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ORDIN DE PLATA NR.: 2334                                TIP.DOC. 1 :
                                DATA EMITERII:luni, 2 octombrie :
=====:
PLATITI: 1100-00                                LEI: Una Mie Una Suta 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 SCM Gh                                CONTUL DE PLATI/CODUL IBAN :
eorghe Paladi                                MD24ML0000000022518094481 :
                                CODUL FISCAL :1003600152673 / :
:
:
=====:
PRESTATORUL BENEFICIAR                                CODUL BANCII:
BC"Moldindconbank"S.A.                                :MOLDMD2X :
=====:
DESTINATIA PLATII:Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la procedura de achizitie public: NORMAL/URGENT :N:
a nr. ocds-b3wdp1-MD-1694075993240 din 0: :
2.10.2023 : :
: :
: :
: L.S. :
=====:
                                _____:
                                CODUL TRANZACTIEI:001: _____:
                                DATA PRIMIRII:02/10/2023 : SEMNATURILE :
                                DATA EXECUTARII: : EMITENTULUI :
:-----:
CONducATOR:Web Poiata Vitalie :
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:
: (semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGZwYJKoZIhvcNAQcCoIIGWDCcBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIb3:
DQEHAaCCBHAWggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
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:
: L.S. (semnatura electronica) :
CONducATOR: _____:
: (semnatura manuala) :
CONTABIL-SEF: _____:
: (semnatura manuala) :
SEMnATURA PRESTATORUL L.S. :
:-----:
MOTIVUL REFUZULUI : L.S. :
-----:

```



# BC "MOLDINDCONBANK" S.A. Filiala "Invest"

Republica Moldova, MD-2068  
mun. Chişinău, bd. Moscovei, 14/1  
Tel. : (373-22) 43-44-81, 43-46-24  
Fax : (373-22) 43-44-22  
cod: MOLDDMD2X329

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

Республика Молдова, MD-2068  
мун. Кишинэу, бул. Московей, 14/1  
Тел. : (373-22) 43-44-81, 43-46-24  
Факс : (373-22) 43-44-22  
код: MOLDDMD2X329

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 MOLDDMD2X329.

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





## AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

### EXTRAS

din Registrul de stat al persoanelor juridice

Nr. 531522 data 15.09.2023

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 (IDNO): **1010600028048**

Data înregistrării de stat: **12.08.2010**

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

Obiectul principal de activitate:

- 1. Activitatea farmaceutică; importul și (sau) producerea articolelor de parfumerie și cosmetică**
