Digitally signed by Poiata Vitalie
Date: 2019.02.06 15:53:13 EET
Reason: MoldSign Signature
Location: Moldova

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

L.Ș.

Notă: Licența este valabilă numai cu anexa autentificată 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. Московей, 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 MD95ML0000000002251429243**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

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

semnătura

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT I.S.
1004600077777
104

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 **Lazari Aliona**
tel. 022-266-252

A A 7 * E A * 0 3 7 0 4 3 1 E A

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: or. Chișinău, str. Albișoara 16/1 of.7
tel.+373-22-808-517, +373-22-808719, fax: +373-22-808-519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Lista fondatorilor Biosistem-mld SRL

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

Data primirii 27.03.2018 13:54:13

Anexe la SNC
"Prezentarea situaţiilor financiare"
Aprobat de Ministerul Finanţelor al Republicii Moldova

SITUAŢIILE 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 (Cod poştal) MUN.CHIŞINĂU; MUN.CHIŞINĂU SEC.RÎŞCANI
Raionul (municipiul, UTA); Localitatea
Albisoara, 16, 1, of.7
strada, nr, bl.

150 Cod CUATM

Activitatea principală: 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 şi coordonatele al contabilului-şef: Dl (dna) +37322808719
Tel. +37369463619

Unitatea de măsură: leu

Anexa 8

Notă informativă privind veniturile şi cheltuielile clasificate după natură

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vînzări	010	15.623.709	20.497.176
Alte venituri din activitatea operaţională	020		500
Venituri din alte activităţi	030	368.943	361.872
Total venituri (rd.010 + rd.020 + rd.030)	040	15.992.652	20.859.548
Variaţia stocurilor	050		
Costul vînzărilor	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
Contribuţii de asigurări sociale de stat obligatorii şi prime de asigurare obligatorie de asistenţă medicală	090	35.709	46.530
Cheltuieli cu amortizarea şi deprecierea activelor imobilizate	100	7.389	90.494
Alte cheltuieli	110	306.855	548.183
Cheltuieli din alte activităţi	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

Anexa 1

BILANŢUL

la 31.12.2017

Nr. crt.	ACTIV	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrşitul perioadei de gestiune
1	2	3	4	5
1.	**Active imobilizate**			
	Imobilizări necorporale	010	2.437	1.787
	Imobilizări corporale în curs de execuţie	020		
	Terenuri	030		
	Mijloace fixe	040	195.525	904.703
	Resurse minerale	050		
	Active biologice imobilizate	060		
	Investiţii financiare pe termen lung în părţi neafiliate	070		
	Investiţii financiare pe termen lung în părţi afiliate	080		
	Investiţii imobiliare	090		
	Creanţe 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**			
	Materiale	140	2.329	457
	Active biologice circulante	150		
	Obiecte de mică valoare şi scurtă durată	160	49.454	63.968
	Producţia în curs de execuţie şi produse	170		
	Mărfuri	180	3.435.875	4.430.031
	Creanţe comerciale	190	5.303.786	3.157.174
	Creanţe ale părţilor afiliate	200		
	Avansuri acordate curente	210	793.582	1.097.547
	Creanţe ale bugetului	220	35.037	4.973
	Creanţe ale personalului	230		
	Alte creanţe curente	240		
	Numerar în casierie şi la conturi curente	250	747.829	4.742.040
	Alte elemente de numerar	260		
	Investiţii financiare curente în părţi neafiliate	270		
	Investiţii financiare curente în părţi 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	Sfîrşitul perioadei de gestiune
1	2	3	4	5
3.	**Capital propriu**			
	Capital social şi suplimentar	320	5.400	5.400
	Rezerve	330		
	Corecţii ale rezultatelor anilor precedenţi	340	X	
	Profit nerepartizat (pierdere neacoperită) al anilor precedenţi	350	8.952.137	5.643.627
	Profit net (pierdere netă) al perioadei de gestiune	360	X	6.996.028
	Profit utilizat al perioadei de gestiune	370	X	
	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 faţă de părţile afiliate	480		
	Avansuri primite curente	490	186.214	7.303
	Datorii faţă de personal	500	7.343	45.149
	Datorii privind asigurările sociale şi medicale	510		
	Datorii faţă de buget	520	318.484	39.698
	Venituri anticipate curente	530		
	Datorii faţă de proprietari	540		
	Finanţări şi încasări cu destinaţie 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

