



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. Chişinău, 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>

**SITUAȚIILE FINANCIARE**pentru perioada 01.01.2018 31.12.2018Entitatea BIOSISTEM MLD SRL

(Denumirea completă)

40717392

(Cod CUIHO)

1010600028048

(Cod IDNO)

Sediul: MD MD-2001 MUN.CHIȘINĂU; MUN.CHIȘINĂU SEC.RÎȘCANI 150

(Cod poștal)

Raionul (municipiul, UTA); Localitatea  
Albisoara, 16, 1, of.7

Cod CUATM

strada, nr, bl.

Activitatea principală: Comert cu ridicata al produselor farmaceuticeG4646

Cod CAEM, rev.2

Forma de proprietate: Proprietate privată 15

Cod CFP

Forma organizatorico-juridică: SOCIETATI CU RASPUNDERE LIMITATA 530

Cod CFOJ

Date de contact: Tel. +37322808719 e-mail biosistem.mld@gmail.com

WEB: \_\_\_\_\_

Numele și coordonatele al contabilului-șef: Dl (dna) NASEDCHIN ALEXANDR

Unitatea de măsură: leu

Tel. +37369463619

Anexa 8

**Notă informativă privind veniturile și cheltuielile clasificate după natură**

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vânzări	010	20.497.176	27.523.075
Alte venituri din activitatea operațională	020	500	0
Venituri din alte activități	030	361.872	296.617
<b>Total venituri</b> (rd.010 + rd.020 + rd.030)	040	20.859.548	27.819.692
Variația stocurilor	050		
Costul vânzării mărfurilor vândute	060	11.372.168	15.709.392
Cheltuieli privind stocurile	070	118.975	149.589
Cheltuieli cu personalul privind remunerarea muncii	080	169.200	231.400
Contribuții de asigurări sociale de stat obligatorii și prime de asigurare obligatorie de asistență medicală	090	46.530	60.512
Cheltuieli cu amortizarea și deprecierea activelor imobilizate	100	90.494	120.807
Alte cheltuieli	110	548.183	597.981
Cheltuieli din alte activități	120	558.776	285.840
<b>Total cheltuieli</b> (rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	12.904.326	17.155.521
Profit (pierdere) pînă la impozitare (rd.040 – rd.130)	140	7.955.222	10.664.171
Cheltuieli privind impozitul pe venit	150	959.194	1.291.160
Profit (pierdere) net al perioadei de gestiune (rd.140 – rd.150)	160	6.996.028	9.373.011

## BILANȚUL

la 31.12.2018

Nr. cpt.	ACTIV	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
1.	<b>Active imobilizate</b>			
	Imobilizări necorporale	010	1.787	1.137
	Imobilizări corporale în curs de execuție	020		
	Terenuri	030		
	Mijloace fixe	040	904.703	938.614
	Resurse minerale	050		
	Active biologice imobilizate	060		
	Investiții financiare pe termen lung în părți neafiliate	070		
	Investiții financiare pe termen lung în părți afiliate	080		
	Investiții imobiliare	090		
	Creanțe pe termen lung	100		
	Avansuri acordate pe termen lung	110		
	Alte active imobilizate	120		
	<b>Total active imobilizate</b> (rd.010 + rd.020 + rd.030 + rd.040 + rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	906.490	939.751
2.	<b>Active circulante</b>			
	Materiale	140	457	
	Active biologice circulante	150		
	Obiecte de mică valoare și scurtă durată	160	63.968	51.520
	Producția în curs de execuție și produse	170		
	Mărfuri	180	4.430.031	4.809.995
	Creanțe comerciale	190	3.157.174	5.528.804
	Creanțe ale părților afiliate	200		
	Avansuri acordate curente	210	1.097.547	2.496.545
	Creanțe ale bugetului	220	4.973	26.401
	Creanțe ale personalului	230		
	Alte creanțe curente	240		
	Numerar în casierie și la conturi curente	250	4.742.040	9.066.228
	Alte elemente de numerar	260		
	Investiții financiare curente în părți neafiliate	270		
	Investiții financiare curente în părți afiliate	280		
	Alte active circulante	290	5.373	3.712
	<b>Total active circulante</b> (rd.140 + rd.150 + rd.160 + rd.170 + rd.180 + rd.190 + rd.200 + rd.210 + rd.220 + rd.230 + rd.240 + rd.250 + rd.260 + rd.270 + rd.280 + rd.290)	300	13.501.563	21.983.205
	<b>Total active (rd.130 + rd.300)</b>	310	14.408.053	22.922.956

Nr. cpt.	P A S I V	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
3.	<b>Capital propriu</b>			
	Capital social și suplimentar	320	5.400	5.400
	Rezerve	330		
	Corecții ale rezultatelor anilor precedenți	340	X	
	Profit nerepartizat (pierdere neacoperită) al anilor precedenți	350	12.639.655	8.809.868
	Profit net (pierdere netă) al perioadei de gestiune	360	X	9.373.011
	Profit utilizat al perioadei de gestiune	370	X	
	Alte elemente de capital propriu	380		
	<b>Total capital propriu</b> (rd.320 + rd.330 + rd.340 + rd.350 + rd.360 - rd.370 + rd.380)	390	12.645.055	18.188.279
4.	<b>Datorii pe termen lung</b>			
	Credite bancare pe termen lung	400		
	Împrumuturi pe termen lung	410		
	Datorii pe termen lung privind leasingul financiar	420		
	Alte datorii pe termen lung	430		
	<b>Total datorii pe termen lung (rd.400 + rd.410 + rd.420 + rd.430)</b>	440		
5.	<b>Datorii curente</b>			
	Credite bancare pe termen scurt	450		
	Împrumuturi pe termen scurt	460		
	Datorii comerciale	470	1.595.609	3.883.519
	Datorii față de părțile afiliate	480		
	Avansuri primite curente	490	7.303	135.390
	Datorii față de personal	500	45.149	152.404
	Datorii privind asigurările sociale și medicale	510		
	Datorii față de buget	520	39.698	492.060
	Venituri anticipate curente	530		
	Datorii față de proprietari	540		
	Finanțări și încasări cu destinație specială curente	550		
	Provizioane curente	560		
	Alte datorii curente	570	75.239	71.304
	<b>Total datorii curente</b> (rd.450 + rd.460 + rd.470 + rd.480 + rd.490 + rd.500 + rd.510 + rd.520 + rd.530 + rd.540 + rd.550 + rd.560 + rd.570)	580	1.762.998	4.734.677
	<b>Total pasive (rd.390 + rd.440 + rd.580)</b>	590	14.408.053	22.922.956



**SITUAȚIA DE PROFIT ȘI PIERDERE**de la 01.01.2018 pînă la 31.12.2018

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vânzări	010	20.497.176	27.523.075
Costul vânzărilor	020	11.372.168	15.709.392
Profit brut (pierdere brută) (rd.010 – rd.020)	030	9.125.008	11.813.683
Alte venituri din activitatea operațională	040	500	
Cheltuieli de distribuire	050	202	46.862
Cheltuieli administrative	060	622.704	729.327
Alte cheltuieli din activitatea operațională	070	350.476	384.100
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 – rd.050 – rd.060 – rd.070)	080	8.152.126	10.653.394
Rezultatul din alte activități: profit (pierdere)	090	-196.904	10.777
Profit (pierdere) pînă la impozitare (rd.080 + rd.090)	100	7.955.222	10.664.171
Cheltuieli privind impozitul pe venit	110	959.194	1.291.160
Profit net (pierdere netă) al perioadei de gestiune (rd.100 – rd.110)	120	6.996.028	9.373.011

