



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

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandru Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2017 31.12.2017

Entitatea BIOSISTEM MLD SRL

(Denumirea completă)

40717392

(Cod CUIIO)

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

Activitatea principală: strada, nr, bl.
Comert cu ridicata al produselor farmaceutice

G4646

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) +37322808719

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	15.623.709	20.497.176
Alte venituri din activitatea operațională	020		500
Venituri din alte activități	030	368.943	361.872
Total venituri (rd.010 + rd.020 + rd.030)	040	15.992.652	20.859.548
Variația stocurilor	050		
Costul vânzărilor	060	9.960.221	11.372.168
Cheltuieli privind stocurile	070	306.856	118.975
Cheltuieli cu personalul privind remunerarea muncii	080	129.850	169.200
Contribuții de asigurări sociale de stat obligatorii și prime de asigurare obligatorie de asistență medicală	090	35.709	46.530
Cheltuieli cu amortizarea și deprecierea activelor imobilizate	100	7.389	90.494
Alte cheltuieli	110	306.855	548.183
Cheltuieli din alte activități	120	289.432	558.776
Total cheltuieli (rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	11.036.312	12.904.326
Profit (pierdere) pînă la impozitare (rd.040 – rd.130)	140	4.956.340	7.955.222
Cheltuieli privind impozitul pe venit	150	595.238	959.194
Profit (pierdere) net al perioadei de gestiune (rd.140 – rd.150)	160	4.361.102	6.996.028

BILANȚUL

Anexa 1

la 31.12.2017

Nr. crt.	ACTIV	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
1.	Active imobilizate			
	Imobilizări necorporale	010	2.437	1.787
	Imobilizări corporale în curs de execuție	020		
	Terenuri	030		
	Mijloace fixe	040	195.525	904.703
	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		
	Total active imobilizate (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	197.962	906.490
2.	Active circulante			
	Material	140	2.329	457
	Active biologice circulante	150		
	Obiecte de mică valoare și scurtă durată	160	49.454	63.968
	Producția în curs de execuție și produse	170		
	Mărfuri	180	3.435.875	4.430.031
	Creanțe comerciale	190	5.303.786	3.157.174
	Creanțe ale părților afiliate	200		
	Avansuri acordate curente	210	793.582	1.097.547
	Creanțe ale bugetului	220	35.037	4.973
	Creanțe ale personalului	230		
	Alte creanțe curente	240		
	Numerar în casierie și la conturi curente	250	747.829	4.742.040
	Alte elemente de numerar	260		
	Investiții financiare curente în părți neafiliate	270		
	Investiții financiare curente în părți afiliate	280		
	Alte active circulante	290	8.004	5.373
	Total active circulante (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	10.375.896	13.501.563
	Total active (rd.130 + rd.300)	310	10.573.858	14.408.053

Nr. crt.	PASIV	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
3.	Capital propriu			
	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		
	Profit net (pierdere netă) al perioadei de gestiune	360	8.952.137	5.643.627
	Profit utilizat al perioadei de gestiune	370	X	6.996.028
	Alte elemente de capital propriu	380		
	Total capital propriu (rd.320 + rd.330 + rd.340 + rd.350 + rd.360 + rd.370 + rd.380)	390	8.957.537	12.645.055
4.	Datorii pe termen lung			
	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		
	Total datorii pe termen lung (rd.400 + rd.410 + rd.420 + rd.430)	440		
5.	Datorii curente			
	Credite bancare pe termen scurt	450		
	Împrumuturi pe termen scurt	460		
	Datorii comerciale	470	1.084.518	1.595.609
	Datorii față de părțile afiliate	480		
	Avansuri primite curente	490	186.214	7.303
	Datorii față de personal	500	7.343	45.149
	Datorii privind asigurările sociale și medicale	510		
	Datorii față de buget	520	318.484	39.698
	Venituri anticipate curente	530		
	Datorii față de proprietari	540		
	Finanțări și încasări cu destinație specială curente	550		
	Provizioane curente	560		
	Alte datorii curente	570	19.762	75.239
	Total datorii curente (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	1.616.321	1.762.998
	Total pasive (rd.390 + rd.440 + rd.580)	590	10.573.858	14.408.053

SITUAȚIA DE PROFIT ȘI PIERDERE

Anexa 2

de la 01.01.2017 pînă la 31.12.2017

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vânzări	010	15.623.709	20.497.176
Costul vânzărilor	020	9.960.221	11.372.168
Profit brut (pierdere brută) (rd.010 - rd.020)	030	5.663.488	9.125.008
Alte venituri din activitatea operațională	040		500
Cheltuieli de distribuție	050	208	202
Cheltuieli administrative	060	513.937	622.704
Alte cheltuieli din activitatea operațională	070	272.514	350.476
Rezultatul din activitatea operațională (profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070))	080	4.876.829	8.152.126
Rezultatul din alte activități: profit (pierdere)	090	79.511	-196.904
Profit (pierdere) pînă la impozitare (rd.080 + rd.090)	100	4.956.340	7.955.222
Cheltuieli privind impozitul pe venit	110	595.238	959.194
Profit net (pierdere netă) al perioadei de gestiune (rd.100 - rd.110)	120	4.361.102	6.996.028