Anexa 2

SITUAŢIA DE PROFIT ŞI PIERDERE

de la 01.01.2017 pînă la 31.12.2017

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vînzări	010	15.623.709	20.497.176
Costul vînzărilor	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 operaţională	040		500
Cheltuieli de distribuire	050	208	202
Cheltuieli administrative	060	513.937	522.704
Alte cheltuieli din activitatea operaţională	070	272.514	350.476
Rezultatul din activitatea operaţională: profit (pier-dere) (rd.030 + rd.040 – rd.050 – rd.060 – rd.070)	080	4.876.829	8.152.126
Rezultatul din alte activităţi: profit (pierdere)	090	79.511	-196.904
Profit (pierdere) pînă la impoztare (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

Anexa 3

SITUAŢIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la 01.01.2017 pînă la 31.12.2017

Nr. d/o	Indicatori	Cod rd.	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrşitul perioadei de gestiune
1	2	3	4	5	6	7
1	**Capital social şi suplimentar**					
	Capital social	010	5.400			5.400
	Capital suplimentar	020				
	Capital nevărsat	030	0	0	0	0
	Capital neînregistrat	040				
	Capital retras	050	0	0	0	0
	Total capital social şi 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 reserve (rd.070 + rd.080 + rd.090)	100				
3	**Profit nerepartizat (pierdere neacoperită)**					
	Corecţii ale rezultatelor anilor precedenţi	110				
	Profit nerepartizat (pierdere neacoperită) al anilor precedenţi	120	8.952.137	4.361.103	7.669.613	5.643.627
	Profit net (pierdere netă) al perioadei de gestiune	130	X	6.996.028		6.996.028
	Profit utilizat al perioadei de gestiune	140	X	0	0	0
	Rezultatul din tranziţia la noile reglementări 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**	170				
	Diferenţe din reevaluare	171				
	Subvenţii entităţilor 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

Anexa 4

SITUAŢIA FLUXURILOR DE NUMERAR

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 operaţională			
Încasări din vînzări	010	16.364.220	30.547.593
Plăţi pentru stocuri şi servicii procurate	020	18.057.882	1.242.716
Plăţi către angajaţi şi organe de asigurare socială şi medicală	030	165.559	205.235
Dobînzi plătite	040		
Plata impozitului pe venit	050	359.402	1.213.720
Alte încasări	060	2.173.630	
Alte plăţi	070	647.102	20.861.222
Fluxul net de numerar din activitatea operaţională (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 investiţii			
Încasări din vînzarea activelor imobilizate	090		
Plăţi aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
Alte încasări (plăţi)	130		
Fluxul net de numerar din activitatea de investiţii (rd.090 – rd.100 + rd.110 + rd.120 + rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite şi împrumuturi	150		
Plăţi aferente rambursării creditelor şi împrumuturilor	160		
Dividende plătite	170	1.127.660	3.110.000
Încasări din operaţiuni de capital	180		
Alte încasări (plăţi)	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
Diferenţe 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 sfîrşitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	747.829	4.742.040

