, rule 8)

#### Disposable endoscopic instruments:

Disposable grasper with ratchet atraumatic fenestrated (class IIb, rule 9)  
Disposable grasper with ratchet-Allis (class IIb, rule 9)  
Disposable grasper with ratchet-Maxi Grip (class IIb, rule 9)  
Disposable toothed grasper with ratchet (class IIb, rule 9)  
Disposable grasper with ratchet –Babcock (class IIb, rule 9)  
Disposable Metzenbaum scissors-curved (class IIb, rule 9)  
Disposable scissors-straight (class IIb, rule 9)  
Disposable scissors-hook (class IIb, rule 9)  
Disposable dissector-Maryland (class IIb, rule 9)  
Disposable dissector with ratchet- Maryland (class IIb, rule 9)  
Disposable endoscopic dissector 3mm – Maryland, non-ratcheted  
Disposable endoscopic dissector 3mm – Maryland, ratcheted  
Disposable endoscopic grasper 3mm – atraumatic fenestrated  
Disposable endoscopic scissors 3mm – curved

#### Limited use endoscopic instruments:

Limited use dissector- Maryland (class IIb, rule 9)  
Limited use dissector with ratchet- Maryland (class IIb, rule 9)  
Limited use Metzenbaum scissors- curved (class IIb, rule 9)  
Limited use scissors-straight (class IIb, rule 9)  
Limited use scissors-hook (class IIb, rule 9)  
Limited use grasper with ratchet atraumatic fenestrated (class IIb, rule 9)  
Limited use disposable grasper with ratchet-Allis (class IIb, rule 9)  
Limited use grasper with ratchet-Maxi Grip (class IIb, rule 9)  
Limited use toothed grasper with ratchet (class IIb, rule 9)  
Limited use grasper with ratchet –Babcock (class IIb, rule 9)

Reusable endoscopic surgical instruments (class IIb, rule 9)  
Disposable linear cutting staplers and cartridges for cutting staplers (class IIb, rule 8)  
Disposable trocars with accessories (class IIa, rule 7)  
Sterile disposable skin staplers (class IIa, rule 7)  
Thoracentesis/paracentesis sets (class IIa, rule 6)  
Suction cannulas and suction sets (class IIa, rule 7)  
Suction-irrigation sets (class IIa, rule 6)  
Disposable skin staples removers (class I sterile, rule 1)  
Chest drainage systems (class I sterile, rule 1)  
Connecting tubes (class I sterile, rule 1)  
Retrieval bags (class IIa, rule 6)  
Veress needles (class IIa, rule 6)  
Silicone slings (class IIa, rule 6)  
Arida® absorbing pads (class I, rule 1)  
Arida® absorbing pads – sterile (class I sterile, rule 1)  
Solidifying agent (class I, rule 1)  
Open surgery and endoscopic clip appliers (class I, rule 6)  
Vomit bags (class I, rule 1)





VAT no. GB 821 2900 64

1000 Great West Road, Brentford, Middlesex TW8 9HH, UK

Phone +44 131 208 207 6 Fax +44 131 777 80 77

Classification

According to Annex IX of Directive 93/42/EEC

*We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the directive 93/42/EEC concerning medical devices which apply to them. All supporting documentation is retained under the premises of the manufacturer.*

Standards Applied

*All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.*

Notified Body

**C E 0197**

TÜV Rheinland LGA Products GmbH  
Lillystrasse 2  
90431 Nürnberg  
Germany

EC Certificate(s)

HD 60040590 0001  
DD 60040589 0001

Brentford, 09.05.2014

Wiesław Brodaczewski  
Director



# Certificate

The Certification Body of  
**TÜV Rheinland LGA Products GmbH**

hereby certifies that the organization

**Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom**

has established and applies a quality management system for medical devices  
for the following scope:

**Design and development, production and distribution  
of disposable and reusable medical devices for surgical and  
patient care procedures. Servicing of suction devices.  
(see attachment for site included)**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-06-29  
Certificate Registration No.: SX 60130220 0001  
An audit was performed. Report No.: 26300270 007  
This Certificate is valid until: 2021-04-13