SITUAȚIA MODIFICĂRII CAPITALULUI PROPRIU

Anexa 3

de la 01.01.2017 pînă la 31.12.2017

Nr. /No.	Indicatori	Cod rd.	Sold la			
			începutul perioadei de gestiune	Majorări	Diminuări	sold la sfârșitul perioadei de gestiune
1	2	3	4	5	6	7
1.	Capital social și suplimentar					
	Capital social	010	5.400			5.400
	Capital suplimentar	020				
	Capital nevărsat	030	0	0	0	0
	Capital neregistrat	040				
	Capital retras	050	0	0	0	0
	Total capital social și suplimentar (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060	5.400			5.400
2.	Rezerve					
	Capital de rezervă	070				
	Rezerve statutare	080				
	Alte rezerve	090				
	Total rezerve (rd.070 + rd.080 + rd.090)	100				
3.	Profit nerepartizat (pierdere neacoperită)					
	Corecții ale rezultatelor anilor precedenți	110				
	Profit nerepartizat (pierdere neacoperită) al anilor precedenți	120	8.952.137	4.361.103	7.669.613	5.643.627
	Profit net (pierdere netă) al perioadei de gestiune	130	X	5.996.028		6.996.028
	Profit utilizat al perioadei de gestiune	140	X	0	0	0
	Rezultatul din tranziția la noile regulamente contabile	150				
	Total profit nerepartizat (pierdere neacoperită) (rd.110 + rd.120 + rd.130 + rd.140 + rd.150)	160	8.952.137	11.357.131	7.669.613	12.639.655
4.	Alte elemente de capital propriu, din care					
	Diferențe din reevaluare	171				
	Subvenții entităților cu proprietate publică	172				

Total capital propriu (rd.060 + rd.100 + rd.160 + rd.170)	180	8.957.537	11.357.131	7.669.613	12.645.055
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SITUAȚIA FLUXURILOR DE NUMERAR

Anexa 4

de la 01.01.2017 pînă la 31.12.2017

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vânzări	010	16.364.220	30.547.593
Plăți pentru stocuri și servicii procurate	020	18.057.882	1.242.716
Plăți către angajați și organisme de asigurare socială și medicală	030	165.559	205.235
Dobânzi plătite	040		
Plata impozitului pe venit	050	359.402	1.213.720
Alte încasări	060	2.173.630	
Alte plăți	070	647.102	20.861.222
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080	-692.095	7.024.700
Fluxuri de numerar din activitatea de investiții			
Încasări din vânzarea activelor imobilizate	090		
Plăți aferente vânzării de active imobilizate	100		
Dobânzi încasate	110		
Dividende încasate	120		
Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 + rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150		
Plăți aferente rambursării creditelor și împrumuturilor	160		
Dividende plătite	170	1.127.660	3.110.000
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 + rd.170 + rd.180 + rd.190)	200	-1.127.660	-3.110.000
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	-1.819.755	3.914.700
Diferențe de curs valutar favorabile (nefavorabile)	220	79.511	79.511
Sold de numerar la începutul perioadei de gestiune	230	2.488.073	747.829
Sold de numerar la sfârșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	747.829	4.742.040

Date generale

- Certificat de înregistrare a entității, eliberat de Camera înregistrării de Stat.
 Număr de înregistrare MD0101250, Data înregistrării 12.08.2014, Seria MD, Număr 0101250
- 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.
- Entitățile, activitatea cărora necesită licență, indică:
 Licența în vigoare:
 1) Număr 044322, data eliberării 2010-10-04 00:00:00
 Termen de valabilitate 03.10.2020
 Tipul de activitate _____
 Organul care a eliberat licența _____
- Numărul mediu scriptic al personalului în perioada de gestiune _____ persoane, inclusiv pe categorii:
 1) personal administrativ _____ persoane,
 2) muncitori _____ persoane.
- Numărul personalului la 31.12.2017 _____ persoane
- Remunerarea personalului entității în perioada de gestiune _____ lei
- Remunerarea membrilor organelor de administrare, de conducere și supraveghere și alte angajamente apărute sau asumate în legătură cu activitatea membrilor organelor de administrare și conducere și supraveghere _____ lei
- Avansurile și creditele acordate membrilor organelor specificate la pct.7 _____ lei, inclusiv rambursate _____ lei.
- Valoarea activelor imobilizate și circulante, înregistrate în calitate de gaj:¹
 1) valoarea de gaj _____ lei,
 2) valoarea contabilă _____ lei.
- Numărul acțiunilor ordinare la finele perioadei de gestiune _____ unități.
- Profit net pentru perioada de gestiune pentru acțiunile ordinare:
 1) profit _____ lei,
 2) pierdere _____ lei.
- Diferențe calculat pentru acțiunile ordinare pentru perioada de gestiune:
 1) plătite _____ lei,
 2) planificate pentru plată _____ lei.
- Valoarea stărilor disponibile, recalculează în moneda națională a Republicii Moldova – leu _____ 849.462 lei, inclusiv (lei, denumirea și codul valutei):
 1) 698537 codul valutei Euro
 2) 150925 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