Anexa 6

Date generale

1. Certificat de înregistrare a entităţii, eliberat de Camera Înregistrării de Stat.
Număr de înregistrare MD0101250 Data înregistrării 12.08.2014 Seria MD Număr 0101250
2. Capital social înregistrat de Camera Înregistrării de Stat:
data 12.08.2010 ,suma 5.400 lei, inclusiv:
1) cota statului ——— lei,
2) cota deţinătorilor a cel puţin 20% ——— lei,
Modificări ulterioare:
a) ———, suma ——— lei, inclusiv cota statului ——— lei,
b) ———, suma ——— lei, inclusiv cota statului ——— lei,
3. Entităţile, activitatea cărora necesită licenţă, indică:
Licenţa 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 licenţa ———
4. Numărul mediu scriptic al personalului în perioada de gestiune 3 persoane, inclusiv pe categorii:
1) personal administrativ 3 persoane,
2) muncitori ——— persoane,
5. Numărul personalului la 31.12.2017 3 persoane.
6. Remunerarea personalului entităţii în perioada de gestiune 169.200 lei.
7. Remunerarea membrilor organelor de administrare, de conducere şi supraveghere şi alte angajamente apărute sau asumate în legătură cu pensiile membrilor actuali sau ale foştilor membri ai acestor organe, pe categorii ——— lei
8. Avansurile şi creditele acordate membrilor organelor specificate la pct.7 ——— lei, inclusiv rambursate ——— lei.
9. Valoarea activelor imobilizate şi circulante, înregistrate în calitate de gaj[1]
1) valoarea de gaj ——— lei,
2) valoarea contabilă ——— lei.
10. Numărul acţiunilor ordinare la finele perioadei de gestiune ——— unităţi.
11. Profit net (pierdere netă) a perioadei de gestiune pentru o acţiune ordinară:
1) profit ——— lei,
2) pierdere ——— lei.
12. Dividende calculate pentru o acţiune ordinară pentru perioada de gestiune:
1) plătite ——— lei,
2) planificate pentru plată ——— lei.
13. Valută străină disponibilă, recalculată în monedă naţională a Republicii Moldova – total 849.462 lei, inclusiv (lei, denumirea şi 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 fracţie se reflectă:
a) la numărător – valoarea de gaj;
b) la numitor – valoarea contabilă

———

Anexa 7

Informatiile privind activele imobilizate

de la 01.01.2017 pînă la 31.12.2017

Indicatori	Nr. rînd	Existenţa 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)	Ieşirea în cursul perioadei (la costul de intrare)	Existenţa la sfîrşitul perioadei (la costul de intrare)	Amortizarea acumulată la sfîrşitul perioadei	Deprecierea acumulată la sfîrşitul perioadei
1		2	3	4	5	6	7	8	9
1. Imobilizări necorporale în curs de execuţie	100								
2. Imobilizări necorporale în utilizare, total inclusiv:	200	3.250	813				3.250	1.463	
2.1 brevete şi mărci	210								
2.2. licenţe de activitate	220	3.250	813				3.250	1.463	
2.3. programe informatice	230								
3. Imobilizări corporale în curs de execuţie	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. construcţii speciale	520								
5.3. maşini, utilaje, instalaţii de transmisie	530	186.815	8.300		796.422	6.100	977.141	85.929	
inclusiv: tehnică de calcul	531								
5.4. mijloace de transport	540								
5.5. instrumente şi inventar	550								
5.6. cesturi ulterioare aferente obiectelor neînregistrate în bilanţ	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	18.385	1.379				18.385	6.894	
6. Resurse minerale	**600**								
7. Investiţii 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 organizaţiei	40717392
Codul fiscal al organizaţiei	1010600028048
IDNO organizaţiei	1010600028048
Denumirea organizaţiei	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. Chişinău
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.

Anexa nr.7 la Instrucțiunea aprobată prin ordinul IFPS nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № A1902990 **din** / от 24.01.2019

1. Destinatar / Получатель

Pentru participarea la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

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

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

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

4. Valabil pînă la / Действителен до 08.02.2019

5. Autentificarea organului fiscal / Подтверждение налогового органа

Sef DAF Riscani — Semnătura/Подпись — Ana Stoicov

Funcția/Должность — **Semnătura**/Подпись — **Numele și prenumele**/Фамилия и имя

L.Ș/ М.П.