Certification Body



Date 2018-06-29

*Maciej Sciera*  
Maciej Sciera



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 1/1, Rev. 0

**Attachment to  
Certificate**

**Registration No.:** SX 60130220 0001  
**Report No.:** 26300270 007

**Organization:** Grena Ltd.  
1000 Great West Road  
Brentford, Middlesex  
TW8 9HH  
United Kingdom

**Scope:**

Site included:

Grena Ltd.  
Chelsea House  
Chelsea Street  
Nottingham NG7 7HP  
United Kingdom

Activity: Design and development, production  
and distribution of disposable and reusable  
medical devices for surgical and patient care  
procedures. Especially: production, purchasing,  
logistics and distribution of disposable  
and reusable medical devices.

**Certification Body**



**Date: 2018-06-29**

**Maciej Sciera**





# CERTIFICATE

Number: 2090418

The management system of the organization(s) and locations mentioned on the addendum belonging to:

**Medtronic EMEA Medtronic B.V.**

Earl Bakkenstraat 10

6422 PJ Heerlen

The Netherlands

including the implementation meets the requirements of the standard:

**EN ISO 13485:2016**  
**ISO 9001:2015**

Scope:

Sales, order management, warehousing and distribution of medical devices.  
Including inventory management, regulatory affairs, post market surveillance, technical service, customer education and spine loaner operations

Certificate expiry date: 1 July 2021

Certificate effective date: 1 July 2018

Certified since: 1 July 2006

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



drs. G.J. Zoetbrood  
Managing Director



ing. A.A.M. Laan  
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed





# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Certified organization(s) and/or locations:

Different scope

Medtronic Portugal LDA-  
Rua Tomas da Fonseca Torre E, 11  
 piso  
1600 Lisboa  
Portugal

Sales, Order Management and distribution of medical devices  
including technical service and customer education.

Warehousing and distribution of medical devices, including spine  
loaner operations

Medtronic Italia S.p.A.  
Via Varesina 162  
20156 Milano  
Italy

Sales, order management and distribution of medical devices.  
Including technical service and customer education.  
Promotion, invoice and order management of medicinal  
products.

Medtronic Danmark A/S.  
Arne Jacobsens Allé 17  
2300 Copenhagen  
Denmark

Sales, order management and distribution of medical devices.  
Including technical service and customer education

Medtronic Medikal Teknoloji Ticaret Ltd  
Sti  
Saray Mah. Esnaf Sk.  
Akkom Ofis Park Laodik Plaza  
Sitesi B Blok Apt: 2/8  
00000 Umraniye - Istanbul  
Turkey

Sales, order management and distribution of medical devices.  
Including technical service and customer education



# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Africa (Pty) Ltd.  
Waterfall Distribution Campus  
CNR K101 and Bridal Veil Road  
Waterfall Midrand  
1685 Gauteng  
South Africa

Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.

Medtronic Ibérica S.A.  
Calle de María de Portugal, 11  
28050 Madrid  
Spain

Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.

Medtronic Romania SRL  
Ploiesti 42-44, Building B, B2  
Wing, 2nd floor, district 1  
Baneasa Business & Technology Park  
013696 Bucharest  
Romania

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Norge AS  
Martin Linges vei 25  
1364 Fornebu  
Norway

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Portugal, LDA-  
Avenida Gomes Pereira 61B  
Benfica  
1600 Lisboa  
Portugal

Sales, Order Management and distribution of medical devices Including technical service and customer education.

Warehousing and distribution of medical devices, including spine loaner operations.



# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Service & Repair CoE  
C-Mill gebouw K  
Jan Campertstraat 21-A  
6416 SG Heerlen

Service and repair of medical devices (excluding Imaging and Navigation products).

Medtronic Ibérica S.A.  
Polígono Industrial La Garena  
Calle Francisco Rabal 7  
28806 Alcalá De Heneras, Madrid  
Spain

Spine loaner operations.