Anexa 3

**SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU**de la 01.01.2018 pînă la 31.12.2018

Nr. d/o	Indicatori	Cod rd.	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
1	<b>Capital social și suplimentar</b>					
	Capital social	010	5.400			5.400
	Capital suplimentar	020				
	Capital nevărsat	030	0	0	0	0
	Capital neînregistrat	040				
	Capital retras	050	0	0	0	0
	<b>Total capital social și suplimentar</b> (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060	5.400			5.400
2	<b>Rezerve</b>					
	Capital de rezervă	070				
	Rezerve statutare	080				
	Alte rezerve	090				
	<b>Total rezerve</b> (rd.070 + rd.080 + rd.090)	100				
3	<b>Profit nerepartizat (pierdere neacoperită)</b>					
	Corecții ale rezultatelor anilor precedenți	110				
	Profit nerepartizat (pierdere neacoperită) al anilor precedenți	120	12.639.655		3.829.787	8.809.868
	Profit net (pierdere netă) al perioadei de gestiune	130	X	9.373.011		9.373.011
	Profit utilizat al perioadei de gestiune	140	X	0	0	0
	Rezultatul din tranziția la noile reglementări contabile	150				
	<b>Total profit nerepartizat (pierdere neacoperită)</b> (rd.110 + rd.120 + rd.130 + rd.140 + rd.150)	160	12.639.655	9.373.011	3.829.787	18.182.879
4	<b>Alte elemente de capital propriu, din care</b>	170				
	Diferențe din reevaluare	171				
	Subvenții entităților cu proprietate publică	172				
	<b>Total capital propriu</b> (rd.060 + rd.100 + rd.160 + rd.170)	180	12.645.055	9.373.011	3.829.787	18.188.279

**SITUAȚIA FLUXURILOR DE NUMERAR**de la 01.01.2018 pînă la 31.12.2018

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
<b>Fluxuri de numerar din activitatea operațională</b>			
Încasări din vânzări	010	30.547.593	27.523.075
Plăți pentru stocuri și servicii procurate	020	1.242.716	17.115.868
Plăți către angajați și organe de asigurare socială și medicală	030	205.235	291.912
Dobînzi plătite	040		
Plata impozitului pe venit	050	1.213.720	1.291.160
Alte încasări	060		
Alte plăți	070	20.861.222	680.937
<b>Fluxul net de numerar din activitatea operațională</b> (rd.010 – rd.020 – rd.030 – rd.040 – rd.050 + rd.060 – rd.070 )	080	7.024.700	8.143.198
<b>Fluxuri de numerar din activitatea de investiții</b>			
Încasări din vânzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
Alte încasări (plăți)	130		
<b>Fluxul net de numerar din activitatea de investiții</b> (rd.090 – rd.100 + rd.110 + rd.120 ± rd.130)	140		
<b>Fluxuri de numerar din activitatea financiară</b>			
Încasări sub formă de credite și împrumuturi	150		
Plăți aferente rambursării creditelor și împrumuturilor	160		
Dividende plătite	170	3.110.000	3.829.787
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
<b>Fluxul net de numerar din activitatea financiară</b> (rd.150 – rd.160 – rd.170 + rd.180 ± rd.190)	200	-3.110.000	-3.829.787
<b>Fluxul net de numerar total</b> (± rd.080 ± rd.140 ± rd.200)	210	3.914.700	4.313.411
Diferențe de curs valutar favorabile (nefavorabile)	220	79.511	10.777
<b>Sold de numerar la începutul perioadei de gestiune</b>	230	747.829	4.742.040
<b>Sold de numerar la sfârșitul perioadei de gestiune</b> (± rd.210 ± rd.220 + rd.230)	240	4.742.040	9.066.228

**Date generale**

1. Certificat de înregistrare a entității, eliberat de Camera Înregistrării de Stat.

Număr de înregistrare MD0101250 Data înregistrării 12.08.2014 Seria MD Număr 0101250

2. Capital social înregistrat de Camera Înregistrării de Stat:

data 12.08.2010, suma 5.400 lei, inclusiv:

1) cota statului \_\_\_\_\_ lei,

2) cota deținătorilor a cel puțin 20% \_\_\_\_\_ lei,

Modificări ulterioare:

a) \_\_\_\_\_, suma \_\_\_\_\_ lei, inclusiv cota statului \_\_\_\_\_ lei,

b) \_\_\_\_\_, suma \_\_\_\_\_ lei, inclusiv cota statului \_\_\_\_\_ lei,

3. Entitățile, activitatea cărora necesită licență, indică:

Licența în vigoare:

) Număr \_\_\_\_\_, data eliberării \_\_\_\_\_

Termen de valabilitate \_\_\_\_\_

Tipul de activitate \_\_\_\_\_

Organul care a eliberat licența \_\_\_\_\_

4. Numărul mediu scriptic al personalului în perioada de gestiune \_\_\_\_\_ 5 persoane, inclusiv pe categorii:

1) personal administrativ \_\_\_\_\_ 5 persoane,

2) muncitori \_\_\_\_\_ persoane,

5. Numărul personalului la 31.12.2018 \_\_\_\_\_ 5 persoane.

6. Remunerarea personalului entității în perioada de gestiune \_\_\_\_\_ 231.400 lei.

7. Remunerarea membrilor organelor de administrare, de conducere și supraveghere și alte angajamente apărute sau asumate în legătură cu pensiile membrilor actuali sau ale foștilor membri ai acestor organe, pe categorii \_\_\_\_\_ lei.

8. Avansurile și creditele acordate membrilor organelor specificate la pct.7 \_\_\_\_\_ lei, inclusiv rambursate \_\_\_\_\_ lei.

9. Valoarea activelor imobilizate și circulante, înregistrate în calitate de gaj<sup>1</sup>

1) valoarea de gaj \_\_\_\_\_ lei,

2) valoarea contabilă \_\_\_\_\_ lei.

10. Numărul acțiunilor ordinare la finele perioadei de gestiune \_\_\_\_\_ unități.

11. Profit net (pierdere netă) a perioadei de gestiune pentru o acțiune ordinară:

1) profit \_\_\_\_\_ lei,

2) pierdere \_\_\_\_\_ lei.

12. Dividende calculate pentru o acțiune ordinară pentru perioada de gestiune:

1) plătite \_\_\_\_\_ lei,

2) planificate pentru plată \_\_\_\_\_ lei.

13. Valută străină disponibilă, recalculată în monedă națională a Republicii Moldova – total \_\_\_\_\_ 475.290 lei, inclusiv (lei, denumirea și codul valutei):

1) 456949 codul valutei Euro

2) 18341 codul valutei US Dollar

14. Numerar legat – total \_\_\_\_\_ lei.

În rîndurile, în care se înscriu sumele de gaj, în toate coloanele prin fracție se reflectă:

a) la numărător – valoarea de gaj;

b) la numitor – valoarea contabilă

\_\_\_\_\_



**NOTĂ INFORMATIVĂ**  
privind relațiile cu nerezidenții

Tabelul 1

Creanțe, investiții financiare și datorii pe termen lung aferente *fondatorilor* nerezidenți