Executor: _____
Numele și prenumele/Фамилия и имя

MINISTERUL FINANȚELOR AL REPUBLICII MOLDOVA · SERVICIUL FISCAL DE STAT · IDNO 1006601001182 · S7

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 24.01.2019 ora 8:54:20 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,89)

ORDIN DE PLATA NR.: 39 TIP.DOC. 1

DATA EMITERII:6 februarie 2019

PLATITI: 1500-00 LEI: Una Mie Cinci Sute lei 00 bani

PLATITOR: (R) 'BIOSISTEM MLD" SRL
CONTUL DE PLATI/CODUL IBAN MD95ML000000002251429243
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. fil."Invest" Chisinau
CODUL BANCII: :MOLDMD2X329

BENEFICIAR (R) I.M.S.P. SP ITALUL CLINIC DE PSIHIATRIE
CONTUL DE PLATI/CODUL IBAN MD96VI022511700000037MDL
CODUL FISCAL :1003600150554 /

PRESTATORUL BENEFICIAR
B.C."VICTORIABANK"S.A.
CODUL BANCII: :VICBMD2X

DESTINATIA PLATII:Pentru garantia pentru: oferta la procedura de achizi?ie public: a nr. ocds-b3wdp1-MD-1548065787945 din 12.02.2019

TIPUL TRANSFERULUI NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001
DATA PRIMIRII:06/02/2019
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web "BIOSISTEM MLD" SRL Director

MIIGQQYJKoZIhvcNAQcCoIIGMjCCBi4CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb:

DQEHAaCCBEowggRGMIIDLqADAgECAhNHAABcVycdZVmKkP29AAAAAFxXMA0GCSq:

SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4:

DTE5MDEyODEwMTYyOFoXDTIxMDEyODEwMjYyOFowfjELMAkGA1UEBhMCTUQxGjA:
gNVBAoTEUJpb3Npc3RlbSBNTEQgU1JMMRIwEAYDVQQLEwkwNjkyMDAzMTQxFzA

(semnatura electronica)

CONTABIL-SEF:Web "BIOSISTEM MLD" SRLContabil

MIIGUgYJKoZIhvcNAQcCoIIGQzCCBj8CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBFswggRXMIIDP6ADAgECAhNHAABcVpWe/gMeSmneAAAAAFxWMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTE5MDEyODEwMTQwNFoXDTIxMDEyODEwMjQwNFowgY4xCzAJBgNVBAYTAk1EMScw:
YDVQQKEx5NZWRlY29yIFNSTCwgQmlvc2lzdGVtIE1MRCBTUkwxEjAQBgNVBAsT

L.S.

(semnatura electronica)

CONDUCATOR:

(semnatura manuala)

CONTABIL-SEF:

(semnatura manuala)

SEMNATURA PRESTATORUL

L.S.

MOTIVUL REFUZULUI

L.S.

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

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2008**

Certificate Registr. No. 01 100 6696

No.	Location	Scope
01 100 6696/02	**BIOSYSTEMS, S.A.** Poligono Industrial Can Tapioles Naves 7, 12 y 13 E – 08110 Montcada I Reixac (Barcelona)	Labelling and Assembling of reagents. Warehousing and Shipment.

2016-12-16

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

TÜVRheinland®

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2016-12-13

Dipl.-Ing. Sven Hoffmann

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

TÜVRheinland®

Doc. 1/1, Rev. 0

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2016-12-13

Dipl.-Ing. Sven Hoffmann

BioSystems
REAGENTS & INSTRUMENTS

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

BioSystems
Costa Brava, 30
08030 BCN

Dr. Antonio Elduque
Managing director
BioSystems S.A.

www.tuv.com ID:9091006696
TÜVRheinland
- Certified Management System
- EN ISO 9001
- EN ISO 13485

Biosystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
biosystems@biosystems.es
www.biosystems.es

CLINICAL CHEMISTRY – BIOCHEMISTRY:

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

CLINICAL CHEMISTRY – TURBIDIMETRY:

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

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

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

CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

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

CLINICAL CHEMISTRY – INSTRUMENTS:

A15
A25
BA400
BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

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

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

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

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

[State seal]
MINISTRY OF HEALTH, SOCIAL SERVICES AND EQUALITY

Agencia Española de Medicamentos y Productos Sanitarios
[Spanish State Agency of Medication and Sanitary Products]

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

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

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

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

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

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

THE HEAD OF THE DEPARTMENT OF SANITARY PRODUCTS
[Illegible signature]
Mª del Carmen Abad Luna
[Seal: Spanish State Agency of Medication and Sanitary Products]
Page 1/1

EMAIL
mpizarro@aemps.es

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

Doña Marta Casanova Hernández, Traductora e Intérprete jurada de inglés nombrada por el Ministerio de Asuntos Exteriores y Cooperación certifica que la que antecede es traducción fiel y completa al inglés de un documento redactado en español. En Salamanca, a 15 de diciembre de 2015	I, Marta Casanova, Sworn Translator and Interpreter of English named by the Ministry of Foreign Affairs and Cooperation, hereby certify that the foregoing is a true and complete translation into English of a document written in Spanish. In Madrid, 15 December 2015

MARTA CASANOVA HERNANDEZ
Traductora-Intérprete Jurada de INGLÉS
Nº 9494

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

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

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

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

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

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

• K3E/EDTA 3K (anticoagulante)	• *K3E/EDTA 3K (anticoagulant)*
• K2E/EDTA 2K (anticoagulante)	• *K2E/EDTA 2K (anticoagulant)*
• 4NC/CITRATO 3Na (anticoagulante)	• *4NC/Citrate 3Na (anticoagulant)*
• 9NC/CITRATO 3Na (anticoagulante)	• *9NC/Citrate 3Na (anticoagulant)*
• LH/Heparina Li (anticoagulante)	• *LH/Li Heparin (anticoagulant)*
• LH/Heparina Li – Gel (anticoagulante)	• *LH/Li Heparin + Gel (anticoagulant)*
• MonoiodoAcetato Li +Gránulos PS activador (antiglicolítico)	• *IodoAcetate Li + Granules activator (antiglycolitic)*
• LH/Heparina Li + MonoiodoAcetato Li (anticoagulante + antiglicolítico)	• *LH/Li Heparin + IodoAcetate Li (anticoagulant + antiglycolitic)*
• FX/Fluoruro Na + Oxalato K (antiglicolítico + anticoagulante)	• *FX/Na Fluoride + K Oxalate (antiglycolitic + anticoagulant)*
• Z/Vacío (sin aditivos)	• *Z/Empty (non additive)*
• Z/ Tubo tratado (para suero)	• *Z/ Treatment Tube (for serum)*
• Z/ Tubo tratado con Gel separador (para suero)	• *Z/ Treatment Tube with Separator Gel (for serum)*
• Z/ Tubo tratado con Gránulos PS (para suero)	• *Z/ Treatment Tube with Granules PS (for serum)*
• Z/ Tubo con activador de la coagulación (para suero)	• *Z/ Tube with clotting activator (for serum)*
• Z/ Tubo con activador + Gel separador (para suero)	• *Z/ Tube with clotting activator + Separator Gel (for serum)*
• Z/ Tubo con activador + Gránulos PS (para suero)	• *Z/ Tube with clotting activator + Granules PS (for serum)*
Accesorios	***Accessories***
• CAP-GALET (Embudo para muestras de sangre)	• *CAP-GALET (Funnels for Blood Sampling)*

Abrera a 09 Octubre de 2014 , *Abrera 09th October 2014*

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

file.:TF-1101-F _10-2014

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

deltalab

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:

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 Epígrafe 1, de Garantía de Calidad de la Producción de acuerdo con los Anexos V y VII de la Directiva 93/42/CEE, emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Organismo Notificado número 0318.