Anexa 7

Informațiile privind activele imobilizate
de la 01.01.2017 până la 31.12.2017

Indicatori	Nr. rînd	Existența la începutul perioadei (la costul de intrare)	Amortizarea acumulată la începutul perioadei	Deprecierea acumulată la începutul perioadei	Intrarea în cursul perioadei (la costul de intrare)	Ieșirea în cursul perioadei (la costul de intrare)	Existența la sfîrșitul perioadei (la costul de intrare)	Amortizarea acumulată la sfîrșitul perioadei	Deprecierea acumulată la sfîrșitul perioadei
		2	3	4	5	6	7	8	9
1. Imobilizări necorporale în curs de execuție	100								
2. Imobilizări corporale în valoare totală în lei	200	3.250	813				3.250	1.463	
2.1. brevete și mărci	210								
2.2. licențe de activitate	220	3.250	813				3.250	1.463	
2.3. programe informatice	230								
3. Imobilizări corporale în curs de execuție	300								
4. Terenuri	400		X					X	
5. Mijloace fixe, total din care:	500	205.204	9.679		796.422	6.100	995.526	90.823	
5.1. clădiri	510								
5.2. construcții speciale	520								
5.3. mașini, utilaje, instalații de transmisie inclusiv: tehnică de calcul	530	186.815	8.900		796.422	6.100	977.141	85.929	
5.4. mijloace de transport	540								
5.5. instrumente și inventar	550								
5.6. costuri aferente obiectelor neînregistrate în bilanț	560								
5.7. mijloace fixe primite în leasing financiar	570								
5.8. mijloace fixe primite în gestiune economică	580								
5.9. alte mijloace fixe	590	18.389	1.379				18.389	6.894	
6. Resurse materiale	600								
7. Investiii imobiliare, total	700								

Recipisa de primire a raportului

ID-ul raportului 289272
 Tipul raportului RSF1
 Tipul perioadei de raportare Anual
 Anul de raportare 2017
 Numărul de raportare a perioadei (număr) 10
 Numărul de raportare a perioadei (text) an
 Codul statistic al organizației 40717392
 Codul fiscal al organizației 1010600028048
 IDNO organizației 1010600028048
 Denumirea organizației BIOSISTEM MLD SRL
 Statutul raportului Primit la BNS
 Data creării raportului 26.03.2018 11:08:42
 Data expedierii raportului 27.03.2018 13:54:13
 Subdiviziunea teritorială a BNS mun. Chișinău
 Telefonul subdiviziunii teritoriale a BNS 0-22-739581

Таблицы финансового отчёта автоматически проверены на арифметические ошибки и логические связи между таблицами.

Контроль показателей на соответствие с предыдущим финансовым отчётом на данный момент НЕ выполнен.

Ответственность за правильность отражения экономических операций в бухгалтерском учёте и применённых методов учёта, а также за достоверность и полноту представленных данных и приложений несёт субъект и его ответственные лица, подписавшие финансовые отчёты.

CERTIFICAT privind lipsa sau existența restanțelor față de bugetul public național

1. Destinatar / Получатель

Nr. № A1906045

din 08.02.2019

Pentru participarea la proceduri de achiziții publice

2. Date despre contribuabil / Информация о налогоплательщике

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

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

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

4. Valabil până la / Действителен до 23.02.2019

5. Autentificarea organului fiscal / Подтверждение налогового органа



Funcția/Dлъжность
 S. Sorbiciu
 I.S./М.П.
 Executor: S. Sorbiciu
 Numele și prenumele/Имя и фамилия

Numele și prenumele/Имя и фамилия
 S. Sorbiciu

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 08.02.2019 ora 16:43:41
 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)
 NOTA (2,21)

BIOSYSTEMS



BioSystems S.A., organizer of the training, CERTIFIES that

Mr. Nasedchin Alexandr

successfully participated in the service engineer's training
"Random Access Biochemistry Analyzer A15, A25"

May 18-22, Moscow 2009

Director of technical service department
Representative office "BioSystems S.A. Russia"

Sergey Vasiliyev



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 6th, 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 (AACA)	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 9001:2008**

Certificate Registr. No. 01 100 6696

Certificate Holder: **BIOSYSTEMS, S.A.**
C/ Costa Brava, 30
E - 08030 Barcelona

(With the locations included in the annex)

Scope: Design, development, manufacture, distribution, servicing of:

- Instruments and reagents for clinical diagnostic.
- Instruments and reagents for agro-alimentary analysis.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2008 are met.

