ORDIN DE PLATA NR.: 505 TIP.DOC. 1

DATA EMITERII:4 decembrie 2020

PLATITI: 1800-00 LEI: Una Mie Opt Sute lei 00 bani

PLATITOR: (R) "BIOSISTEM MLD" S.R.L.

CONTUL DE PLATI/CODUL IBAN
MD95ML000000002251429243
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. fil."Invest" Chisinau

CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R)IP USMF N.Te stemitanu

CONTUL DE PLATI/CODUL IBAN
MD19AG000000022512015544
CODUL FISCAL :1007600000794 /

PRESTATORUL BENEFICIAR
BC"MOLDOVA-AGROINDBANK"S.A.

CODUL BANCII:
:AGRNMD2X

DESTINATIA PLATII:Pentru garantia pentru: oferta la procedura de achizi?ie public: a nr. ocds-b3wdp1-MD-1606391187523 din 07.12.2020

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:

DATA PRIMIRII:04/12/2020

DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGQQYJKoZIhvcNAQcCoIIGMjCCBi4CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb:

DQEHAaCCBEowggRGMIIDLqADAgECAhNHAABcVycdZVmKkP29AAAAAFxXMA0GCSq:

SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4:

DTE5MDEyODEwMTYyOFoXDTIxMDEyODEwMjYyOFowfjELMAkGA1UEBhMCTUQxGjA:
gNVBAoTEUJpb3Npc3RlbSBNTEQgU1JMMRIwEAYDVQQLEwkwNjkyMDAzMTQxFzA

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

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.

Digitally signed by Poiata Vitalie
Date: 2020.12.04 16:03:27 EET
Reason: MoldSign Signature
Location: Moldova

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 MD95ML000000002251429243**.

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

MINISTERUL JUSTIȚIEI AL REPUBLICII MOLDOVA
CAMERA ÎNREGISTRĂRII DE STAT Î.S.
1004600077777 * 101

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

Date cu caracter personal. **Deținător:** Î.S. „Camera Înregistrării de Stat", **NUID (număr de identificare unic)** 0000151-001

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

Anexa nr.7.2 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existenţa restanţelor faţă de bugetul public naţional

Nr. № A2030318 **din** от 02.12.2020

1. Destinația / Назначение

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 Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de 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 17.12.2020

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Şef DDF Rîşcani
a DGAF mun.Chişinău
Funcția/Должность

Semnătura/Подпись

Viorica CĂUŞ
Numele şi prenumele/Фамилия и имя

L.Ş/ М.П.

Executor: **Claudia GOJAN**
Numele şi prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 02.12.2020 ora 15:56:58 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (1,42)

Data prezentării 21.05.2020 10:13:29
SITUATIILE FINANCIARE

Anexe la SNC
"Prezentarea situatiilor financiare"
Aprobat de Ministerul Finantelor
al Republicii Moldova

2019 pentru perioada 01.01.2019 - 31.12.2019 de lichidare
BIROUL NAȚIONAL DE STATISTICĂ

Entitatea: BIOSISTEM MLD S.R.L.
Sediul:SEC.RISCANI, STR.ALBISOARA NR.16 BL.1 OF.7
Raionul(municipiul):106, DDF RISCANI
Satul(comuna):
Strada:SEC.RISCANI, STR.ALBISOARA NR.16 BL.1 OF.7
Cod postal:2001
Cod CUATM:0150, SEC.RISCANI
Activitatea principala:G4646, Comert cu ridicata al produselor farmaceutice
Forma proprietate:16, Proprietate colectivă
Forma organizatorico-juridica:530, Societăți cu răspundere limitată
Cod CUIÎO: 40717392
Codul fiscal:1010600028048
WEB:
Numele si coordonatele al contabilului-sefNasedchin Alexandr
Telefon:+37322808719
Numărul mediu scriptic al personalului în perioada precedentă: 6 persoane.

Unitatea de masura: leu

Notă informativă privind veniturile și cheltuielile clasificate după natură

Anexa 8

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vinzari	010		
Alte venituri din activitatea operationala	020		
Venituri din alte activitati	030		
Total venituri (rd.010 + rd.020 + rd.030)	040		
Variatia stocurilor	050		
Costul vinzarilor mărfurilor vândute	060		
Cheltuieli privind stocurile	070		
Cheltuieli cu personalul privind remunerarea muncii	080		
Contributii de asigurari sociale de stat obligatorii si prime de asigurare obligatorie de asistenta medicala	090		
Cheltuieli cu amortizarea si deprecierea activelor imobilizate	100		
Alte cheltuieli	110		
Cheltuieli din alte activitati	120		
Total cheltuieli (rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130		
Profit (pierdere) pina la impozitare (rd.040 – rd.130)	140		
Cheltuieli privind impozitul pe venit	150		
Profit (pierdere) net al perioadei de gestiune (rd.140 – rd.150)	160		