OTHER INFORMATION:
Regarding the swabs, this documentation is supported by the CE Certificate number 2005 06 0474 CP Epigraph 1, Production Quality Assurance according to Annexes V and VII of Directive 93/42/EEC issued by the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Notified Body number 0318.

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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.***

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DELTALAB S.L.
Plaza de la Verneda 1, Pol. Ind. La Llana
08191 Rubí - Barcelona

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*
300200	ESCOBILLON MAD.+ALGODON PEEL/1	SWAB I/W PEEL/1 WOOD+COTTON
300201	ESCOBILLON PS+ALGODON PEEL/1	SWAB I/W PEEL/1 PS+COTTON
300202	ESCOBILLON PS+VISCOSA PEEL/1	SWAB I/W PEEL/1 PS+VISCOSE
300203	ESCOBILLON ALU+ALGODON PEEL	SWAB I/W PEEL ALUM+COTTON
300210	ESCOBILLON MAD.+ALGOD.B/2 PEEL	SWAB B/2 PEEL/2 WOOD+COTTON
300250	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300251	ESCOBILLON ALU.+ALGODON TUBO	SWAB IN TUBE ALUM+COTTON
300252	ESCOBILLON PS+VISCOSA TUBO	SWAB IN TUBE PS+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 + POLIESTER	VIRUS SWAB ALUMINIUM POLYESTER
300295	STUART 13X165MM PS C/VISCOSA	STUART 13X165MM PS W/VISCOSE
300296	H. VIRUS ALUM. ALGODÓN	SWAB FOR VIRUS WIRE+COTTON TIP
300297	VIRUS PS+POLIESTER	VIRUS SWAB PS POLYESTER
300299	CHLAMYDIA PS+POLIESTER	CHLAMYDIA SWAB PS+POLYESTER
310200	ESCOBILLON MAD.+ALGODON FLOW	WOOD+COTTON SWAB FLOW
310202	ESCOBILLON PS+VISCOSA FLOW	PS+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+POLIESTER PEEL PACK	SWAB PS+POLIESTER IND.WRAPPED
300280.2	CARY BLAIR PS+VISCOSA	CARY BLAIR SWAB PS+VISCOSE
300281/1	ESC. AMIES+CARBON ALUM.VISCOSA	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+VISCO
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+VISCOS
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.***

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José Saez
Director General / *Managing Director*

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

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

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

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DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*:

DELTALAB S.L.
Plaza de la Verneda, 1
Pol. Ind. La Llana
08191 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 Diagnostico "in vitro". Transposición a la legislación española en Real Decreto 1662/2000.
Directive 98/79/EC: *"In-vitro" Diagnostics Medical Devices Directive. Transposition to Spanish legislation in Real Decreto 1662/2000.*

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

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

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ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

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

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*

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*

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/PRECI 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*

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

REF	DESCRIPCIÓN	*DESCRIPTION*
409502G.4	FR.60 GRAD.S/ROSCAR TAP.SEPARA	*CONT.60 GRAD.UNCAPPED SEP.CAP*
409507G	FRASCO 60ml PP GRAD.T/VERDE	*60ml CONT.PP GRAD.GREEN CAP*
409511.4	FR.60ML AZUL CLARO S/ETIQUETA	*60ML LIGHT BLUE CONTAINER*
409511.5	FR.60ML AZUL TRANSL. 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 TRANSL.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 Verneda, 1
Pol. Ind. La Llana
08191 RUBI (BARCELONA) – SPAIN

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

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

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

Código GMDN / *GMDN Code:* 58139

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

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

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

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

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

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DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*:

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

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

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

Finalidad Prevista: Recogida y conservación y/o transporte, de sangre para análisis y/u otra investigación (por ejemplo, hematología de sangre como conteo sanguíneo completo (SCS), y determinación cuantitativa de drogas.
Intended Use: *Collection and preservation and/or transport of blood for analysis and/or other investigation (e.g.whole blood hematology such as complete blood count (CBC) and quantitative drug assay determinations.*