Validity: The certificate is valid from 2016-12-14 until 2018-09-14.
First certification 1996

2016-12-16



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Annex to certificate

Standard **ISO 9001:2008**

Certificate Registr. No. 01 100 6696

No.

01 100 6696/02

Location

BIOSYSTEMS, S.A.
Poligono Industrial
Can Tapioles
Naves 7, 12 y 13
E – 08110 Montcada I Reixac
(Barcelona)

Scope

Labelling and Assembling of
reagents.
Warehousing and Shipment.

2016-12-16



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

CERTIFICAT DE AUTORIZARE

Prin prezentul este autorizata

SRL Biosistem-MLD
cu sediul 16/1-7, Albisoara Str., Chisinau, R.Moldova

de a reprezenta in calitate de ***distribuitor oficial*** in Republica
Moldova produsele

BIOSYSTEMS SA
cu sediul C/Costa Brava 30
08030 Barcelona (Spain)



Xavier Palomar
Area Manager
27-April-2013



Prin prezenta compania Biosystems SA producătorul Analizorului biochimic A-15 / A-25 / BA-400 confirmă faptul, că produsele următoare sunt certificate de DECLARAȚIA DE CONFORMITATE CE № Ref . I-010 fiind parte integrală și indispensabilă al aparatului A-15 / A-25 / BA-400:

1. Rotor de reacție AC11485
2. Cuvă pentru ser AC10770
3. Soluție concentrată de spălare BO13416
4. Soluție de sistem BO11524
5. Lampă Halogenă LA10429
6. Ac pentru dozare AC11500
7. Reactivi biochimici, turbidimetrici, cromatografici, standarde, controale, aglutinație latex, indicate in anexa declarației de conformitate CE.

Produsele sus menționate sunt confecționate in conformitate cu standardele ISO 9001 si ISO 13485.



Xavier Palomar
Area Manager
27-April-2011



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 site(s) included)**

Proof has been furnished that the requirements specified in

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

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

Effective Date: 2016-12-13
Certificate Registration No.: SX 60114603 0001
An audit was performed. Report No.: 28300434 001
This Certificate is valid until: 2019-03-30

Certification Body



Date 2016-12-13



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 60114603 0001
Report No.: 28300434 001

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: 2016-12-13




Dipl.-Ing. Sven Hoffmann

S/REF DELTALAB, S.L.
N/REF: PS/DP/MST PLAZA DE LA VERNEDA, 1
Date: 01/12/2015 POLIGONO INDUSTRIAL LA LLANA
Subject: Information to the addressee 081191 RUBÍ
(BARCELONA)

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

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

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

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

THE HEAD OF THE DEPARTMENT OF SANITARY PRODUCTS

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

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

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

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

MARTA CASANOVA HERNANDEZ
Traductora-Intérprete Jurada de INGLÉS

Marta Casanova

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

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

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

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


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

"Tubos AQUISEL"; contenedores para la recogida de muestras de sangre, variantes:
The "AQUISEL tube"; containers for blood sampling collection, kinds:

- | | |
|--|---|
| • K3E/EDTA 3K (anticoagulante) | • K3E/EDTA 3K (anticoagulant) |
| • K2E/EDTA 2K (anticoagulante) | • K2E/EDTA 2K (anticoagulant) |
| • 4NC/Citrato 3Na (anticoagulante) | • 4NC/Citrato 3Na (anticoagulant) |
| • 5NC/Citrato 3Na (anticoagulante) | • 5NC/Citrato 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 aditivo) | • 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) Accesorios • CAP-GALET (Funnels for Blood Sampling) |

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

Firmado/Signed: 
(Gerente / Manager)

AQUISEL, S.L. 08630 ABRERA (Barcelona) España Tel: (93) 770 38 00 Fax: (93) 770 38 15

file:TF-1004_F_03-2014



DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

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

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

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

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

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

Código GMDN / GMDN Code: 33722

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

ESCOBILLON - Swab

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

Clasificación: Clase IIa
Classification: Class IIa

INFORMACIÓN ADICIONAL

En referencia a los escobillones, este documento tiene su apoyo en el Certificado CE número 2005.06.0474 CP
Especificación de Garantía de Calidad de la Producción de acuerdo con los Anexos V y VII de la Directiva 93/42/CEE,
emitió 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, European
Production Quality Assurance according to Annexes V and VII of Directive 93/42/EEC issued by the Agencia Española
de Medicamentos y Productos Sanitarios (AEMPS), Notified Body number 0318.