- 2. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 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,**

Asociații:

1. **POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%**

Beneficiar efectiv:

1.1. **POIATA VITALIE, IDNP 0983103892591,**

2. **NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

2.1. **NASEDCHIN ALEXANDR, IDNP 2002001070747,**

3. **KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

3.1. **KOJEVNIKOV DMITRII, IDNP 0972305012362**

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: **15.09.2023.**

**Registrator în domeniul  
înregistrării de stat**

Digitally signed by Rusu Diana  
Date: 2023.09.15 16:44:17 EEST  
Reason: MoldSign Signature  
Location: Moldova



**Rusu Diana**



**EB 0461494**

## **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>Alexandr Nasedchin</b>	<b>2002001070747</b>
<b>3.</b>	<b>Dmitrii Kojevnikov</b>	<b>0972305012362</b>

## 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)

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

**CE 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



**Liga<sup>2</sup>**<sup>®</sup>  
**Titanium Ligating Clips**



**TITANIUM**

**Reliable Ligation**



## Ligating Clips

### *LigaV*<sup>®</sup>

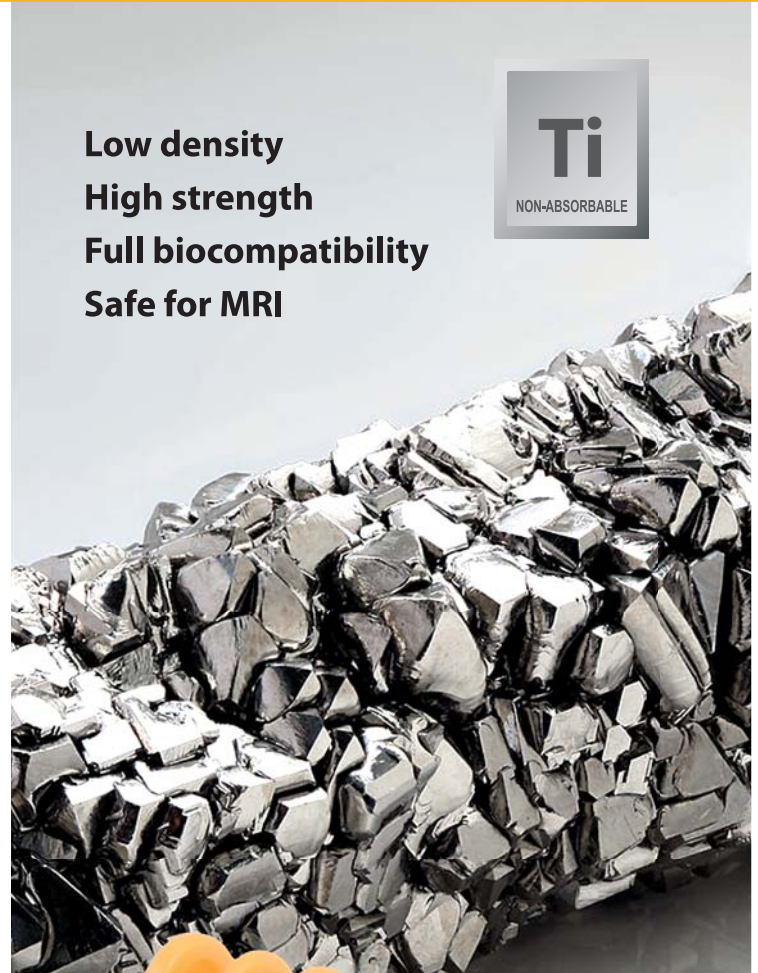
LigaV<sup>®</sup> Ligating clips are implantable medical devices. They are widely used in surgery for marking and ligating purposes. Medical practitioners value the product for its hemostatic features.

LigaV<sup>®</sup> manufactured by Grena Ltd., comes with inner and outer serration which enhances its function. The outer serration helps to grip the clip in the applicator's jaws; the inner serration enables its proper nourishment.

The product is offered in 4 standard sizes ensuring every user will be able to find appropriate clip for the given tissue. The LigaV<sup>®</sup> clips are delivered in colour coded cartridges to ensure easy and intuitive identification. A cartridge includes 4 or 6 clips that ensure economical and comfortable use. The product is disposable, sterilised with EO.

Clip applicators with proper sized jaws depending on the clip should be used. Clip applicators are made of highest quality surgical grade steel. Handle rings are color coded matching cartridge hue.

**Low density**  
**High strength**  
**Full biocompatibility**  
**Safe for MRI**



## Ligating Clips

### *Liga<sup>2</sup>*®

The LigaV® ligating clips are manufactured of a medical grade titanium which ensures proper level of biocompatibility. The applied technology guarantees the product meets the requirements of even the most demanding clinical institutes.