Código GMDN / GMDN *Code:* 58143

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

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

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

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

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ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

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

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DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*:

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

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

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

Finalidad Prevista: Recogida y conservación y/o transporte, de sangre para análisis y/u otra investigación (por ejemplo, determinación química del suero sanguíneo).
Intended Use: *Collection and preservation and/or transport, of blood for analysis and/or other investigation (e.g. blood serum chemistry determinations)*

Código GMDN / GMDN *Code:* 58138

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

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

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

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

deltalab

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

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

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

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
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SGS 13485-2 1114

TÜRKLAB
let us diagnose

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ITOB 10031 Sk. No:15 Menderes – Izmir / TURKEY
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Tel: +90 232 376 80 81 Fax: +90 232 376 80 40

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

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

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:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 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
Vice President of PCBC

CE 1434

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

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

Module H6

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

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.
ITOB 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
Vice President of PCBC

CE 1434

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

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

Module H7

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

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.
ITOB 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
Vice President of PCBC

CE 1434

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

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

Module H6

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

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.
ITOB 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
Vice President of PCBC

CE 1434

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

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

Module H7

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

EC CERTIFICATE No. 1434-IVDD-54/2016

EC Design-Examination

Directive 98/79/ECon 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.
ITOB 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
Vice President of PCBC

CE 1434

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

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

Module H6

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

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.
ITOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

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

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

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

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

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

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

Anna Wyroba
Vice President of PCBC

CE 1434

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

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

Module H7

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

EC CERTIFICATE No. 1434-IVDD-58/2016

EC Design-Examination

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

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

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

manufactured by:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 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
Vice President of PCBC

CE 1434

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

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

Module H6

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

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.
ITOB 10031 Sokak No: 15 Tekeli Menderes
Izmir, Turkey

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

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

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

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

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

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

Anna Wyroba
Vice President of PCBC

CE 1434

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

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

Module H7

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

POLISH CENTRE FOR TESTING AND CERTIFICATION

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.
ITOB 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
Vice President of PCBC

CE 1434

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

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

Module A1

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

PCA
POLSKIE CENTRUM AKREDYTACJI
CERTYFIKACJA SYSTEMÓW ZARZĄDZANIA
AC 019
QMS

IAF
MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

PARTNER OF

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

PCA
Polskie Centrum Akredytacji
Certyfikacja Systemów Zarządzania
AC 019
QMS

PARTNER OF

Anna Wyroba, M.Sc.
Vice President

Date of certification decision: 2017-12-05

CE Declaration of Conformity CE

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
Molenstraat 15 2513 BH The Hague
The Netherlands

Medical Device : Product Name: Reagent strips for Urinalysis
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 M10** **DIRUI H10-800**
DIRUI H11 **DIRUI H11-MA** **DIRUI H11-800**
DIRUI H11-800MA **DIRUI H12-800MA**
DIRUI H13-Cr **DIRUI H14-Ca**
DIRUI H13-Cr (H-800) **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 Directive98/79/EC, Annex III.

Valid Since
May 9th, 2012
Changchun, China

Representative:
Yu Ge
Dirui Industrial Co., Ltd.
于歌

(place and date of issue)

(name and signature or equivalent marking of authorized person)

TÜVRheinland®

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

X. Ren

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

TÜVRheinland®

Doc. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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)

Certification Body

Date: 2017-02-23

X. Ren

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

TÜVRheinland®

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2017-02-23

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

X. Ren

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

TÜVRheinland®

Doc. 1/1, Rev.0

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2017-02-23

X. Ren

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: **Auto Hematology Analyzer**

Model: **BC-5000**
Including reagents as following:
M-52D DILUENT
M-52DIFF LYSE
M-52LH LYSE
PROBE CLEANSER

Classification: The device not in IVDD annex II and not for self testing/performance evaluation

Conformity Assessment Route: IVDD Annex III(excluding Section 6)