TUBO CON MEDIO DE TRANSPORTE - Tube with transport medium

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


José Saez
Director General / Managing Director


Anna Mir
Responsable Técnico / Technical Director

ANEXO 1 – DESCRIPCIÓN DE ARTICULOS
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+VISCOSE
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+VISCOSE
300253	ESCOBILLON ALU.+VISCOSA TUBO	SWAB IN TUBE ALUM+VISCOSE
300254	ESC.ALUM.TRENZADO+VISCOSA TUBO	SWAB TWISTED ALUM+VISCOSE TUBE
300259	ESCOBILLON MAD.+VISCOSA TUBO	SWAB IN TUBE WOOD+VISCOSE
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+VISCOSE
300284	AMIES LIQUIDO PS+VISCOSA	AMIES SWAB LIQUID PS+VISCOSE
300285	AMIES CARBON PS+VISCOSA	AMIES+CHARCOAL SWAB PS+VISCOSE
300287	AMIES PS+VISCOSA	AMIES SWAB PS+VISCOSE
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 + POLIÉSTER	VIRUS SWAB ALUMINIUM POLYESTER
300296	STUART 13X165MM PS C/VISCOSA	STUART 13X165MM PS W/VISCOSE
300296	H. VIRUS ALUM. ALGODÓN	SWAB FOR VIRUS WIRE+COTTON TIP
300297	VIRUS PS+POLIÉSTER	VIRUS SWAB PS POLYESTER
300299	CHLAMYDIA PS+POLIÉSTER	CHLAMYDIA SWAB PS+POLYESTER
310200	ESCOBILLON MAD.+ALGODON FLOW	WOOD+COTTON SWAB FLOW
310202	ESCOBILLON PS+VISCOSA FLOW	PS+VISCOSE 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+VISCOSE
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+POLIÉSTER PEEL PACK	SWAB PS+POLIESTER IND.WRAPPED
300280.2	CARY BLAIR PS+VISCOSA	CARY BLAIR SWAB PS+VISCOSE
300281/1	ESC. AMIES+CARBON ALUM.VISCOSE	AMIES CHARCOAL SWAB WIRE+VISCOSE
300281T	AMIES ALUMINIO TRENZADO+ VISCOS	AMIES SWAB TWIST WIRE+VISCOSE
300281TC	AMIES+CARBON ALU.TRENZADO+ VISC	AMIES+CHARCOAL TWIS.WIRE+VISCOSE
300285.M	AMIES CARBON PS VISCOSA 6x100	AMIES CHARCOAL PS RAYON 6X100
300287.5	AMIES PS VISCOSA CAJAS 6x100	AMIES PS VISCOSE CASES 6X100
300287.A	ESCOB.AMIES PS+VISCOSA	AMIES SWAB PS+VISCOSE
300295C	STUART CARBÓN PS + VISCOSA	STUART+CHARCOAL SWAB PS+VISCOSE
310253.1	ESCOB. ALUM+VISCOSA FLOW	ALUM+VISCOSE 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
300261AV	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PS+COTTON

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DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

DELTALAB S.L.
Plaza de la Verneda, nº 1
Pol. Ind. La Llana
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, Epígrafe 6, de Garantía de Calidad de la Producción de acuerdo con los Anexos VII punto 5 y V punto 3 de la Directiva 93/42/CEE, emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Organismo Notificado número 0318.

OTHER INFORMATION:

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

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TUBO CON MEDIO DE TRANSPORTE – Tube with transport medium

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



 José Saez
Director General / Managing Director
 Anna Mir
Responsable Técnico / Technical Director