Indicatori	Cod rd./ cod țară	Sold la începutul perioadei de gestiune	Modificări în perioada de gestiune			Sold la sfârșitul perioadei de gestiune
			Intrări/ majorări	Ieșiri/ diminuări	Diferențe de curs valutar	
1	2	3	4	5	6	7
<b>Creanțe și investiții financiare pe termen lung – total</b>	<b>010</b>					
Creanțe comerciale, <i>inclusiv pe țări:</i>	020					
Avansuri acordate, <i>inclusiv pe țări:</i>	030					
Împrumuturi acordate și creanțe privind leasingul financiar, <i>inclusiv pe țări:</i>	040					
Alte creanțe și investiții financiare, <i>inclusiv pe țări:</i>	050					
<b>Datorii pe termen lung – total</b>	<b>060</b>					
Datorii comerciale, <i>inclusiv pe țări:</i>	070					
Avansuri primite, <i>inclusiv pe țări:</i>	080					
Credite bancare, împrumuturi și datorii privind leasingul financiar, <i>inclusiv pe țări:</i>	090					
Alte datorii, <i>inclusiv pe țări:</i>	100					

Creanțe, investiții financiare și datorii pe termen lung aferente nerezidenților, *cu excepția fondatorilor*

Indicatori	Cod rd./ cod țară	Sold la începutul perioadei de gestiune	Modificări în perioada de gestiune			Sold la sfârșitul perioadei de gestiune
			Intrări/ majorări	Ieșiri/ diminuări	Diferențe de curs valutar	
1	2	3	4	5	6	7
<b>Creanțe și investiții financiare pe termen lung – total</b>	<b>010</b>					
Creanțe comerciale, <i>inclusiv pe țări:</i>	020					
Avansuri acordate, <i>inclusiv pe țări:</i>	030					
Împrumuturi acordate și creanțe privind leasingul financiar, <i>inclusiv pe țări:</i>	040					
Depozite, <i>inclusiv pe țări:</i>	050					
Alte creanțe și investiții financiare, <i>inclusiv pe țări:</i>	060					
<b>Datorii pe termen lung – total</b>	<b>070</b>					
Datorii comerciale, <i>inclusiv pe țări:</i>	080					
Avansuri primite, <i>inclusiv pe țări:</i>	090					
Credite bancare, împrumuturi și datorii privind leasingul financiar, <i>inclusiv pe țări:</i>	100					
Alte datorii, <i>inclusiv pe țări:</i>	110					







## Investiții financiare în străinătate și participarea nerezidenților în capitalul social

Indicatori	Cod rd./ cod țară	Sold la începutul perioadei de gestiune	Intrări/ majorări	Ieșiri/ diminuări	Sold la sfârșitul perioadei de gestiune
1	2	3	4	5	6
<b>Investiții financiare</b>	010				
Cote de participație și acțiuni de pînă la 10% inclusiv, în capitalul social al entităților nerezidente, <i>inclusiv pe țări:</i>	020				
Cote de participație și acțiuni de peste 10% în capitalul social al entităților nerezidente, <i>inclusiv pe țări:</i>	030				
<b>Capital social</b>	040				
Cote de participație și acțiuni de pînă la 10% inclusiv, <i>inclusiv pe țări:</i>	050				
Cote de participație și acțiuni de peste 10%, <i>inclusiv pe țări:</i>	060				

## Bunuri ale nerezidenților înregistrate în conturi extrabilanțiere

Indicatori	Cod rd./ cod țară	Sold la începutul perioadei de gestiune	Intrări/ diminuări	Ieșiri/ micșorări	Sold la sfârșitul perioadei de gestiune
1	2	3	4	5	6
<b>Bunuri primite în baza contractelor de comision, <i>inclusiv pe țări</i></b>	010				
Bunuri primite spre prelucrare, <i>inclusiv pe țări</i>	020				
Bunuri obținute din materialele prelucrate, <i>inclusiv pe țări</i>	030				

## Venituri și cheltuieli aferente tranzacțiilor cu nerezidenții

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
<b>Venituri – total</b>	010		
Venituri aferente bunurilor procurate și vândute peste hotare fără trecerea frontierei de stat a Republicii Moldova, <i>inclusiv pe țări:</i>	020		
Venituri din dobânzi aferente activității operaționale și altor activități, <i>inclusiv pe țări:</i>	030		
Venituri din dividende și participații în alte entități, <i>inclusiv pe țări:</i>	040		
Venituri din decontarea datoriilor cu termenul de prescripție expirat, <i>inclusiv pe țări:</i>	050		
Alte venituri, <i>inclusiv pe țări:</i>	060		
<b>Cheltuieli – total</b>	070		
Cheltuieli aferente bunurilor procurate și vândute peste hotare fără trecerea frontierei de stat a Republicii Moldova, <i>inclusiv pe țări:</i>	080		
Cheltuieli privind dobânzile, <i>inclusiv pe țări:</i>	090		
Cheltuieli și provizioane aferente creanțelor comerciale și altor creanțe compromise, <i>inclusiv pe țări:</i>	100		
Alte cheltuieli, <i>inclusiv pe țări:</i>	110		

**Persoanele responsabile de semnarea rapoartelor financiare ale entității\***

\* conform art.36 din Legea contabilității

**CERTIFICAT**  
**privind lipsa sau existența restanțelor față de bugetul public național**

Nr.  
№ **A1910795**

din  
от **12.03.2019**

**1. Destinatar /** Получатель

Pentru participarea la proceduri de achizitii publice

**2. Date despre contribuabil /** Информация о налогоплательщике

Denumirea Наименование	Codul fiscal / Numărul de identificare Фискальный код / Идентификационный номер
<b>BIOSISTEM MLD S.R.L.</b>	<b>1010600028048</b>
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	Codul - Denumirea localității Код - Наименование населенного пункта
<b>Albisoara nr.16 bl.1 of.7</b>	<b>0150-SEC.RISCANI</b>

**3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat /**  
Подтверждение отсутствия или наличия недоимки согласно данных Автоматизированной Информационной Системы

La data emiterii prezentului certificat restanța la bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет:  
**0,00 lei/лей.**

**4. Valabil pînă la /** Действителен до 27.03.2019

**5. Autentificarea organului fiscal /** Подтверждение налогового органа

*Șef. Serv. Riscani*  
Funcția/Dолжность



*Ana Leicon*  
Numele și prenumele/Фамилия и имя

L.S./ М.П.

Executor:

*Ștefan C.*  
Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 12.03.2019 ora 10:26:54  
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (1,33)



## EC DECLARATION OF CONFORMITY

### WORKSTATIONS

Apacor Ltd declares that the devices listed below conform to the relevant provisions of the EC Council Directive In Vitro Diagnostic Devices Directive 98/79/EC dated 27 October 1998, the Low-Voltage Directive 2006/95/CE, also comply with the requirements of EMC Directive 2004/108/CE, tested to standards EN 61326-2-4:2006; EN 61000-4-2:2009; EN 61000-4-3:2006 CISPR 22:2008 Class B. This compliance has been properly documented using checklist created from Annex III excluding point 6 of the Directive, linked to all supporting Technical Documentation.

PARASYS (170000)

Category: Other/General Device

CE Classification # 28011001

Apacor Ltd has a Quality System in place, which complies with ISO 9001 - 2008 regulations and agrees to develop, implement and maintain the Quality Management System to ensure continued adequacy and efficacy.  
Certificate Number GB96/8685.

This Declaration of Conformity is signed below, certifying these requirements have been met.