# TITANIUM

# Ligating Clips

## Ligating Clips

**Cost-effective alternative  
for simple procedures**








4 clips per cartridge

### Key features

- 4 sizes to ligate tissue structures,
- made of apyrogenic titanium,
- easy loading system,
- clips delivered in color-coded cartridges for easy identification,
- 4 or 6 clips per cartridge to ensure economical and comfortable use of the product,
- V-shaped,
- color-coded applicator rings for easy identification



REF	Clip size	Compatible with applicators (jaws grip) (mm)	Product specification	Colour	Pcs per cartridge	Pcs cartridges per box
0301-01S	Small	0,59-0,75	V-shaped titanium ligating clips		6	50
0301-01M	Medium	0,84-1,00			6	50
0301-01ML	Medium-Large	1,16-1,32			6	20
0301-01ML04	Medium-Large	1,16-1,32			4	20
0301-01L	Large	1,26-1,42			6	20

## Open Surgery Clip Appliers

- S
- M
- ML
- L



Open Surgery Clip Appliers

**Ergonomic and effective approach  
in endoscopic procedures**

# Open Surgery Clip Appliers

## Open Surgery Clip Appliers

### Key features

- available for Small, Medium, Medium-Large and Large non-absorbable LigaV® clips to be used on large spectrum of tissue sizes,
- 15cm, 20cm and 28cm clip,
- non-detachable design for easier maintenance and durability, appliers with proper sized jaws made of high quality stainless steel,
- colour-coded rings matching cartridge hue,
- compatible with corresponding sizes of LigaV® titanium non-absorbable clips.



REF	Clip size	Applier length	Pcs per box
0301-02S15*	Small	15	1
0301-02S20	Small	20	1
0301-02S28*	Small	28	1
0301-02M15*	Medium	15	1
0301-02M20	Medium	20	1
0301-02M28*	Medium	28	1
0301-02ML20	Medium-Large	20	1
0301-02ML28	Medium-Large	28	1
0301-02L20	Large	20	1
0301-02L28	Large	28	1



\* Manufactured on request.

# Endoscopic Clip Appliers

## Endoscopic Clip Appliers

### Key features

- available for Medium, Medium-Large and Large non-absorbable LigaV<sup>®</sup> clips to be used on large spectrum of tissue sizes,
- jaws activated by front handle for better stability,
- 360° shaft rotation by index finger allows one-hand operation,
- flushing port facilitates easy cleaning, thus eliminating potential contamination,
- made of high quality stainless steel,
- colour coded size matching cartridge hue,
- compatible with corresponding sizes of LigaV<sup>®</sup> titanium non-absorbable clips.

REF 0301-02ME	
Size	M
Colour	○
Shaft diameter (mm)	5
Trocar diameter (mm)	5
Working length (cm)	33
Loading	front - loaded
Box quantity (pcs)	1






REF 0301-02MLE	
Size	ML
Colour	●
Shaft diameter (mm)	10
Trocar diameter (mm)	10
Working length (cm)	33
Loading	front - loaded
Box quantity (pcs)	1



REF 0301-02LE	
Size	L
Colour	●
Shaft diameter (mm)	10
Trocar diameter (mm)	10
Working length (cm)	33
Loading	front - loaded
Box quantity (pcs)	1



## Endoscopic Clip Appliers

-  M
-  ML
-  L



Endoscopic Clip Appliers

**Ergonomic and effective approach  
in endoscopic procedures**



## Endoscopic Clip Appliers



Bariatric Endoscopic Clip Appliers - 45 cm

**Extra length for bariatric surgery**



# Endoscopic Clip Appliers

## Bariatric Endoscopic Clip Appliers

### Key features

- 45 cm long shaft,
- available for Medium, Medium-Large and Large non-absorbable LigaV<sup>®</sup> clips to be used on large spectrum of tissue sizes,
- jaws activated by front handle for better stability,
- 360° shaft rotation by index finger allows one-hand operation,
- flushing port facilitates easy cleaning, thus eliminating potential contamination,
- made of high quality stainless steel,
- colour coded size matching cartridge hue,
- compatible with corresponding sizes of LigaV<sup>®</sup> titanium non-absorbable clips.