BILANȚUL

la

Anexa 1

Nr. cpt.	A C T I V	Cod rd.	Sold la	
			Inceputul perioadei de gestiune	Sfirsitul perioadei de gestiune
1	2	3	4	5
1.	**Active imobilizate**			
	Imobilizari necorporale	010	1137	487
	Imobilizari corporale in curs de executie	020		
	Terenuri	030		
	Mijloace fixe	040	938614	2208593
	Resurse minerale	050		
	Active biologice imobilizate	060		
	Investitii financiare pe termen lung in parti neafiliate	070		
	Investitii financiare pe termen lung in parti afiliate	080		
	Investitii imobiliare	090		
	Creante 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	939751	2209080
	Active circulante			
	Materiale	140		6209

Nr. cpt.	A C T I V	Cod rd.	Sold la	
			Inceputul perioadei de gestiune	Sfirsitul perioadei de gestiune
1	2	3	4	5
2.	Active biologice circulante	150		
	Obiecte de mica valoare si scurta durata	160	51520	47842
	Productia in curs de executie si produse	170		
	Marfuri	180	4809995	5710647
	Creante comerciale	190	5528804	4337729
	Creante ale partilor afiliate	200		
	Avansuri acordate curente	210	2496545	1647170
	Creante ale bugetului	220	26401	166486
	Creante ale personalului	230		
	Alte creante curente	240		
	Numerar in casierie si la conturi curente	250	9066228	8911899
	Alte elemente de numerar	260		
	Investitii financiare curente in parti neafiliate	270		
	Investitii financiare curente in parti afiliate	280		
	Alte active circulante	290	3712	742
	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	21983205	20828724
	Total active (rd.130 + rd.300)	310	22922956	23037804
3.	**Capital propriu**			
	Capital social si suplimentar	320	5400	5400
	Rezerve	330		
	Corectii ale rezultatelor anilor precedenti	340	x	
	Profit nerepartizat (pierdere neacoperita) al anilor precedenti	350	18182879	12119049
	Profit net (pierdere neta) al perioadei de gestiune	360	x	8902416
	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	18188279	21026865
4.	**Datorii pe termen lung**			
	Credite bancare pe termen lung	400		
	Imprumuturi 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		
	Imprumuturi pe termen scurt	460		
	Datorii comerciale	470	3883519	1331928
	Datorii fata de partile afiliate	480		
	Avansuri primite curente	490	135390	159545
	Datorii fata de personal	500	152404	2913
	Datorii privind asigurarile sociale si medicale	510		
	Datorii fata de buget	520	492060	434590
	Venituri anticipate curente	530		
	Datorii fata de proprietari	540		
	Finantari si incasari cu destinatie speciala curente	550		
	Provizioane curente	560		
	Alte datorii curente	570	71304	81963
	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	4734677	2010939
	Total pasive (rd.390 + rd.440 + rd.580)	590	22922956	23037804

SITUATIA DE PROFIT SI PIERDERE

de la pina la

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vinzari	010	27523075	27319617
Costul vinzarilor	020	15709392	15672962
Profit brut (pierdere bruta) (rd.010 – rd.020)	030	11813683	11646655
Alte venituri din activitatea operationala	040		28586
Cheltuieli de distribuire	050	46862	16306
Cheltuieli administrative	060	729327	964136

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Alte cheltuieli din activitatea operationala	070	384100	417394
Rezultatul din activitatea operationala: profit (pierdere) (rd.030 + rd.040 – rd.050 – rd.060 – rd.070)	080	10653394	10277405
Rezultatul din alte activitati: profit (pierdere)	090	10777	-195996
Profit (pierdere) pina la impozitare (rd.080 + rd.090)	100	10664171	10081409
Cheltuieli privind impozitul pe venit	110	1291160	1178993
Profit net (pierdere neta) al perioadei de gestiune (rd.100 – rd.110)	120	9373011	8902416

SITUATIA MODIFICARILOR CAPITALULUI PROPRIU

de la pina la

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la inceputul perioadei de gestiune	Majorari	Diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6	7
1	**Capital social si suplimentar**					
	Capital social	010				
	Capital suplimentar	020				
	Capital nevarsat	030	()	()	()	()
	Capital neinregistrat	040				
	Capital retras	050	()	()	()	()
	Total capital social si suplimentar (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
2	**Rezerve**					
	Capital de rezerva	070				
	Rezerve statutare	080				
	Alte rezerve	090				
	Total reserve (rd.070 + rd.080 + rd.090)	100				
3	**Profit nerepartizat (pierdere neacoperita)**					
	Corectii ale rezultatelor anilor precedenti	110	X			
	Profit nerepartizat (pierdere neacoperita) al anilor precedenti	120				
	Profit net (pierdere neta) al perioadei de gestiune	130	X			
	Profit utilizat al perioadei de gestiune	140	X			
	Rezultatul din tranzitia la noile reglementari contabile	150				
	Total profit nerepartizat (pierdere neacoperita) (rd.110 + rd.120 + rd.130 - rd.140 + rd.150)	160				
4	**Alte elemente de capital propriu, din care**	170				
	Diferente din reevaluare	171				
	Subventii entitatilor cu proprietate publica	172				
	Total capital propriu (rd.060 + rd.100 + rd.160 + rd.170)	180				