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Start of CE-Marking: 2013-9-26
Place, Date of Issue: Shenzhen, 2013-9-26

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-5150** Including reagents as following: **M-52D DILUENT** **M-52DIFF LYSE** **M-52LH LYSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

Conformity Assessment Route: IVDD Annex III(excluding Section 6)

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Start of CE-Marking: 2013-9-26

Place, Date of Issue: Shenzhen, 2013-9-26

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Applied Standards List

Product: **Auto Hematology Analyzer**

BC-5150、BC-5000

Including reagents as following:

M-52D DILUENT
M-52DIFF LYSE
M-52LH LYSE
PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2009	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
ENISO 18113-2:2009	I In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1：2003+A1：2003	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Declaration of Conformity V 1.0

IEC 61010-2-010：2005	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2008	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q5 17 03 44751 089

Holder of Certificate: **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**

Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

Scope of Certificate:

**Design and development,
production and distribution of
Active medical devices (intended) for monitoring,
diagnosis, anesthesia, breathing and intensive care;
In-vitro diagnostic instruments;
Non-active accessories
for breathing therapy and anesthesia;
In-vitro diagnostic reagents and kits (intended)
for hematology, clinical chemistry,
immunology and cell analysis
(For detail information see following pages)**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1705528

Valid from: 2017-09-01
Valid until: 2020-08-31

0405276870507S

Date, 2017-06-28

Stefan Preiß

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE
No. Q5 17 03 44751 089

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**

**Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Bldg 9-13, Baiwangxin High-Tech Industrial Park, Baimang, Xili Town, Nanshan, 518108 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**

**Shenzhen Mindray Biomedical Electronics Co., Ltd.
1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen, PEOPLE'S REPUBLIC OF CHINA**

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Attachment for Certificate No. Q5 17 03 44751 089
Dated: 2017-06-28

For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder,
Anesthesia Machine and Accessories, Ventilator,
Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System,
Ultrasonic Diagnostic Equipment and Accessories,
Digital Radiography System, Radiography System, Magnetic Resonance Imaging System
Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader,
Microplate Washer for invitro diagnostic use, Chemiluminescence Immunossay Analyzer,
Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker&Stainer,
Glycohemoglobin Analyzer, Specific Protein Analyzer,
Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer,
Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer,
Calibrators and Controls for Glycohemoglobin Analyzer,
Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask,
Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger,
Filter, Breathing Bag

Munich, CRT, 2017-06-28

Stefan Preiß

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV®

ZERTIFIKAT • CERTIFICATE • 認證證書 • СЕРТИФИКАТ • CERTIFICADO • CERTIFICAT

America

CERTIFICATE

No. QS5 17 07 44751 097

Certificate Holder:

Shenzhen Mindray Bio-Medical
Electronics Co., Ltd.
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD ISO 9001

Scope of Certificate:

Design and Development, Production and Distribution of Medical Electronic Equipment (Including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker & Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger,

Standard(s): ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: M2606
Effective Date: 2017-07-01
Expiry Date: 2020-06-30

Earl Buckmiller
Director, Quality Systems & MS Cert. Body

040527682186 43

TÜV SÜD America Inc.
10 Centennial Drive
Peabody, MA 01960
USA

TÜV®

SCC Accredited CB-MS OCSM Accrédité CCN

UCB_F_12.04 2012-02

ZERTIFIKAT • CERTIFICATE • 認證證書 • СЕРТИФИКАТ • CERTIFICADO • CERTIFICAT

America

CERTIFICATE

No. QS5 17 07 44751 097

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan, 518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Design and Development, Production and Distribution of Medical Electronic Equipment (Including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine and Accessories, Ventilator, Infusion Pump, Syringe Pump, Enteral Feeding Pump, Infusion Supervision System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for Invitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker & Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

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PEOPLE'S REPUBLIC OF CHINA

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Effective Date: **2017-07-01**
Expiry Date: **2020-06-30**

Earl Buckmiller
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