Medtronic Ibérica S.A.  
WTC Almeda Park  
Placa de la Pau, s/n. Edificio 7, 3 piso  
08940 Cornellà de Llobregat, Barcelona  
Spain

Warehousing and distribution of medical devices, including spine loaner operations

Medtronic France SAS  
27/33 Quai Alphonse Le Gallo  
92513 Boulogne-Billancourt  
France

Sales, order management and distribution of medical devices. Including technical Service and customer education

Medtronic Trading NL B.V.  
Larixplein 4  
5616 VB Eindhoven

Sales, order management and distribution of medical devices. Including technical service and customer education

Medtronic GmbH  
Earl-Bakken-Platz 1  
40670 Meerbusch  
Germany

Distribution of medical Devices, medical equipment and related services.



# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Österreich GmbH  
Millennium Tower, 20th floor  
Handelskai 94-96  
1200 Wien  
Austria

Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education

Medtronic (Schweiz) AG  
Talstrasse 9  
3053 Munchenbuchsee  
Switzerland

Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education

Medtronic Hellas S.A.  
Avenue Kifisias 24 Building B  
151 25 Marousi Pref. Attica  
Greece

Sales, order management and distribution of medical devices. Including technical service and customer education.

Medtronic Serbia Ltd.  
Bulevar Zorana Djindjica, 64a  
11070 Belgrade  
Serbia

Sales, order management and distribution of medical devices.

Medtronic Hungária Kft.  
Bocskai út 134-146  
Céplét 3. emelet  
1113 Budapest  
Hungary

Sales, order management and distribution of medical devices. Including customer education.

Medtronic CCO SSC Warsaw  
Polna 11  
00-633 Warszawa  
Poland

Order management of medical devices.



# ADDENDUM

To certificate: 2090418

The management system of the organization(s) and/or location(s) of:

## Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10  
6422 PJ Heerlen

Medtronic Finland Oy  
Lentäjätie 3  
01530 Vantaa  
Finland

Sales, order management and distribution of medical devices.  
Including technical service and customer education.

Medtronic AB  
P.O. Box 1034  
164 21 Kista  
Sweden

Sales, order management and distribution of medical devices.  
Including technical service and customer education

Medtronic Trading Ltd.  
10 Hamada Street  
4673344 Herzlya  
Israel

Import, sales, order management and distribution of medical  
devices. Including technical service and customer education

Addendum expiry date: 1 July 2021  
Addendum effective date: 1 July 2018





Product Service

# EC Certificate

## Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

No. G1 16 02 77608 012

**Manufacturer:****Covidien Inc**

15 Hampshire Street  
Mansfield, MA 02048  
USA

**EC-Representative:****Covidien Ireland Limited**

IDA Business and Technology Park  
Tullamore  
IRELAND

**Product  
Category(ies):**

Medical Instruments, Surgical Products  
and Hemostatic Materials:

- Surgical Suture Products, Pledgets and Retention Tapes
- Endoscopy Instruments and Accessories  
including Lubricant
- Surgical Staple, Clip Products and Accessories
- Manual Surgical Instruments
- Implantable Wound Dressing Materials
- Ultrasonic Surgical Devices and Accessories
- Suction / Irrigation Devices and Accessories
- Arthroscopy Implants, Instruments and Accessories
- Bone Wax
- Temporary Cardiac Pacing Lead

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:**

713078138

**Valid from:**

2016-04-17

**Valid until:**

2021-04-16

**Date,** 2016-04-05

Stefan Preiß



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

**EC Certificate****Full Quality Assurance System**

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 16 02 77608 012****Facility(ies):**

Covidien (U.S.S.C. Puerto Rico, Inc.)  
Building 911-67, Sabanetas Industrial Park, Ponce PR 00731,  
USA

Covidien (Davis & Geck Caribe, Ltd.)  
Zona Franca de San Isidro, Carretera San Isidro Km 17, Santo  
Domingo, DOMINICAN REPUBLIC

Covidien  
Boulevard Insurgentes, 19030 Libramiento, 22225 Tijuana, B.C.,  
MEXICO

Covidien Deutschland Manufacturing GmbH  
Gewerbepark 1, 93333 Neustadt/ Donau, GERMANY

Covidien  
60 Middletown Avenue, North Haven CT 06473, USA

Covidien Medical Products (Shanghai) Manufacturing L.L.C.  
Building#10,789 Puxing Road, 201114 Shanghai, PEOPLE'S  
REPUBLIC OF CHINA