SITUATIA FLUXURILOR DE NUMERAR

de la pina la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Fluxuri de numerar din activitatea operationala			
Incasari din vinzari	010		
Plati pentru stocuri si servicii procurate	020		
Plati catre angajati si organe de asigurare sociala si medicala	030		
Dobinzi platite	040		
Plata impozitului pe venit	050		
Alte incasari	060		
Alte plati	070		
Fluxul net de numerar din activitatea operationala (rd.010 – rd.020 – rd.030 – rd.040 – rd.050 + rd.060 – rd.070)	080		
Fluxuri de numerar din activitatea de investitii			
Incasari din vinzarea activelor imobilizate	090		
Plati aferente intrarilor de active imobilizate	100		
Dobinzi incasate	110		
Dividende incasate	120		
Alte incasari (plati)	130		

Indicatori	Cod rd	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Fluxul net de numerar din activitatea de investitii (rd.090 – rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiara			
Incasari sub forma de credite si imprumuturi	150		
Plati aferente rambursarii creditelor si imprumuturilor	160		
Dividende platite	170		
Incasari din operatiuni de capital	180		
Alte incasari (plati)	190		
Fluxul net de numerar din activitatea financiara (rd.150 – rd.160 – rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210		
Diferente de curs valutar favorabile (nefavorabile)	220		
Sold de numerar la inceputul perioadei de gestiune	230		
Sold de numerar la sfirsitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Date generale

Anexa 6

1. Certificat de inregistrare a entitatii, eliberat de Camera Inregistrarii de Stat.
   Numar de inregistrare Data inregistrarii Seria Numar
2. Capital social inregistrat de Camera Inregistrarii de Stat:
   data , suma lei, inclusiv:
   1) cota statului lei,
   2) cota detinatorilor a cel putin 20% Increase lei.
   Modificari ulterioare:
   a) , suma lei, inclusiv cota statului lei,
   b) , suma lei, inclusiv cota statului lei.
3. Entitatile, activitatea carora necesita licenta, indica:
   Licenta in vigoare:

Nr. Ord.	Numar	Data eliberarii	Termen de valabilitate	Tipul de activitate	Organul care a eliberat licenta
1					

4. Numarul mediu scriptic al personalului in perioada de gestiune 6 persoane, inclusiv pe categorii:
   1) personal administrativ 6 persoane,
   2) muncitori persoane.
5. Numarul personalului la 31 decembrie 2019 6 persoane.
6. Remunerarea personalului entitatii in perioada de gestiune 326523 lei.
7. Remunerarea membrilor organelor de administrare, de conducere si supraveghere si alte angajamente aparute sau asumate in legatura cu pensiile membrilor actuali sau ale fostilor membri ai acestor organe, pe categorii lei.
8. Avansurile si creditele acordate membrilor organelor specificate la pct.7 lei, inclusiv rambursate lei.
9. Valoarea activelor imobilizate si circulante, inregistrate in calitate de gaj
   1) valoarea de gaj lei,
   2) valoarea contabila lei.
10. Numarul actiunilor ordinare la finele perioadei de gestiune unitati.
11. Profit net (pierdere neta) a perioadei de gestiune pentru o actiune ordinara:
    1) profit lei,
    2) pierdere lei.
12. Dividende calculate pentru o actiune ordinara pentru perioada de gestiune:
    1) platite lei,
    2) planificate pentru plata lei.
13. Valuta straina disponibila, recalculata in moneda nationala a Republicii Moldova – total lei, inclusiv (lei, denumirea si codul valutei):

Nr. Ord.	lei	denumirea	codul valutei
1			

14. Numerar legat – total lei.
    In rindurile, in care se inscriu sumele de gaj, in toate coloanele prin fractie se reflecta:
    a) la numarator – valoarea de gaj;
    b) la numitor – valoarea contabila

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 1

Creante, investitii financiare si datorii pe termen lung aferente fondatorilor nerezidenti

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune	Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune
			Intrari / majorari	Iesiri / diminuari	Diferente de curs valutar	
1	2	3	4	5	6	7
Creante si investitii financiare pe termen lung - total	010					
Creante comerciale, *inclusiv pe tari:*	020					

1	2	3	4	5	6	7

1	2	3	4	5	6	7
Avansuri acordate, *inclusiv pe tari:*	030					

1	2	3	4	5	6	7
Imprumuturi acordate si creante privind leasingul financiar, *inclusiv pe tari:*	040					

1	2	3	4	5	6	7
Alte creante si investitii financiare, *inclusiv pe tari:*	050					

1	2	3	4	5	6	7
Datorii pe termen lung - total	060					
Datorii comerciale, *inclusiv pe tari:*	070					

1	2	3	4	5	6	7
Avansuri primite, *inclusiv pe tari:*	080					

1	2	3	4	5	6	7
Credite bancare, imprumuturi si datorii privind leasingul financiar, *inclusiv pe tari:*	090					

1	2	3	4	5	6	7
Alte datorii, *inclusiv pe tari:*	100					

Rd.010= rd.020 + rd.030 + rd.040 + rd.050
Rd.060= rd.070 + rd.080 + rd.090 + rd.100
Col.7 = col.3+col.4-col.5±col.6

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 2

Creante, investitii financiare si datorii pe termen lung aferente nerezidentilor, cu exceptia fondatorilor

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune	Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune
			Intrari / majorari	Iesiri / diminuari	Diferente de curs valutar	
1	2	3	4	5	6	7
Creante si investitii financiare pe termen lung - total	010					
Creante comerciale, *inclusiv pe tari:*	020					