#### REF 0301-02MEB

<b>Size</b>	M
<b>Colour</b>	○
<b>Shaft diameter (mm)</b>	5
<b>Trocar diameter (mm)</b>	5
<b>Working length (cm)</b>	45
<b>Box quantity (pcs)</b>	1



#### REF 0301-02MLEB

<b>Size</b>	ML
<b>Colour</b>	●
<b>Shaft diameter (mm)</b>	10
<b>Trocar diameter (mm)</b>	10
<b>Working length (cm)</b>	45
<b>Box quantity (pcs)</b>	1



#### REF 0301-02LEB

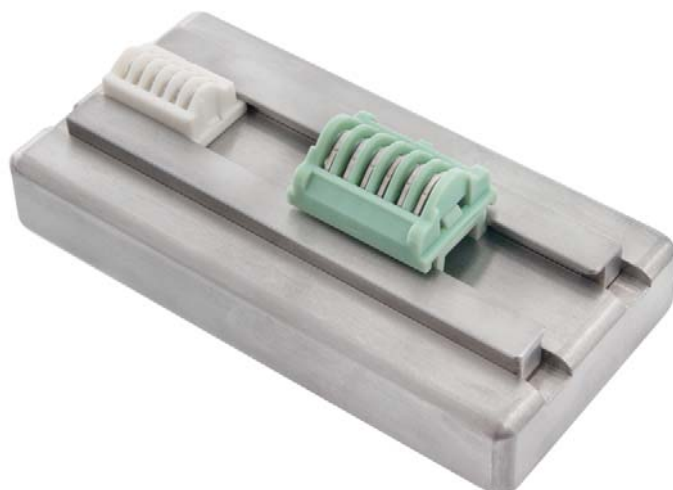
<b>Size</b>	L
<b>Colour</b>	●
<b>Shaft diameter (mm)</b>	10
<b>Trocar diameter (mm)</b>	10
<b>Working length (cm)</b>	45
<b>Box quantity (pcs)</b>	1



## Accessories

# Accessories

REF	Product	Clip size	Pcs per box
0301-05CB	Cartridge base	S, M, ML, L	1



## New International Initiative

**GRENA<sup>®</sup> DG**  
*Think Medical*

**Grena forges Talents!**



**Who's next?**

**Visit us**

**<http://talents.grena.co.uk>**

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 be 'N. Manzoni', written over a horizontal line.

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.

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

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

Declara 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/Citrate 3Na (anticoagulant)                                 |
| • 9NC/CITRATO 3Na (anticoagulante)                                       | • 9NC/Citrate 3Na (anticoagulant)                                 |
| • LH/Heparina LI (anticoagulante)  | • LH/LI Heparin (anticoagulant)                                   |
| • LH/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 (Embudo para muestras de sangre) | • CAP-GALET (Funnels for Blood Sampling) |
|--|--|

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

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

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

file:TF-1004\_F\_10-2014



## DECLARACIÓN DE CONFORMIDAD CE CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

DELTALAB S.L.  
Plaza de la Verneda, 1  
Pol. Ind. La Llana  
081191 RUBÍ (BARCELONA) - SPAIN

Declara 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 suero con los Anexos V y VII de la Directiva 93/42/CEE  
emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEPS), 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 (AEPS), 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: 0300. F. +34 93

  
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 IWV PEEL/1 WOOD+COTTON
300201	ESCOBILLON PS+ALGODON PEEL/1	SWAB IWV PEEL/1 PS+COTTON
300202	ESCOBILLON PS+VISCOSA PEEL/1	SWAB IWV PEEL/1 PS+VISCOSSE
300203	ESCOBILLON ALU+ALGODON PEEL	SWAB IWV 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+VISCOSSE
300253	ESCOBILLON ALU.+VISCOSA TUBO	SWAB IN TUBE ALUM+VISCOSSE
300254	ESC.ALUM.TRENZADO+VISCOSA TUBO	SWAB TWISTED ALUM+VISCOSSE TUBE
300259	ESCOBILLON MAD.+VISCOSA TUBO	SWAB IN TUBE WOOD+VISCOSSE
300261	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PP+COTTON
300263	ESCOBILLÓN 13X165MM PS C/POLIÉSTER	SWAB 13X165MM PS W/POLYESTER
300280	CARY BLAIR MADERA+ALGODON	CARY BLAIR SWAB WOOD+COTTON
300281	AMIES ALUMINIO+VISCOSA	AMIES SWAB ALUMINIUM+VISCOSSE
300284	AMIES LIQUIDO PS+VISCOSA	AMIES SWAB LIQUID PS+VISCOSSE
300285	AMIES CARBON PS+VISCOSA	AMIES+CHARCOAL SWAB PS+VISCOSSE
300287	AMIES PS+VISCOSA	AMIES SWAB PS+VISCOSSE
300290	STUART MADERA+ALGODÓN	STUART SWAB WOOD+COTTON
300291	STUART ALUMINIO+ALGODÓN	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/VISCOSSE
300296	H. VIRUS ALUM. ALGODÓN	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+VISCOSSE SWAB FLOW

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REF	DESCRIPCIÓN	DESCRIPTION
300211.1	ESCOBILLÓN PS+ALG. PACK PEEL/2	SWAB B/2 PS+COTTON PEEL/2
300212.1	ESCOBILLON PS+VISCOSA PEEL/2	SWAB PEEL/2 PS+VISCOSSE
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+VISCOSSE
300281/1	ESC. AMIES+CARBON ALUM.VISCOSA	AMIES CHARCOAL SWAB WIRE+VISCOSSE
300281T	AMIES ALUMINIO TRENZADO+ VISCOS	AMIES SWAB TWIST.WIRE+VISCOSSE
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 VISCOSSE CASES 6X100
300287.A	ESCOB.AMIES PS+VISCOSA	AMIES SWAB PS+VISCOSSE
300295C	STUART CARBÓN PS + VISCOSA	STUART+CHARCOAL SWAB PS+VISCOSSE
310253.1	ESCOB. ALUM+VISCOSA FLOW	ALUM+VISCOSSE 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	ESCOBILLÓN PS+ALG. PACK PEEL/10	SWAB PS+COTTON PEEL/10