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

REF	DESCRIPCIÓN	DESCRIPTION
300265	ESCOBILLON PS+FLOCK EN TUBO	SWAB / TUBE PS + FLOCK
303806	ESCOB.FLOCK ULTRA PEEL P.	FLOCKED SWAB PS STAND.NO/8P 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 TAPÓN VERDE	30ML CONTAINER PS GREEN CAP
309202.WO	FRASCO 30ML PS SIN TAPÓN	CONT. 30ML PS NO CAP
309222.1	FRASCO 30ML PS B/U ETIQUETADO	CONTAINER 30 ML. UNIT BAG LABEL
309501BE	FRASCO 60ML PS B/50 CÓD. BARRAS	60ML PS CONTAINER B/50 BAR COD
309502.10	FP-60 S/ROSCAR C/600 T/ROJO	CONT. 60ML C/600 RED CAP
309502.6	FRASCO 60 ML. PS ETIQUETA BLANC	PS 60 ML. CONTAINER PLAIN LABEL
309602E	FRASCO 30ML PS CON ESPATULA ETIQUETADO	30ML CONTAINER WITH SPOON PS
309622.1	FCO. 30 CUCH. ETIQ. ESP. B/UNIT.	PS 30ML SPOON+LABEL+UNIT BAG CONT.
400004.1	FRASCO 125ML PP 57X73	125ML CONTAINER PP
400500.B	TUBO 11x55 PP B/400	TUBE 11x55 PP B/400
400706E	TUBO 10ML C/A. BORICO TAP. ETIQ. B/U	100ML TUBE W/BORIC A. CAP. LAB. I/W
400800.1	TUBO 5 ML PP 12X75 MM SIN ENRASES	TUBE 12X75 WITHOUT RINGS PP
400906BOR	TUBO 16X100 TAP- 308106 AC. BOR	TUBE 16X100 PP CAP ACID BORIC
400906MD	TUBO 16x100 PP TAPADO 308106	16x100 TUBE PP CAPPED 308106
409201.S	FRASCO 30ML PP ETIQUETADO	30ML CONTAINER LABEL PP
409201.SE	FRASCO 30ML PP ETIQUETADO B100	30ML CONTAINER LABEL PP B/100
409202.8	FRASCO 30 ML TAPADO TAPON AZUL	30ML CONTAINER PP BLUE CAP
409202.WO	FRASCO 30ML PP SIN TAPÓN	CONT. 30ML PP NO CAP
409203.2	FRASCO 30ML PP T/BLAN ENV. SEP	PP 30 ML+ WHITE CAP SEPARAT. C/1800
409203.2A	FR. 30ML PP T/BL. ENV. SEP. C/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

Fecha / Date: 17/01/2017
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CDCE-14 Rev.13.15

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

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

DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

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

Declaro 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 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 Sáez
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 Liana
08191 RUBI (BARCELONA) – SPAIN

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

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

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

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

Código GMDN / GMDN Code: 58143

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

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

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

José Sáez
Director General / Managing Director

Anna Mir
Responsable Técnico / Technical Director

Fecha / Date: 22/11/2013
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CDCE-77 Rev.2

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

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

Fecha / Date: 20/06/2016
Pag. 2/2

CDCE-77 Rev.2

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

El fabricante / The manufacturer:

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

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

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

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

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

Código GMDN / GMDN Code: 58138

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

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

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

José Sáez
Director General / Managing Director

Anna Mir
Responsable Técnico / Technical Director

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

CDCE-45 Rev. 10

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

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

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

CDCE-45 Rev. 10

Certificate ES10/81671

The management system of

DELTALAB, S.L.

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

has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

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 11 October 2016 until 31 March 2019
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 March 2019
Issue 6. Certified since 12 October 2010

Authorised by

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

SGS 13485-2 1114

Page 1 of 1



Certificate ES10/81672

The management system of

DELTALAB, S.L.

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

has been assessed and certified as meeting the requirements of

ISO 9001:2008

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.

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 11 October 2016 until 15 September 2018 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 15 September 2018

Issue 6. Certified since 12 October 2010

Authorised by

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

SGS 9001-8 01 0216

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0005



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

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

Proof has been furnished that the requirements specified in

EN ISO 9001:2008

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

Certificate Registration No.: SY 60089707 0001

An audit was performed. Report No.: 10042449 001

This Certificate is valid until: 17.09.2018

Certification Body

Date 14.01.2014



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

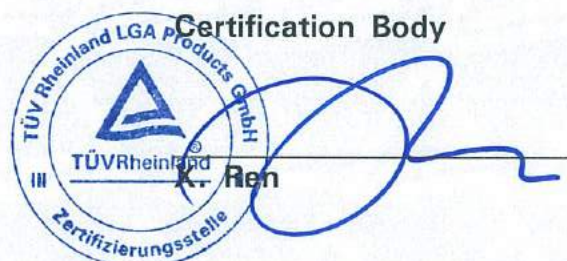
Attachment to
Registration No.: SY 60089707 0001
Report No.: 10042449 002

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

Scope: Products:

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

Date: 2014-03-13





TÜVRheinland®

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6

Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60088590 0001

Report No.: 10042449 001

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

Products: in-vitro diagnostica for self-testing
(see attachment for products included)
Replaces Approval, Registration No.: HL 60027676 0001

Expiry Date: 2018-09-17

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

Effective Date: 2013-09-18

Date: 2013-09-18



Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HL 60088590 0001
Report No.: 10042449 001