1	2	3	4	5	6	7
Avansuri acordate, *inclusiv pe tari:*	030					

1	2	3	4	5	6	7
Imprumuturi acordate si creante privind leasingul financiar, *inclusiv pe tari:*	040					

1	2	3	4	5	6	7
Depozite, *inclusiv pe tari:*	050					

1	2	3	4	5	6	7
Alte creante si investitii financiare, *inclusiv pe tari:*	060					

1	2	3	4	5	6	7
Datorii pe termen lung - total	070					
Datorii comerciale, *inclusiv pe tari:*	080					

1	2	3	4	5	6	7
Avansuri primite, *inclusiv pe tari:*	090					

1	2	3	4	5	6	7

Tabelul 4

Creante, investitii financiare si datorii curente aferente nerezidentilor, cu exceptia fondatorilor

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune		Modificari in perioada de gestiune				Sold la sfirsitul perioadei de gestiune	
		La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an	Total	Transferari din active si datorii pe termen lung in active si datorii curente	Iesiri / diminuari	Diferente de curs valutar	La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an
1	2	3	4	5	6	7	8	9	10
Creante si investitii financiare curente - total	010								
Creante comerciale, *inclusiv pe tari:*	020								

1	2	3	4	5	6	7	8	9	10
Avansuri acordate, *inclusiv pe tari:*	030								

1	2	3	4	5	6	7	8	9	10
Imprumuturi acordate si creante privind leasingul financiar, *inclusiv pe tari:*	040								

1	2	3	4	5	6	7	8	9	10
Depozite, *inclusiv pe tari:*	050								

1	2	3	4	5	6	7	8	9	10
Alte creante si investitii financiare, *inclusiv pe tari:*	060								

1	2	3	4	5	6	7	8	9	10
Datorii curente - total	070								
Datorii comerciale, *inclusiv pe tari:*	080								

1	2	3	4	5	6	7	8	9	10
Avansuri primite, *inclusiv pe tari:*	090								

1	2	3	4	5	6	7	8	9	10
Credite bancare, imprumuturi si datorii privind leasingul financiar, *inclusiv pe tari:*	100								

1	2	3	4	5	6	7	8	9	10
Alte datorii, *inclusiv pe tari:*	110								

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060
Rd.070= rd.080 + rd.090 + rd.100 + rd.110
Col.(9+10) = col.(3+4) + col.5 – col.7 ± col.8

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 5

Investitii financiare in strainatate si participarea nerezidentilor in capitalul social

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune	Intrari/ majorari	Iesiri/ diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6
Investitii financiare	010				
Cote de participatie si actiuni de pina la 10% inclusiv, in capitalul social al entitatilor nerezidente, *inclusiv pe tari:*	020				

1	2	3	4	5	6
Cote de participatie si actiuni de peste 10% in capitalul social al entitatilor nerezidente, *inclusiv pe tari:*	030				

1	2	3	4	5	6

1	2	3	4	5	6	7
Credite bancare, imprumuturi si datorii privind leasingul financiar, *inclusiv pe tari:*	100					

1	2	3	4	5	6	7
Alte datorii, *inclusiv pe tari:*	110					

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.60
Rd.070= rd.080 + rd.090 + rd.100 + +rd.110
Col.7 = col.3+col.4-col.5±col.6

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 3

Creante, investitii financiare si datorii curente aferente fondatorilor nerezidenti

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune		Modificari in perioada de gestiune				Sold la sfirsitul perioadei de gestiune	
		La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an	Total	Transferari din active si datorii pe termen lung in active si datorii curente	Iesiri / diminuari	Diferente de curs valutar	La care termenul de plata nu a sosit sau este expirat pina la un an	Termenul expirat mai mult de un an
1	2	3	4	5	6	7	8	9	10
Creante si investitii financiare curente - total	010								
Creante comerciale, *inclusiv pe tari:*	020								

1	2	3	4	5	6	7	8	9	10
Avansuri acordate, *inclusiv pe tari:*	030								

1	2	3	4	5	6	7	8	9	10
Imprumuturi acordate si creante privind leasingul financiar, *inclusiv pe tari:*	040								

1	2	3	4	5	6	7	8	9	10
Alte creante si investitii financiare, *inclusiv pe tari:*	050								

1	2	3	4	5	6	7	8	9	10
Datorii curente - total	060								
Datorii comerciale, *inclusiv pe tari:*	070								

1	2	3	4	5	6	7	8	9	10
Avansuri primite, *inclusiv pe tari:*	080								

1	2	3	4	5	6	7	8	9	10
Credite bancare, imprumuturi si datorii privind leasingul financiar, *inclusiv pe tari:*	090								

1	2	3	4	5	6	7	8	9	10
Datorii privind dividendele calculate, *inclusiv pe tari:*	100								

1	2	3	4	5	6	7	8	9	10
Alte datorii, *inclusiv pe tari:*	110								

Rd.010= rd.020 + rd.030 + rd.040 + rd.050
Rd.060= rd.070 + rd.080 + rd.090 + rd.100 + rd.110
Col.(9+10) = col.(3+4) + col.5 – col.7 ± col.8