300281AV	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 Lliana  
 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/ECC** 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 Epigraph 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


  
**DELTALAB S.L.**  
 Plaza de la Verneda 1, Pol. Ind. La Lliana  
 08191 Rubí - Barcelona  
 T. +34 936 995 000

**Anna Mir** 994 512  
 Responsable Técnico / Technical Director

Fecha / Date: 20/05/2016  
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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 ESTANDAR 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 ESTANDAR 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 ESTANDAR 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 ESTANDAR 80MM	CARY BLAIR 2ML FLOCKED SWAB STANDARD 80MM
304281	AMIES 1ML ESC.FLOCK ESTANDAR 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 ESTANDAR 80MM	AMIES 2ML FLOCKED SWAB STANDARD 80MM
304291	VIRUS 1ML ESC.FLOCK ESTANDAR 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 ESTANDAR 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

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

**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:

**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

**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

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 12 ML TUBE CAPPED
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/PREC. 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. WHITE CAP
444603306	ANTI-CHILD. VERDE TAPON BLANCO	CHILD PROOF GREEN CONT. WHITE CAP
444603308	ANTI-CHILD. ROJO TAPON BLANCO	CHILD PROOF RED CONT. WHITE 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 TAPON VERDE	30ML CONTAINER PS GREEN CAP
309202.WO	FRASCO 30ML PS SIN TAPON	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 TAPON	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/IANO	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
409502.G.4	FR.60 GRAD.S/ROSCAR TAP.SEPARA	CONT.60 GRAD.UNCAPPED SEP.CAP
409507.G	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
409552.G	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.WHITE 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
420900.E	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

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

**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

**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

**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 – 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 Saez  
Director General / Managing Director

Anna Mir  
Responsable Técnico / Technical Director

Fecha / Date: 22/11/2013  
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**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 Llana  
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 Saez  
Director General / Managing Director

Anna Mir  
Responsable Técnico / Technical Director

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

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**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



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



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 077790 0060 Rev. 00**

**Manufacturer:**

**Covidien LLC**

15 Hampshire Street  
Mansfield MA 02048  
USA

**Product Category(ies): Oximetry and Capnography Monitor Systems  
Temperature Monitor Systems, Patient Warming  
Device Systems, Disposable Airway Management  
Devices, Tracheal Tubes, Tracheostomy Tubes,  
Speaking Valves, and Intubating Stylets, Ventilator  
Systems and Patient Interface Circuit Systems,  
EEG Monitoring Systems, Breathing Therapy and  
Humidification, Heated Inspiratory Line  
Humidifiers, Multi-patient Physiologic Monitoring  
System and Data Analytics Software,  
Gastrointestinal Measurement and Dilation System,  
Electrosurgical Diathermy System Electrode.**

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.:** 72145607

**Valid from:** 2020-06-29

**Valid until:** 2024-05-26

**Date,** 2020-06-29

Christoph Dicks  
Head of Certification/Notified Body



**AB UYGUNLUK BEYANI**  
**EC DECLARATION OF CONFORMITY**