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

Products:

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

Date: 2013-09-18



Notified Body

X Ren

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Bioptik Technology, Inc.
No. 188, Jhonghua South Road
Gongguan Village
Jhunan Township
Miaoli County, 35057
Taiwan

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

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

Proof has been furnished that the requirements specified in

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

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

Certificate Registration No.: SX 60089706 0001

An audit was performed. Report No.: 10042449 001

This Certificate is valid until: 17.09.2018



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Certification Body



X. Ren

Date 14.01.2014

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60089706 0001
Report No.: 10042449 002

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

Scope: Products:

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



Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-ZQ-995.00.01-46

Certification Body



Date: 2014-03-13

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

02-699 Warszawa, ul. Kłobucka 23A



CERTIFICATE

No. J - 2670/1/2017

This is to certify that:

TÜRKLAB TIBBI MALZEMELER SAN. ve TIC. A.Ş.

**ITOB 10031 Sokak No: 15 Tekeli - Menderes / Izmir
Turkey**

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**

is in conformance with

EN ISO 9001:2008

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

The certificate holds good if the Organization observes
of the above mentioned standard and of the Contract No. 2897/JM/3/2017

This certificate is valid:
from 2017-12-22 to 2018-09-14



AC 019
QMS



Anna Wyroba
Anna Wyroba, M.Sc.
Vice President

Date of certification decision: 2017-12-05

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

02-699 Warszawa, ul. Kłobucka 23A



CERTIFICATE

No. M - 56/1/2017

This is to certify that:

TÜRKLAB TIBBI MALZEMELER SAN. ve TIC. A.Ş.
ITOB 10031 Sokak No: 15 Tekeli - Menderes / Izmir
Turkey

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

is in conformance with

EN ISO 13485:2012

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

The certificate holds good if the Organization observes
of the above mentioned standard and of the Contract No. 2897/JM/3/2017

This certificate is valid:
from 2017-12-22 to 2019-02-28



AC 019
QMS



Anna Wyroba
Anna Wyroba, M.Sc.
Vice President

Date of certification decision: 2017-12-05

21.08.2016
Izmir / 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
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

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:

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

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
devices, 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:

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

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 II7



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



Declaration of Conformity



According to the In Vitro Diagnostic Medical Devices Directive 98/79/EC

Manufacturer: Dirui Industrial Co., Ltd.
95 Yunhe Street New& High Tech. Development Zone
Changchun Jilin 130012 P.R. China

Authorized Representative: Emergo Europe

Representative: Molenstraat 15 2513 BH The Hague
The Netherlands

Medical Device: Product Name: Reagent strips for Urinalysis

Device: IVDD-Classification: Professional use

Lot/batches/Serial mber, Type, Periods of manufacture
(where applicable)

- | | | |
|--|----------------------------------|----------------------|
| DIRUI 1 ITEMS (GLU) | DIRUI 1 ITEMS (KET) | DIRUI 1 ITEMS (PRO) |
| DIRUI 2 ITEMS (PRO, GLU) | DIRUI 2 ITEMS (KET, GLU) | |
| DIRUI 3 ITEMS (PRO, PH, GLU) | DIRUI 3 ITEMS (PRO, KET, GLU) | |
| DIRUI 4 ITEMS (PRO, PH, BLD, GLU) | DIRUI 4 ITEMS (PRO, PH, SG, GLU) | |
| DIRUI 5 ITEMS (PRO, PH, BLD, KET, GLU) | | |
| DIRUI 8 ITEMS | DIRUI H8 | |
| DIRUI 9 ITEMS | | |
| DIRUI A10 | DIRUI H10 | DIRUI E10 |
| DIRUI H11 | DIRUI H11-MA | DIRUI M10 |
| DIRUI H11-800MA | | DIRUI H10-800 |
| DIRUI H13-Cr | | DIRUI H11-800 |
| DIRUI H13-Cr (H-800) | | DIRUI H12-800MA |
| | | DIRUI H14-Ca |
| | | DIRUI H14-Ca (H-800) |

The undersigned hereby declares that the In Vitro Diagnostic medical device as specified above conforms with the essential requirements listed in the Annex 1 of the European In Vitro Diagnostic Medical Device Directive 98/79/EC (IVDD)

This declaration of conformity is based on the European In Vitro Diagnostic Medical Device Directive 98/79/EC, Annex III.