Janet MacKenzie

**General Manager –Apacor Limited**

3<sup>rd</sup> September 2014



Certificate GB96/8685

The management system of

# Apacor Ltd

Unit 5, The Sapphire Centre, Fishponds Road,  
Wokingham, Berkshire, RG41 2QL, UK

has been assessed and certified as meeting the requirements of



## ISO 9001:2008

For the following activities

**Design and manufacture of filtration devices for the scientific,  
diagnostic, medical and industrial markets.**

Further clarifications regarding the scope of this certificate and the applicability of  
ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 26 January 2015 until 26 January 2018  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 09 October 2017

Issue 12. Certified since 06 December 1996

Authorised by

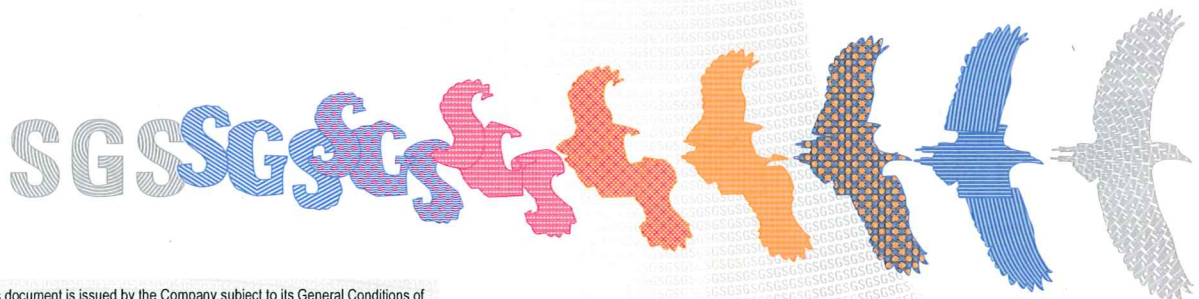


0005

SGS United Kingdom Ltd Systems & Services Certification  
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 9001-8 01 0614

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content or appearance of this document is unlawful and offenders may be  
prosecuted to the fullest extent of the law.



Certificate GB15/92533

The management system of

# Apacor Ltd

Unit 5, The Sapphire Centre, Fishponds Road,  
Wokingham, Berkshire, RG41 2QL, UK

has been assessed and certified as meeting the requirements of



## ISO 13485:2003 EN ISO 13485:2012

For the following activities

**Design and manufacture of filtration devices for the medical market.**

This certificate is valid from 26 January 2015 until 26 January 2018  
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 09 October 2017

Issue 1. Certified since 26 January 2015

Authorised by

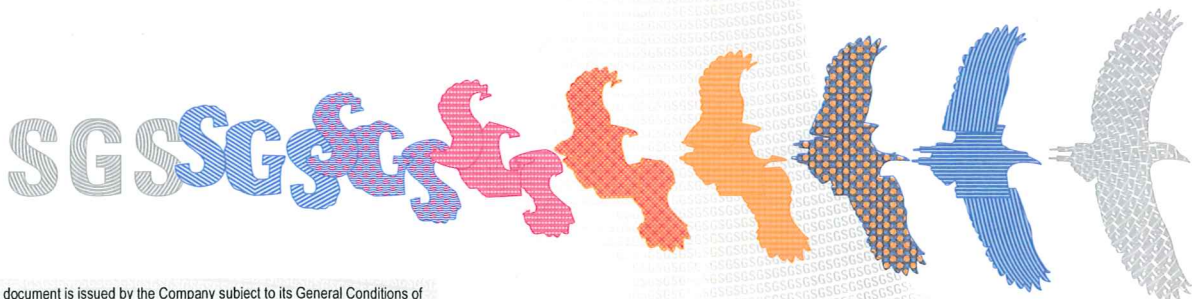
SGS United Kingdom Ltd Systems & Services Certification  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
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SGS 13485-2 0714

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## EC DECLARATION OF CONFORMITY

BioSystems S.A., a company placed in Costa Brava 30, 08030 Barcelona (Spain) dedicated to the design, development and manufacturing of *in vitro* diagnostic medical devices,

### **Hereby DECLARES**

That the products stated in the annex of five (5) pages joined herewith, meet the applicable provisions of the

### **Directive on in Vitro Diagnostic Medical Devices (98/79/EC)**

under the specifications declared by BioSystems S.A.

It means that the products:

- complies with all applicable Essential Requirements as set out in the Annex I, and its technical documentation is performed following the requirements of the Annex III
- is classified as Other Device (all devices except Annex II and Self-Testing Devices), that is why the Conformity Assessment follows the procedure stated in the Annex III of the Directive without the intervention of a Notified Body.

Barcelona, November 6<sup>th</sup>, 2012


Dr. Antonio Elduque  
Managing director  
BioSystems S.A.



• Certified Management System  
• EN ISO 9001  
• EN ISO 13485



## **CLINICAL CHEMISTRY – BIOCHEMISTRY:**

a-Amylase-Direct	Creatine Kinase (CK)
a-Amylase-EPS	Creatine Kinase-MB (CK-MB)
a-Amylase-Pancreatic	Creatinine
Acid Phosphatase (ACP)	Fructosamine
Alanine Aminotransferase (ALT/GPT)	Fructose
Albumin	g-Glutamyltransferase (g-GT)
Alkaline Phosphatase (ALP)-AMP	Glucose
Alkaline Phosphatase (ALP)-DEA	Iron – Chromazurol
AspartateAminotranferase (AST/GOT)	Iron – Ferrozine
Bilirubin (direct)	Iron Binding Capacity
Bilirubin (total and direct)	Lactate Dehydrogenase (LDH)
Bilirubin (total)	Lactate Dehydrogenase (LDH) – IFCC
Calcium – Arsenazo	Lipase
Calcium – MTB	Magnesium
Cholesterol	Phosphorus
Cholesterol HDL	Protein (total)
Cholesterol HDL direct	Protein (urine)
Cholesterol HDL Precipitating reagent	Pyridoxal Phosphate
Cholesterol LDL direct	Triglycerides
Cholesterol LDL Precipitating reagent	Urea/BUN-Color
Cholinesterase (CHE)	Urea/BUN-UV
Citrate	Uric Acid

## **CLINICAL CHEMISTRY – TURBIDIMETRY:**

a1-acid Glycoprotein	C-Reactive Protein (CRP)
Albumin (Microalbuminuria)	C-Reactive Protein-hs (CRP-hs)
Anti-Streptolysin O (ASO)	Ferritin
Antithrombin III	Immunoglobulin A (IgA)
Apolipoprotein A-I (Apo A-I)	Immunoglobulin G (IgG)
Apolipoprotein B (Apo B)	Immunoglobulin M (IgM)
b2-Microglobulin	Prealbumin
Complement Component C3	Rheumatoid Factors (RF)
Complement Component C4	Transferrin

## **CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:**

17-Hydroxycorticosteroids	Hemoglobin A1C
17-Ketosteroids	Hemoglobin A2
5-Aminolevulinic Acid (ALA) / Porphobilinogen (PBG)	Metanephrines
5-Hydroxyindoleacetic acid (5-HIAA)	Vanilmandelic Acid





## **CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:**

a-1-acid Glycoprotein Standard	Biochemistry Calibrator (Human)
Adenosine Deaminase (ADA) Standard	Cholesterol HDL/LDL Calibrator
Albumin (Microalbuminuria) Standard	CRP/CRP-hs Standard
Anti-Streptolysin O (ASO) Standard	Ferritin Standard
Antithrombin III Standard	Hemoglobin A1C-Turbi (HbA1C-Turbi) Standard
Apolipoprotein A-I Standard	Prealbumin Standard
Apolipoprotein B Standard	Protein Calibrators
b2-Microglobulin Standard	Protein (urine) Standard
Bilirubin Standard	Rheumatoid Factors (RF) Standard
Biochemistry Calibrator	