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

1	2	3	4	5	6
Capital social	040				
Cote de participatie si actiuni de pina la 10% inclusiv, *inclusiv pe tari:*	050				

1	2	3	4	5	6
Cote de participatie si actiuni de peste 10%, *inclusiv pe tari:*	060				

Rd.010= rd.020 + rd.030
Rd.040= rd.050 + rd.060
Col.6 = col.3+col.4-col.5

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 6

Venituri si cheltuieli aferente tranzactiilor cu nerezidentii

Indicatori	Cod rd./ cod tara	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri - total	010		
Venituri aferente bunurilor procurate si vindute peste hotare fara trecerea frontierei de stat a Republicii Moldova, *inclusiv pe tari:*	020		

1	2	3	4
Venituri din dobinzi aferente activitatii operationale si altor activitati, *inclusiv pe tari:*	030		

1	2	3	4
Venituri din dividende si participatii in alte entitati,*inclusiv pe tari:*	040		

1	2	3	4
Venituri din decontarea datoriilor cu termenul de prescriptie expirat, *inclusiv pe tari:*	050		

1	2	3	4
Alte venituri, *inclusiv pe tari:*	060		

1	2	3	4
Cheltuieli - total	070		
Cheltuieli aferente bunurilor procurate si vindute peste hotare fara trecerea frontierei de stat a Republicii Moldova, *inclusiv pe tari:*	080		

1	2	3	4
Cheltuieli privind dobinzile, *inclusiv pe tari:*	090		

1	2	3	4
Cheltuieli si provizioane aferente creantelor comerciale si altor creante compromise, *inclusiv pe tari:*	100		

1	2	3	4
Alte cheltuieli, *inclusiv pe tari:*	110		

Rd.010= rd.020 + rd.030 + rd.040 + rd.050 + rd.060
Rd.070= rd.080 + rd.090 + rd.100 + rd.110

Anexa 9

NOTA INFORMATIVA
privind relatiile cu nerezidentii

Tabelul 7

Bunuri ale nerezidentilor inregistrate in conturi extrabilantiere

Indicatori	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune	Intrari/ majorari	Iesiri/ diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6
Bunuri primite in baza contractelor de comision, *inclusiv pe tari:*	010				

1	2	3	4	5	6

1	2	3	4	5	6
Bunuri primite spre prelucrare,*inclusiv pe tari:*	020				

1	2	3	4	5	6
Bunuri obtinute din materialele prelucrate, *inclusiv pe tari:*	030				

Col.6 = col.3+col.4-col.5

Informaţiile privind activele imobilizate

Anexa 7

Indicatori	Nr. rind	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
A	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								
2.1 brevete şi mărci	210								
2.2. licenţe de activitate	220								
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								
5.1. clădiri	510								
5.2. construcţii speciale	520								
5.3. maşini, utilaje, instalaţii de transmisie	530								
inclusiv: tehnică de calcul	531								
5.4. mijloace de transport	540								
5.5. instrumente şi inventar	550								
5.6. costuri 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								
6. Resurse minerale	600								
7. Investiţii imobiliare, total	700								

Persoanele responsabile de semnarea rapoartelor financiare ale entităţii*
* conform art.36 din Legea contabilităţii

Documente atașate - Notă explicativă (fișierul pdf)

Biosistem 2019.pdf

Versiune de imprimare

Salvare

Recipisa 2

Respondent
Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.
A prezentat raportul: RSF1
Pentru perioada fiscala: A/2019
Data prezentarii: 31.03.2020
Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 21.05.2020 10:13:29

Biroul Național de Statistică (BNS) a recepționat varianta electronică a raportului, expediat de DVs. Urmează verificarea și validarea raportului de către specialistul BNS pe domeniu.

Versiune de imprimare

Salvare

Recipisa

Respondent
Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.
A prezentat raportul: RSF1
Pentru perioada fiscala: A/2019
Data prezentarii: 31.03.2020
Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 31.03.2020 17:42:37

BIOSISTEM-MLD S.R.L.
Cod Fiscal: 1010600028048; IBAN: MD95ML000000002251429243;
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;
Adresa poştală a băncii: mun. Chişinău, bd. Moscovei, 14/1;

Către Grupul de lucru pentru evaluarea
licitației publice Nr. ocds-b3wdp1-MD-1606391187523
din 1 dec 2020, 13:00 - 7 dec 2020, 11:30
din cadrul IP Universitatea de Stat de Medicină și
Farmacie ”Nicolae Testemițanu”

Declarație

Prin prezenta, SRL „Biosistem-MLD”, declara ca:

- Va asigura transportarea și descărcarea bunurilor la depozitul/sediul indicat de către Cumpărător;
- Termenul de valabilitate al reactivelor și consumabilelor ce au termen de valabilitate, la momentul livrării, nu va fi mai mic de min 80% din termenul de valabilitate total al produsului, cu excepția loturilor pentru care este indicat termenul minim de valabilitate în Anexa nr. 1;

04.12.2020 _____Poiata Vitalie

L.Ş.

adresa: str. Albișoara 16/1 of.7, MD-2001 Chișinău, Republica Moldova
tel.+373-22-808517, +373-22-808719, fax +373-22-808519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

CE CE

Declaration of Conformity

Manufacturer:	Lansion Biotechnology Co., Ltd. Add: No.2, Qiande Road, Science Park, Jiangning District, 210000 Nanjing, Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA Tel: 025-58577660
Authorized Representative:	Llins Service & Consulting GmbH Obere Seegasse 34/2, 69124, Heidelberg, Germany

We declare under our sole responsibility that:

Product Name:	HbA1c Test Kit (Dry Fluorescence Immunoassay)
Type/Model:	25T
Classification:	Others
Conformity Assessment Peocedure:	Directive 98/79/EC Annex III

We herewith declare that the product meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

Medical Device Directive: COUNCIL DIRECTIVE 98/79/EC of 27 October 1998 concerning medical devices (IVDD 98/79/EC) and its transpositions in national laws which apply to it.