Valid Since
May 9th, 2012
Changchun, China

Representative:
Yu Ge
Dirui Industrial Co., Ltd. 
于歌
(name and signature or equivalent marking of authorized person)

(place and date of issue)

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Dirui Industrial Co., Ltd.
95 Yunhe Street
New & High Tech.
Development Zone
Changchun
Jilin Province 130012
China

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

Design and Development, Manufacture and Distribution of
In vitro Diagnostic Medical Test Systems
(see attachment for products included)

Proof has been furnished that the requirements specified in

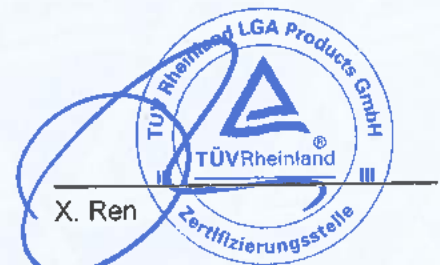
EN ISO 9001:2008

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

Effective Date: 2017-03-02
Certificate Registration No.: SY 60116876 0001
An audit was performed. Report No.: 15047317 006
This Certificate is valid until: 2018-09-14

Certification Body

Date 2017-02-23



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.0

**Attachment to
Certificate**

Registration No.: SY 60116876 0001
Report No.: 15047317 006

Organization: Dirui Industrial Co., Ltd.
95 Yunhe Street
New & High Tech.
Development Zone
Changchun
Jilin Province 130012
China

Scope:

Products:

- Urine Analysis Systems (Reagents, Analyzers, Controls)
- Hematology Test Systems (Reagents, Analyzers, Controls)
- Clinical Chemistry Test Systems (Reagents, Analyzers, Controls)
- Fecal Test Systems (Reagents, Analyzers, Controls)

(This certificate information can be searched on CNCA official website <http://www.cnca.gov.cn>)

Date: 2017-02-23



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Dirui Industrial Co., Ltd.
95 Yunhe Street
New & High Tech.
Development Zone
Changchun
Jilin Province 130012
China

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

Design and Development, Manufacture and Distribution of
In vitro Diagnostic Medical Test Systems
(see attachment for products included)

Proof has been furnished that the requirements specified in

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

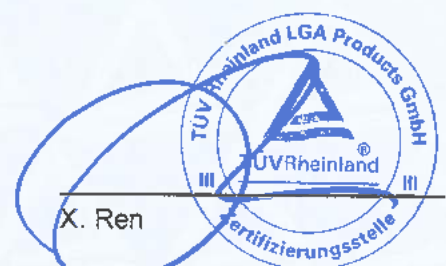
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-03-02
Certificate Registration No.: SX 60116875 0001
An audit was performed. Report No.: 15047317 006
This Certificate is valid until: 2019-02-28

Certification Body



Date 2017-02-23



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 60116875 0001
Report No.: 15047317 006

Organization: Dirui Industrial Co., Ltd.
95 Yunhe Street
New & High Tech.
Development Zone
Changchun
Jilin Province 130012
China

Scope:

Products:

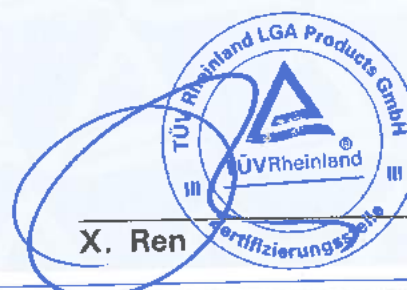
- Urine Analysis Systems (Reagents, Analyzers, Controls)
- Hematology Test Systems (Reagents, Analyzers, Controls)
- Clinical Chemistry Test Systems (Reagents, Analyzers, Controls)
- Fecal Test Systems (Reagents, Analyzers, Controls)

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2017-02-23





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 (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



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 (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).



Product Compliance Management
Munich, 2016-11-25



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT

EU Declaration of Conformity

OSRAM

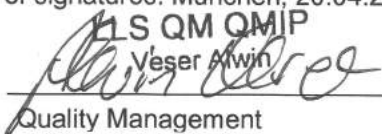
Document number: 2016 / 9C1-3364256-EN-00
Manufacturer or representative: OSRAM GmbH
Address: Marcel-Breuer-Str. 6
80807 München
Germany
Brand name or trade mark: OSRAM
Product type: Lamp controlgear
Product designation: QUICKTRONIC
 See attached list


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, Steinerte 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"/> | EN 61347-1:
2008 + A1:2011 + A2:2013 | Lamp controlgear — Part 1: General and safety requirements |
| <input checked="" type="checkbox"/> | EN 61347-2-3:
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"/> | EN 55015:
2013 | Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment |
| <input checked="" type="checkbox"/> | EN 61000-3-2:
2014 | Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) |
| <input checked="" type="checkbox"/> | EN 61000-3-3:
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"/> | EN 61547:
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"/> | EN 62442-1: 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"/> | EN 50581: 2012 | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances |
| <input checked="" type="checkbox"/> | internal report | |

EU Declaration of Conformity

Attached list

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

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

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	