## **CLINICAL CHEMISTRY – INSTRUMENTS:**

A15	BA400
A25	BTS-350

## **CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:**

a-Amylase-Direct	Creatine Kinase (CK)
a-Amylase-Pancreatic	Creatine Kinase-MB (CK-MB)
Adenosine Deaminase (ADA)	Creatinine
Alanine Aminotransferase (ALT/GPT)	g-Glutamyltransferase (g-GT)
Albumin	Glucose
Alkaline Phosphatase (ALP)-AMP	Iron Ferrozine
Alkaline Phosphatase (ALP)-DEA	Lactate dehydrogenase (LDH)
Aspartate Aminotransferase (AST/GOT)	Lipase
Bilirubin (direct)	Magnesium
Bilirubin (total)	Phosphorus
Calcium-Arsenazo	Protein (total)
Cholesterol	Protein (urine)
Cholesterol HDL direct	Triglycerides
Cholesterol LDL direct	Urea/BUN UV
	Uric acid



## **CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:**

Albumin (Microalbuminuria)	Ferritin
Anti-Streptolysin O (ASO)	Hemoglobin A1C-Turbi (HbA1C-Turbi)
Antithrombin III	Immunoglobulin A (IgA)
Complement Component C3	Immunoglobulin G (IgG)
Complement Component C4	Immunoglobulin M (IgM)
C-Reactive Protein (CRP)	Rheumatoid Factors (RF)
C-Reactive Protein-hs (CRP-hs)	Transferrin

## **CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:**

ADA Controls	
Biochemistry Control Serum (Human) I	Hemoglobin A1C Control (Normal)
Biochemistry Control Serum (Human) II	Hemoglobin A2 Control
Biochemistry Control Serum I	Lipid Control Serum I
Biochemistry Control Serum II	Lipid Control Serum II
CK-MB Control Serum	Protein Control Serum I
Control Urine	Protein Control Serum II
Fertility Biochemistry Control	Rheumatoid Control Serum I
Hemoglobin A1C Control (Elevated)	Rheumatoid Control Serum II

## **AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):**

Anti-Adrenal Cortex Antibodies (AACCA)	Anti-Thyroid Antibodies (ATA)
Anti-Endomysium Antibodies (AEA)	Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML)
Anti-Islet Cell Antibodies (AICA)	Autoantibodies MsK/MsS (AA-MsK/MsS)
Anti-Keratin Antibodies (AKA)	Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS)
Anti-Mitochondrial Antibodies (AMA)	Autoantibodies RK/RS (AA-RK/RS)
Anti-nDNA antibodies (nDNA)	Autoantibodies RL/RK/RS (AA-RL/RK/RS)
Anti-Neutrophil Cytoplasmic Antibodies (ANCA)	Autoantibodies RL/RKm/RS (AA-RL/RKm/RS)
Anti-Nuclear Antibodies HEp-2 (ANA HEp-2)	Glomerular Basement Membrane Antibodies (GBMA)
Anti-Nuclear Antibodies RL (ANA-RL)	
Anti-Skin Antibodies (ASA)	
Anti-Smooth Muscle Antibodies (ASMA)	
Anti-Striated Muscle Antibodies (AStMA)	



## ***AUTOIMMUNITY – ELISA:***

ANA Screening  
Anti-Annexin V IgG/IgM (ANX)  
Anti-b2-Glycoprotein 1 IgG/IgM  
(b2GP1)  
Anti-Cardiolipin Antibodies (ACA-  
IgG/IgM)  
Anti-Centromere B Antibodies (CENP-  
B)  
Anti-Citrullinated Protein Antibodies  
(ACPA)  
Anti-Deamidated Gliadin Peptides IgA  
(DGP IgA)  
Anti-Deamidated Gliadin Peptides IgG  
(DGP IgG)  
Anti-dsDNA Antibodies  
Anti-GBM Antibodies - EIA (GBM)  
Anti-Gliadin Antibodies (AGA-IgG/IgA)  
Anti-Histones Antibodies (HIST)  
Anti-Insulin Antibodies (INS)  
Anti-Jo1 Antibodies  
Anti-M2 Antibodies (M2)

Anti-MPO Antibodies  
Anti-Nucleosome Antibodies (NCL)  
Anti-Phospholipid IgG/IgM (APLA)  
Anti-PR3 Antibodies  
Anti-Ribosomal P Antibodies (Rib P)  
Anti-Scl70 Antibodies  
Anti-Sm Antibodies  
Anti-Sm/RNP Antibodies  
Anti-SSA (Ro) Antibodies  
Anti-SSB (La) Antibodies  
Anti-Thyroglobulin Antibodies (Anti-Tg)  
Anti-Thyroid Peroxidase Antibodies  
(Anti-TPO)  
Anti-tTransglutaminase IgA Antibodies  
(Anti- tTG IgA)  
Anti-tTransglutaminase IgG Antibodies  
(Anti- tTG IgG)  
ASCA-IgG/IgA (ASCA)  
ENA 4-Profile  
ENA 6-Screening

## ***AUTOINMUNIDAD – INSTRUMENTOS:***

## ***AUTOIMMUNITY – INSTRUMENTS:***

iPRO



### ***RAPID TESTS – LATEX AGGLUTINATION:***

Anti-Streptolysin O (ASO) - Slide  
C-Reactive Protein (CRP) - Slide

Rheumatoid factors (RF) - Slide

### ***INFECTIOUS IMMUNOLOGY – SYPHILIS:***

RPR-Carbon

TPHA

### ***INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:***

Febrile Serodiagnostics Multiscreening

Febrile Serodiagnostics Salmonella

Brucella abortus

Brucella abortus, Rose Bengal

Proteus Ox19

Salmonella paratyphi AH

Salmonella paratyphi AO

Salmonella paratyphi BH

Salmonella paratyphi BO

Salmonella paratyphi CH

Salmonella paratyphi CO

Salmonella typhi H

Salmonella typhi O

Brucella Positive Control

Proteus Positive Control

Salmonella Positive Control

Serology Negative Control

# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 6696

Certificate Holder: **BIOSYSTEMS S.A.**  
Costa Brava, 30  
08030 Barcelona  
Spain

(including the locations according to annex)

Scope: Design, development, manufacture, distribution, installation and servicing of:  
- Instruments and reagents for clinical diagnostic.  
- Instruments and reagents for agro-alimentary analysis.  
Distribution and servicing of instruments and reagents for veterinary diagnosis.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2017-12-13 until 2019-12-18.  
First certification 1996

2017-12-14



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

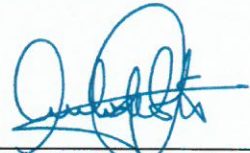
# Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 6696

No.	Location	Scope
/01	<b>BIOSYSTEMS, S.A.</b> Pl. Can Tapioles naus 7-12-13 08110 Montcada i Reixac Spain	Labelling and assembling of reagents. Warehousing and shipment of: -Instruments and Reagents for clinical diagnostic. -Instruments and Reagents for agro-alimentary analysis. -Instruments and Reagents for veterinary diagnosis.