Nanjing, China March, 12,2020

Place, Date

Signature

南京岚煜生物科技有限公司 20115093554

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

Product Service

Certificate

No. Q5 002596 0002 Rev. 00

Holder of Certificate:

Lansion Biotechnology Co., Ltd.
No.2 Qiande Road, Science Park, Jiangning District
210000 Nanjing, Jiangsu Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Lansion Biotechnology Co., Ltd.
No.2 Qiande Road, Science Park, Jiangning District, 210000
Nanjing, Jiangsu Province, 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
Dry Fluorescence Immunoassay Analyzer,
Dry Fluorescence Immunoassay test kits,
Hemagglutination Assay Kit(electrochemical method), Handheld coagulation Analyzer**

Applied Standard(s):

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

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.: SH19126603
Valid from: 2020-02-26
Valid until: 2021-04-02

Date, 2020-02-26

Christoph Dicks
Head of Certification/Notified Body

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

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

CERTIFICATE

Number: 2090418

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

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

including the implementation meets the requirements of the standard:

EN ISO 13485:2016
ISO 9001:2015

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

Certificate expiry date: 1 July 2021
Certificate effective date: 1 July 2018
Certified since: 1 July 2006

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

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

MGMT. SYS.
RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

ADDENDUM

To certificate: 2090418

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

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Certified organization(s) and/or locations:

	Different scope
Medtronic Portugal LDA- Rua Tomas da Fonseca Torre E, 11 piso 1600 Lisboa Portugal	Sales, Order Management and distribution of medical devices including technical service and customer education. Warehousing and distribution of medical devices, including spine loaner operations
Medtronic Italia S.p.A. Via Varesina 162 20156 Milano Italy	Sales, order management and distribution of medical devices. Including technical service and customer education. Promotion, invoice and order management of medicinal products.
Medtronic Danmark A/S. Arne Jacobsens Allé 17 2300 Kopenhagen Denmark	Sales, order management and distribution of medical devices. Including technical service and customer education
Medtronic Medikal Teknoloji Ticaret Ltd Sti Saray Mah. Esnaf Sk. Akkom Ofis Park Laodik Plaza Sitesi B Blok Apt: 2/8 00000 Umraniye - Istanbul Turkey	Sales, order management and distribution of medical devices. Including technical service and customer education

ADDENDUM

To certificate: 2090418

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

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Africa (Pty) Ltd. Waterfall Distribution Campus CNR K101 and Bridal Veil Road Waterfall Midrand 1685 Gauteng South Africa	Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.
Medtronic Ibérica S.A. Calle de María de Portugal, 11 28050 Madrid Spain	Sales, order management, warehousing and distribution of medical devices. Including technical service, customer education and spine loaner operations.
Medtronic Romania SRL Ploiesti 42-44, Building B, B2 Wing, 2nd floor, district 1 Baneasa Business & Technology Park 013696 Bucharest Romania	Sales, order management and distribution of medical devices. Including technical service and customer education.
Medtronic Norge AS Martin Linges vei 25 1364 Fornebu Norway	Sales, order management and distribution of medical devices. Including technical service and customer education.
Medtronic Portugal, LDA- Avenida Gomes Pereira 61B Benfica 1600 Lisboa Portugal	Sales, Order Management and distribution of medical devices Including technical service and customer education. Warehousing and distribution of medical devices, including spine loaner operations.

ADDENDUM

To certificate: 2090418

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

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Service & Repair CoE C-Mill gebouw K Jan Campertstraat 21-A 6416 SG Heerlen	Service and repair of medical devices (excluding Imaging and Navigation products).
Medtronic Ibérica S.A. Polígono Industrial La Garena Calle Francisco Rabal 7 28806 Alcalá De Heneras, Madrid Spain	Spine loaner operations.
Medtronic Ibérica S.A. WTC Almeda Park Placa de la Pau, s/n. Edificio 7, 3 piso 08940 Cornellà de Llobregat, Barcelona Spain	Warehousing and distribution of medical devices, including spine loaner operations
Medtronic France SAS 27/33 Quai Alphonse Le Gallo 92513 Boulogne-Billancourt France	Sales, order management and distribution of medical devices. Including technical Service and customer education
Medtronic Trading NL B.V. Larixplein 4 5616 VB Eindhoven	Sales, order management and distribution of medical devices. Including technical service and customer education
Medtronic GmbH Earl-Bakken-Platz 1 40670 Meerbusch Germany	Distribution of medical Devices, medical equipment and related services.