**ÜRETİCİ FİRMA ADI:** Turkuaz Sağlık Hizmetleri Medikal Temizlik  
**COMPANY NAME:** Kimyasal Ürünler Sanayi ve Ticaret A.Ş.  
**ADRES:** Yakuplu Mahallesi, Birlik Caddesi, No: 32/1,  
**ADDRESS:** 34524, Beylikdüzü / İstanbul / Türkiye  
**TELEFON:** +902124286848  
**TELEPHONE:**  
**FAKS:** +902124286853  
**FAX:**  
**E-MAIL:** info@turkuazsaglik.com.tr

**Avrupa Yetkili Temsilcisi** Obelis s.a Tel: +(32) 2.732.59.54  
**European Authorized** Bd. Général Wahis 53 Fax: +(32) 2.732.60.03  
**Representative** 1030 Brussels, BELGIUM E-Mail :  
mail@obelis.net

**ÜRÜN ADI:** Ultrasonografi Jeli  
**PRODUCTS:** Non-Sterile Ultrasound Gel  
**MARKA:** Konix  
**TRADE MARK:**

20 ml	T01.01.01.0134
60 ml	T01.02.0039
250 ml	T06.02.0007
500 ml	T06.02.0111
1000 ml	T06.02.0008
5000 ml	T06.02.0009
5000 ml (Gallon)	T06.02.0145

**Modeller ve Referans No.:** 15321  
**MODEL(S) and Ref No.:**

**GMDN KODU:** 15321  
**GMDN CODE:**

**SINIFLANDIRMA:** Annex IX of The MDD 93/42 EEC Class I, Rule 1  
**CLASSIFICATION:**

**UYGUNLUK DEĞERLENDİRME YOLU:** MDD 93/42/EEC ANNEX 7  
**CONFORMITY ASSESSMENT ROUTE:**

**UYGULANABİLİR STANDARTLAR:** EK I'e bakınız  
**APPLICABLE STANDARDS:** See Appendix I

**VERİLİŞ TARİHİ:** 6.06.18  
**ISSUE DATE:**

**YUKARIDA ADI GEÇEN ÜRÜNLERİN 2007/47/EC EKLENTİSİ DAHİL 93/42/EEC TIBBİ CİHAZLAR YÖNETMELİĞİ GEREKSİNİMLERİNİ KARŞILADIĞINI BEYAN EDERİZ. İLGİLİ DESTEKLEYİCİ TÜM DOKÜMANLAR ÜRETİCİ TESİSİNDE BULUNMAKTADIR.**

WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC INCLUDING 2007/47/EC AMENDMENT FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

**İMZA:**  
**SIGNATURE:**

Nurhan IRMAK  
**GENEL MÜDÜR YARDIMCISI**  
**DEPUTY GENERAL MANAGER**

**TURKUAZ SAĞLIK HİZMETLERİ MEDİKAL**  
**TEMİZLİK KİMYASAL ÜRÜNLER SAN ve TİC. A.Ş.**  
Yakuplu Mah. Birlik Cad. No:32/1 İç Kapı No: 32/1  
Beylikdüzü / İSTANBUL  
Tel: +90 212 428 68 48 Fax: +90 212 428 68 53  
Yenikapı Cad. No: 71 055 40 10  
Tic. Sic. No: 2750836

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