2017-12-14



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

Page 1 of 1

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**BIOSYSTEMS S.A.**  
**Costa Brava 30**  
**08030 Barcelona**  
**Spain**

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

**Design and development, manufacture, distribution and  
servicing of instruments and reagents for  
clinical diagnostic  
(see attachment for sites 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: 2017-11-28  
Certificate Registration No.: SX 60124804 0001  
An audit was performed. Report No.: 28300434 002  
This Certificate is valid until: 2019-12-12

Certification Body



Date 2017-11-28



**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  
Certificate**

**Registration No.:** SX 60124804 0001  
**Report No.:** 28300434 002

**Organization:** BIOSYSTEMS S.A.  
Costa Brava 30  
08030 Barcelona  
Spain

**Scope:**

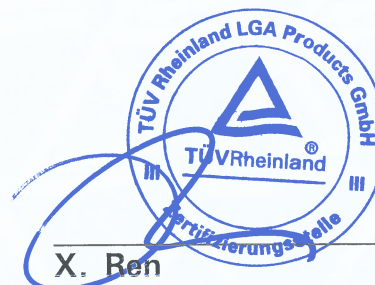
Site included:  
Polígono Industrial "Can Tapioles"  
Naves 7, 12 y 13  
08110 Montcada i Reixac (Barcelona)  
Spain

Scope:  
Labelling and Assembling of reagents and  
Warehousing and Shipment of instruments and  
reagents for clinical diagnostic

**Certification Body**



**Date:** 2017-11-28





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

EMAIL  
mpizarro@aemps.es

[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

Tf: (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 (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: 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.**



  
**DELTALAB S.L.**  
Plaza de la Verneda 1, Pol. Ind. La Lliana  
08191 Rubí - Barcelona  
T. +34 936 995 000
   
**José Saez**      **Anna Mir**  
 Director General / Managing Director      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 TIAMA	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/IAN.	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 Sáez  
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 Sáez  
Director General / Managing Director

Anna Mir  
Responsable Técnico / Technical Director

Fecha / Date: 22/11/2013  
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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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Certificado ES10/81672

The management system of

# DELTALAB, 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.

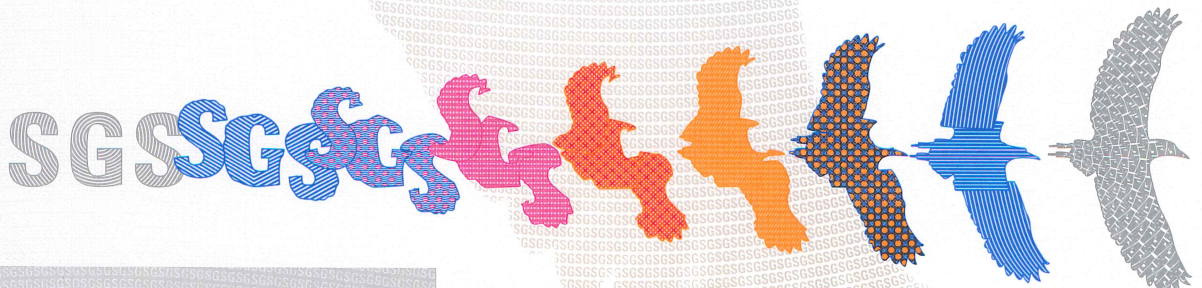
Este certificado es válido desde  
29 de noviembre de 2017 hasta 11 de octubre de 2019.  
Edición 7. Certificado desde octubre de 2010..

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**

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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

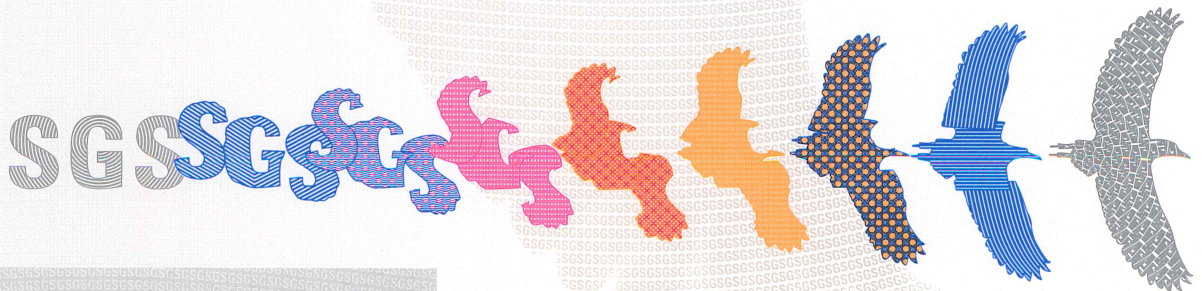
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Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
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SGS 13485 2016 0417

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0005







Management Service

# CERTIFICATE

The Certification Body  
of TÜV SÜD Management Service GmbH

certifies that

## OSRAM

Opto Semiconductors

### OSRAM Opto Semiconductors GmbH

Leibnizstraße 4  
93055 Regensburg  
Germany

has established and applies  
a Quality Management System for

**Design, development and production of  
opto semiconductor wafer,  
opto electronic components and displays.**

An audit was performed, Report No. **707056398**.

Proof has been furnished that the requirements  
according to

### ISO 9001:2008

are fulfilled.

The certificate is valid in conjunction  
with the main certificate from **2016-12-21** until **2018-09-14**.

Certificate Registration No.: **12 100 52177/11 TMS**.

Product Compliance Management  
Munich, 2016-11-25



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Management Service

# CERTIFICATE

The Certification Body  
of TÜV SÜD Management Service GmbH

certifies that

## OSRAM

Opto Semiconductors

**OSRAM Opto Semiconductors (Malaysia) SDN. BHD**

Bayan Lepas Free Industrial Zone Phase 1  
11900 Bayan Lepas, Penang  
Malaysia

has established and applies  
a Quality Management System for

**Design, development and production of  
opto semiconductor wafer,  
opto electronic components and displays.**

An audit was performed, Report No. **707056398**.

Proof has been furnished that the requirements  
according to

**ISO 9001:2008**

are fulfilled.

The certificate is valid in conjunction  
with the main certificate from **2016-12-21** until **2018-09-14**.

Certificate Registration No.: **12 100 52177/12 TMS**.



Product Compliance Management  
Munich, 2016-11-25



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Management Service

# CERTIFICATE

The Certification Body  
of TÜV SÜD Management Service GmbH

certifies that

**OSRAM**

Opto Semiconductors

**OSRAM Opto Semiconductors, Inc.**

Kifer Road 1150

Sunnyvale, California, CA 94086

USA

has established and applies  
a Quality Management System for

**Sales, marketing, customer service and logistics.**

An audit was performed, Report No. **707056398**.

Proof has been furnished that the requirements  
according to

**ISO 9001:2008**

are fulfilled.

The certificate is valid in conjunction  
with the main certificate from **2016-12-21** until **2018-09-14**.

Certificate Registration No.: **12 100 52177/14 TMS**.



Product Compliance Management  
Munich, 2016-11-25



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ZERTIFIKAT



Management Service

# CERTIFICATE

The Certification Body  
of TÜV SÜD Management Service GmbH

certifies that

## OSRAM

Opto Semiconductors

**OSRAM Opto Semiconductors (China) Co. Ltd.**

No. 57, XiQin Rd

Wuxi New District, Jiangsu, P.R. China

Post Code: 214028

Organisation code: 05524191-X

has established and applies  
a Quality Management System for

**Production of  
Opto Semiconductor components and displays.**

An audit was performed, Report No. **707056398**.

Proof has been furnished that the requirements  
according to

### ISO 9001:2008

are fulfilled.

The certificate is valid in conjunction  
with the main certificate from **2016-12-21** until **2018-09-14**.

Certificate Registration No.: **12 100 52177/18 TMS**.

Information about this certificate can be inquired at the official website of Certification and  
Accreditation Administration of the People's Republic of China ([www.cnca.gov.cn](http://www.cnca.gov.cn)).