ADDENDUM

To certificate: 2090418

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

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Osterreich GmbH Milennium Tower, 20th floor Handelskai 94-96 1200 Wien Austria	Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education
Medtronic (Schweiz) AG Talstrasse 9 3053 Munchenbuchsee Switzerland	Sales, order management, warehousing and distribution of medical devices. Including technical Service and customer education
Medtronic Hellas S.A. Avenue Kifisias 24 Building B 151 25 Marousi Pref. Attica Greece	Sales, order management and distribution of medical devices. Including technical service and customer education.
Medtronic Serbia Ltd. Bulevar Zorana Djindjica, 64a 11070 Belgrade Serbia	Sales, order management and distribution of medical devices.
Medtronic Hungária Kft. Bocskai út 134-146 Cépület 3. emelet 1113 Budapest Hungary	Sales, order management and distribution of medical devices. Including customer education.
Medtronic CCO SSC Warsaw Polna 11 00-633 Warszawa Poland	Order management of medical devices.

ADDENDUM

To certificate: 2090418

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

Medtronic EMEA Medtronic B.V.

Earl Bakkenstraat 10
6422 PJ Heerlen

Medtronic Finland Oy Lentäjäntie 3 01530 Vantaa Finland	Sales, order management and distribution of medical devices. Including technical service and customer education.
Medtronic AB P.O. Box 1034 164 21 Kista Sweden	Sales, order management and distribution of medical devices. Including technical service and customer education
Medtronic Trading Ltd. 10 Hamada Street 4673344 Herzlya Israel	Import, sales, order management and distribution of medical devices. Including technical service and customer education

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

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

Product Service

EC Certificate

Full Quality Assurance System

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

No. G1 16 02 77608 012

Manufacturer:

Covidien llc
15 Hampshire Street
Mansfield, MA 02048
USA

EC-Representative:

Covidien Ireland Limited
IDA Business and Technology Park
Tullamore
IRELAND

Product Category(ies):

Medical Instruments, Surgical Products and Hemostatic Materials:

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

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

Report No.: 713078138

Valid from: 2016-04-17
Valid until: 2021-04-16

Date, 2016-04-05

Stefan Preiß

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

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

Product Service

EC Certificate
Full Quality Assurance System

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

No. G1 16 02 77608 012

Facility(ies):

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

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

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

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

Covidien
60 Middletown Avenue, North Haven CT 06473, USA

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

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 13485:2016
EN ISO 13485:2016

For the following activities

Design, manufacture and sale of sterile and nonsterile medical devices for the collection, transport and conservation of biological samples for clinical and IVD analysis.
Distribution of non-active medical devices and in vitro diagnostic medical devices.

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.
Distribución de productos sanitarios no activos y productos sanitarios para diagnóstico in vitro.

This certificate is valid from 11 October 2019 until 11 October 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 10 September 2022
Issue 9. Certified since 12 October 2010

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

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

HC SGS 13485 2016 0118

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Certificate ES16/20725

The management system of

DELTALAB GROUP

DELTALAB, S.L., KEYLAB, S.L.U., NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A.

Pol. Ind. La Llana
Plaza de la Verneda, 1
08191 Rubí, Barcelona

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis, general labware, containers and healthcare products. Manufacture and commercialization of consumables for the laboratory. Commercialization and distribution of equipment for the storage of prepared samples, cryogenic stored samples, syringes, general labware and industrial packages. Commercialization and distribution of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes. Commercialization, distribution, installation and technical service of equipment and instrumentation for the laboratory.

This certificate is valid from
11 October 2019 until 11 October 2022.
Issue 4. Company certified since October 2010.
Certified with SGS since 11 October 2016.

This is a multisite certification. See following page(s).

Authorised by

Certification Management

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.
C/Trespaderne, 29 28042 Madrid España
t 3491 313 8115 f 34 91 313 8102 www.sgs.com

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Certificate ES16/20725

DELTALAB GROUP

DELTALAB, S.L., KEYLAB, S.L.U., NIRCO, S.L., ENVASES FARMACÉUTICOS, S.A.

ISO 9001:2015

Issue 4

Sites where these activities are totally or partially carried out

DELTALAB, S.L.
Pol. Ind. La Llana, Plaza de la Verneda, 1 – 08191 Rubí, Barcelona (España)

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.
Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes.

KEYLAB, S.L.U.
Pol. Ind. La Llana, Avda. de la Llana, 115-117 – 08191 Rubí -Barcelona (España)

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.
Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes.

NIRCO, S.L.
Pol. Ind. Expansión, Puerto de Navafría, 12 - 28935 Móstoles -Madrid (España)
Pol. Ind. La Llana, Avda. de la Llana, 115-117 – 08191 Rubí -Barcelona (España)

Manufacture and commercialization of consumables for the laboratory.
Commercialization and distribution of diagnostic kits
Commercialization, distribution, installation and technical service of equipment and instrumentation for the laboratory.

ENVASES FARMACÉUTICOS, S.A.
C/ Paralela, 15 - 28860 Paracuellos de Jarama (Madrid)

Design, manufacture and commercialization of laboratory material for the collection, transport and conservation of samples for analysis, laboratory material for general use, containers and products for personal care
Commercialisation and distribution of laboratory material for general use, products and equipment for personal care, syringes and cosmetic products.