Product Compliance Management  
Munich, 2016-11-25



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT

# EU Declaration of Conformity

# OSRAM

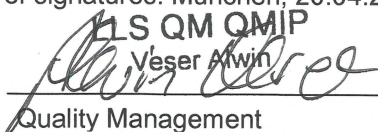
Document number: 2016 / 9C1-3364256-EN-00  
Manufacturer or representative: OSRAM GmbH  
Address: Marcel-Breuer-Str. 6  
80807 München  
Germany  
Brand name or trade mark: OSRAM  
Product type: Lamp controlgear  
Product designation: QUICKTRONIC  
 See attached list

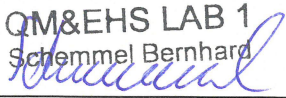
The designated product(s) is (are) in conformity with the relevant Union harmonisation legislation:

- Low Voltage Directive:** 2006/95/EC: Directive of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (until 19.04.2016)  
2014/35/EU: Directive of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits; Official Journal of the EU L96, 29/03/2014, p. 357-374 (from 20.4.2016)
- EMC Directive:** 2004/108/EC: Directive of the European Parliament and of the Council of 15 September 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility (until 19.04.2016)  
2014/30/EU: Directive of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility; Official Journal of the EU L96, 29/03/2014, p. 79-106 (from 20.4.2016)
- 2009/125/EC**  
and amendments  
Directive of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products
- 244/2009**  
and amendments  
Commission Regulation (EC) implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for non-directional household lamps
- 245/2009**  
and amendments  
Commission Regulation (EC) implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for fluorescent lamps without integrated ballast, for high intensity discharge lamps, and for ballasts and luminaires able to operate such lamps, and repealing Directive 2000/55/EC of the European Parliament and of the Council
- 1194/2012**  
and amendments  
Commission Regulation (EU) No 1194/2012 of 12 December 2012 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for directional lamps, light emitting diode lamps and related equipment
- 2011/65/EU**  
and amendments  
Directive of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment; Official Journal of the EU L174, 1/07/2011, p. 88-110
- 1999/5/EC**  
and amendments  
Directive of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity

Last two digits of the year in which the CE marking was affixed: 16

Place and date of signatures: München, 20.04.2016

Signatures:   
Quality Management

  
Quality Assurance

Names: Mr. Alwin Vesper

Mr. Bernhard Schemmel

Customer service contact: OSRAM GmbH, Steinerne Furt 62, 86167 Augsburg, Deutschland

This declaration of conformity is issued under the sole responsibility of the manufacturer or representative. It certifies compliance with the indicated Directives, but implies no warranty of properties.

# EU Declaration of Conformity

## Annex

Document number: 2016 / 9C1-3364256-EN-00

The conformity of the designated product(s) with the provisions of the European **Low Voltage Directive** is given by the compliance with the following European Standard(s) or other specifications. If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

- |                                     |  |  |
|-------------------------------------|--|--|
| <input checked="" type="checkbox"/> | <b>EN 61347-1:</b><br>2008 + A1:2011 + A2:2013 | Lamp controlgear — Part 1: General and safety requirements   |
| <input checked="" type="checkbox"/> | <b>EN 61347-2-3:</b><br>2011 + Corr. 2011      | Lamp controlgear — Part 2-3: Particular requirements for a. c. and/or d. c. supplied electronic ballasts for fluorescent lamps |

The conformity of the designated product(s) with the provisions of the European **EMC Directive** is given by the compliance with the following European Standard(s) or other specifications. If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

- |                                     |                              |  |
|-------------------------------------|------------------------------|--|
| <input checked="" type="checkbox"/> | <b>EN 55015:</b><br>2013     | Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment  |
| <input checked="" type="checkbox"/> | <b>EN 61000-3-2:</b><br>2014 | Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)  |
| <input checked="" type="checkbox"/> | <b>EN 61000-3-3:</b><br>2013 | Electromagnetic compatibility (EMC) — Part 3-3: Limits — Limitation of voltage changes, voltage fluctuations and flicker in public low voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subjected to conditional connection |
| <input checked="" type="checkbox"/> | <b>EN 61547:</b><br>2009     | Equipment for general lighting purposes — EMC immunity requirements  |

The conformity of the designated product(s) with the provisions of the European Directive **2009/125/EC** is given by the compliance with the following European Standard(s). If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

- |                                     |                         |   |
|-------------------------------------|-------------------------|---|
| <input checked="" type="checkbox"/> | <b>EN 62442-1:</b> 2011 | Energy performance of lamp controlgear - Part 1: Controlgear for fluorescent lamps - Method of measurement to determine the total input power of controlgear circuits and the efficiency of the controlgear |
|-------------------------------------|-------------------------|---|

The conformity of the designated product(s) with the provisions of the European Directive **2011/65/EU** is given by the compliance with the following European Standard(s) or other specifications. If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

- |                                     |                        |  |
|-------------------------------------|------------------------|--|
| <input type="checkbox"/>            | <b>EN 50581:</b> 2012  | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances |
| <input checked="" type="checkbox"/> | <b>internal report</b> |  |

# EU Declaration of Conformity

## Attached list

Document number: 2016 / 9C1-3364256-EN-00

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QTi 1x14/24/21/39 GII	QTP-OPTIMAL 1x18-40
QTi 1x28/54/35/49 GII	QTP-OPTIMAL 2x18-40
QTi 2x14/24/21/39 GII	QTP-OPTIMAL 1x54-58
QTi 2x28/54/35/49 GII	QTP-OPTIMAL 2x54-58
QTi 1x/35/49/80 GII	
QTi 2x35/49/80 GII	
QTP5 1x49	QTP-FC 1x55
QTP5 1x80	QTP-M 1x26-42
QTP5 1x14-35	QTP-M 2x26-32
QTP5 2x14-35	QT-M 2x26-42/220-240 S
QTP5 2x49	QT-FQ 2x80
QTP5 3x14, 4x14	
QTP-DL 1x18-24	QTP-T/E 1x26-42, 2x26
QTP-DL 1x36-40	QTP-T/E 1x18, 2x18
QTP-DL 2x18-24	
QTP-DL 2x36-40	QT-FIT 5/8 1x18-39
QTP-DL 1x55 GII	QT-FIT 5/8 2x18-39
QTP-DL 2x55 GII	QT-FIT 5/8 1x54-58
QTP-D/E 1x10-13	QT-FIT 5/8 2x54-58
QTP-D/E 2x10-13	

# Declaration of Conformity

## Attached list

Document number: 2016 / 9C1-3364256-EN-00

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QT-FIT5 1x14-35	QT-FIT8 1x18
QT-FIT5 2x14-35	QT-FIT8 1x36
QT-FIT5 3x14, 4x14	QT-FIT8 1x58-70
QT-FIT5 1x49	QT-FIT8 2x18
QT-FIT5 2x49	QT-FIT8 2x36
	QT-FIT8 3x18, 4x18
QT-ECO 1x4-16/220-240 S	QT-FIT8 3x36
QT-ECO 1x4-16/220-240 L	QT-FIT8 2x58
QT-ECO 1x18-21/220-240 S	QT-FIT8 2x58-70
QT-ECO 2x5-11/220-240 S	
QT-ECO 1x18-24/220-240 S	
QT-ECO 1x18-24/220-240 L	
QT-ECO 1x26/220-240 S	
QT-COMBI 1x36/220-240	QT ENDURA 70-100/120-240 S
QT-COMBI 1x58/220-240	QT ENDURA 100-150/120-240 S
QT-ECO 1x18-24/220-240 LI	
QT-ECO 1x4-16/220-240 LI	



21.08.2016  
İzmir / Turkey

## DECLARATION FOR THE ISSUANCE OF QUALITY CERTIFICATES

To Whom It May Concern,

According to IVD 98/79/EC directive,

FOR ANNEX II LIST A which includes HIV, Hepatitis B and Hepatitis C tests; the Notified Body must verify that the product meets the Common Technical Specification (CTS) and must release each batch of product before it is placed on the European market. The batch release often requires testing. These have EC Design Examination certificates by the notified body.

FOR ANNEX III which includes all other tests for Professional use; the manufacturer prepares a declaration of conformity in a similar way to the general devices.

For the above mentioned reason, we hereby declare that we provide CE Certificate for only the Hepatitis B, Hepatitis C and HIV tests for Professional use. For the group of other Professional tests; it is enough to present a self-Declaration of Conformity to the EU standards.

Cordially,

TURKLAB TIBBİ MALZEMELER SAN TİC A.Ş



## EC CERTIFICATE No. 1434-IVDD-56/2016

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical device, List A:

**HBsAg Test**

**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

manufactured by:

**TURKLAB Tıbbi Mal. San. Tic. A.Ş.**  
**İTOB 10031 Sokak No: 15 Tekeli Menderes**  
**İzmir, Turkey**

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC (with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

**CE 1434**

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

Application No. 45/2016  
Contract No. MD-18/2016

Module H6



**EC CERTIFICATE No. 1434-IVDD-57/2016**

Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies quality assurance system in company:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.  
İTOB 10031 Sokak No: 15 Tekeli Menderes  
Izmir, Turkey**

for the design, manufacture and final inspection of in vitro diagnostic medical devices,  
List A:

**HBsAg Test  
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

complies with the requirements of Annex IV excl. 4, 6 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law. The audit of the quality assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
Anna Wyroba  
Vice President of PCBC

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

**CE 1434**

Application No. 45/2016  
Contract No. MD-18/2016

Module H7



**EC CERTIFICATE No. 1434-IVDD-52/2016**

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical device, List A:

**Anti-HCV Test  
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

manufactured by:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.  
İTOB 10031 Sokak No: 15 Tekeli Menderes  
Izmir, Turkey**

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law and comply with the essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
Anna Wyroba  
Vice President of PCBC

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

**CE 1434**

Application No. 43/2016  
Contract No. MD-16/2016

Module H6



**EC CERTIFICATE No. 1434-IVDD-53/2016**

Full Quality Assurance System

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies quality assurance system in company:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**  
**İTOB 10031 Sokak No: 15 Tekeli Menderes**  
**Izmir, Turkey**

for the design, manufacture and final inspection of in vitro diagnostic medical devices,  
List A:

**Anti-HCV Test**  
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law. The audit of the quality  
assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

**CE 1434**

Application No. 43/2016  
Contract No. MD-16/2016

Module H7



**EC CERTIFICATE No. 1434-IVDD-54/2016**

EC Design-Examination

Directive 98/79/EC on in vitro diagnostic medical devices

PCBC certifies that the design documentation relating to in vitro diagnostic medical  
device, List A:

**Anti-HBs Test**  
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

manufactured by:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**  
**İTOB 10031 Sokak No: 15 Tekeli Menderes**  
**Izmir, Turkey**

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law and comply with the  
essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

**CE 1434**

Application No. 44/2016  
Contract No. MD-17/2016

Module H6



**EC CERTIFICATE No. 1434-IVDD-55/2016**

Full Quality Assurance System

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies quality assurance system in company:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**  
**İTOB 10031 Sokak No:15 Tekeli Menderes**  
**Izmir, Turkey**

for the design, manufacture and final inspection of in vitro diagnostic medical devices,  
List A:

**Anti-HBs Test**  
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law. The audit of the quality  
assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

**CE 1434**

Application No. 44/2016  
Contract No. MD-17/2016

Module H7



**EC CERTIFICATE No. 1434-IVDD-58/2016**

EC Design-Examination

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies that the design documentation relating to in vitro diagnostic medical  
device, List A:

**Anti - HIV 1/2 Test**  
**Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**  
manufactured by:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.**  
**İTOB 10031 Sokak No: 15 Tekeli Menderes**  
**Izmir, Turkey**

was examined by PCBC according to Annex IV p. 4 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law and comply with the  
essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

**CE 1434**

Application No. 46/2016  
Contract No. MD-19/2016

Module H6



**EC CERTIFICATE No. 1434-IVDD-59/2016**

Full Quality Assurance System

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies quality assurance system in company:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.  
İTOB 10031 Sokak No: 15 Tekeli Menderes  
Izmir, Turkey**

for the design, manufacture and final inspection of in vitro diagnostic medical devices,  
List A:

**Anti - HIV 1/2 Test  
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®**

complies with the requirements of Annex IV excl. p. 4, 6 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law. The audit of the quality  
assurance system carried out by PCBC has provided evidence of the above.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

**CE 1434**

Application No. 46/2016  
Contract No. MD-19/2016

Module H7



**EC CERTIFICATE No. 1434-IVDD-51/2016**

EC Design-Examination

**Directive 98/79/EC on in vitro diagnostic medical devices**

PCBC certifies that the design documentation relating to in vitro diagnostic medical  
device for self-testing:

**hCG Pregnancy Test  
Brands: Rapidan Nova®, Rapidan Optima®, Info®, Toyo®, Rapidan  
Tester®, Rapidan Compact®, Labmen®**  
manufactured by:

**TÜRKLAB Tibbi Mal. San. Tic. A.Ş.  
İTOB 10031 Sokak No: 15 Tekeli Menderes  
Izmir, Turkey**

was examined by PCBC according to Annex III p. 6 Directive 98/79/EC  
(with subsequent amendments) transposed into the Polish law and comply with the  
essential requirements of the Directive.

This certificate is valid from **2016-08-29** to **2019-08-28**

Date of certificate issue: **2016-08-29**

Date of first certificate issue: **2008-08-29**



*Anna Wyroba*  
**Anna Wyroba**  
Vice President of PCBC

PCBC Notified Body  
23A, Kłobucka Str., PL-02-699 Warsaw

**CE 1434**

Application No. 42/2016  
Contract No. MD-15/2016

Module A1



# CERTIFICATE

No. J - 2670/2/2018

This is to certify that:

**TÜRKLAB TIBBI MALZ. SAN. VE TIC. A.Ş.**  
**Sasalı Merkez Mh. Doğa Dostları Sitesi 131 Sk. No: 2/5**  
**35621 Çiğli, İzmir, Turkey**  
**Factory: ITOB 10031 Sk. No: 15 Menderes / İzmir - Turkey**

is in conformance with

**EN ISO 9001:2015**

in the following scope of activities:

**design, development, manufacturing, final control  
and distribution of in vitro diagnostic medical devices  
intended for self-testing and professional use,  
ECG electrodes and antibiotic susceptibility discs**

The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from **24.08.2018** to **21.12.2020**



AC 019  
QMS



  
**Anna Wyroba, M.Sc.**  
Vice President



Certificate No. **J-2670/2/2018**  
Issued under the Contract No. 2897/JM/3/2017  
Date of certification decision: 24.08.2018  
Bears the PCBC hologram.  
Warsaw, 24.08.2018



# CERTIFICATE

No. M - 56/2/2018

This is to certify that:

**TÜRKLAB TIBBI MALZ. SAN. VE TIC. A.Ş.**  
**Sasalı Merkez Mh. Doğa Dostları Sitesi 131 Sk. No: 2/5**  
**35621 Çiğli, İzmir, Turkey**  
**Factory: ITOB 10031 Sk. No: 15 Menderes / İzmir - Turkey**

is in conformance with

**EN ISO 13485:2016**

in the following scope of activities:

**design, development, manufacturing, final control  
and distribution of in vitro diagnostic medical devices  
intended for self-testing and professional use,  
ECG electrodes and antibiotic susceptibility discs**

The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from **24.08.2018** to **21.12.2020**



AC 019  
QMS



*Anna Wyroba*  
**Anna Wyroba, M.Sc.**  
Vice President





Certificate No. **M - 56/2/2018**

Issued under the Contract No. 2897/JM/3/2017

Date of certification decision: 24.08.2018

Bears the PCBC hologram.

Warsaw, 24.08.2018