Certificate ES16/20725.01

DELTALAB, S.L.

Pol. Ind. La Llana
Plaza de la Verneda, 1
08191 Rubí, Barcelona

has been assessed as part of the management system of DELTALAB GROUP certified organization as meeting the requirements of

ISO 9001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, hematology, biochemistry, histology, microscopy and colorimetric analysis. Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages. Commercialization of equipment and instrumentation for the laboratory, diagnostic kits, healthcare products, cosmetics and food for special medical purposes.

in / from the following sites

Pol. Ind. La Llana, Plaza de la Verneda, 1 - 08191 Rubi (Barcelona)

Valid from
11 October 2019 until 11 October 2022.
Issue 1.

This document is part of Certificate ES16/20725.
The validity of this document is subject to the certificate.

CERTIFICACIÓN
Nº 05 / C - SC001

Authorized by

Certification Management

SGS INTERNATIONAL CERTIFICATION SERVICES IBERICA, S.A.U.
C/Trespaderne, 29. 28042 Madrid. España.
t 34 91 313 8115 f 34 91 313 8102 www.sgs.com

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[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

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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:

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
Tel. +34 93 586 20 000. F. +34 93

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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08191 Rubí - Barcelona
T. +34 936 995 000, F. +34 936 994 512

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*
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*

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

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

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REF	DESCRIPCIÓN	DESCRIPTION
409852	FRASCO 50ML PP CON ESPATULA	50ML CONTAINER WITH SPOON PP
409902	FRASCO 200ML PP	200ML CONTAINER PP
409905	FRASCO 200ML PP AZUL TRANS. ETI	CONTAINER 200 ML PP BLUE-PLAIN LBL
409915	FRASCO 200ML PP AZUL TRANS S/E	CONTAINER 200 ML PP BLUE
409926	FRASCO 200ML PP B/U	200ML CONTAINER PP I/W
410046	FRASCO 50 ML PP T/PRECINTO	TAMPER EVIDENT CONT.50ml H80mm
410047	FRASCO T/BISAGRA 50ml H=80mm	HINGED LID CONT.50ml H=80mm
410056	FRASCO PRECINTO 50ml H80mm B/U	HINGED LID CONT.50ml H80mm I/B
419802	FRASCO 50ML PP T/PRECINTO	50ML CONT SEALED CAP PP
419805	FRASCO 50ML PP T/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

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

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REF	DESCRIPCIÓN	*DESCRIPTION*
409502G.4	FR.60 GRAD.S/ROSCAR TAP.SEPARA	*CONT.60 GRAD.UNCAPPED SEP.CAP*
409507G	FRASCO 60ml PP GRAD.T/VERDE	*60ml CONT.PP GRAD.GREEN CAP*
409511.4	FR.60ML AZUL CLARO S/ETIQUETA	*60ML LIGHT BLUE CONTAINER*
409511.5	FR.60ML AZUL 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*

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

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DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / *The manufacturer*:

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

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

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

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

Código GMDN / *GMDN Code:* 58139

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

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

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

José Saez
Director General / *Managing Director*

Anna Mir
Responsable Técnico / *Technical Director*

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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*

deltalab

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

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:

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

EC Certificate

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

Registration No.: HD 60147050 0001

Report No.: 26300270 016

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

Products: (see attachments for products and site included)

Replaces approval, registration no.: HD 60100981 0001

Expiry Date: 2024-05-26

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

Effective Date: 2020-02-25

Date: 2020-02-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Sebastian Mniszek

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: **HD 60147050 0001**
Report No.: **26300270 016**

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

Products included)

- Reusable endoscopic surgical instruments
- Disposable endoscopic surgical instruments
- Disposable linear cutting staplers with cartridges
- Disposable linear staplers with cartridges
- Disposable circular staplers with related surgical instruments
- Staples cartridges for reusable circular staplers
- Staples cartridges for reusable linear staplers
- Ligating clips
- Surgical meshes
- Cartridges for disposable endoscopic linear cutting staplers
- Disposable endoscopic linear cutting staplers
- Staples cartridge for reusable linear cutting staplers
- Ligating clip cartridge to be used with reusable automatic clip appliers

Notified Body

Date: 2020-02-25

Sebastian Mniszek

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: **HD 60147050 0001**
Report No.: **26300270 016**

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

Site included:

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

Activity: Desing, development and manufacture

Notified Body

Date: 2020-02-25

Sebastian Mniszek

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

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EC Certificate

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

Registration No.: DD 60147049 0001

Report No.: 26300270 017

Manufacturer:

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

Products: (see attachments for products and site included)

Replaces EC Certificate, registration no.: DD 60100980 0001

Expiry Date: 2024-05-26

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

Effective Date: 2020-02-25

Date: 2020-02-25

TÜV Rheinland LGA Products GmbH
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Zertifizierungsstelle

Notified Body

Sebastian Mniszek

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

Attachment to Certificate
Registration No.: **DD 60147049 0001**
Report No.: **26300270 017**

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

Products included:

- Disposable trocars
- Retrieval bags
- Veress needles
- Disposable wound protectors /retractors

Notified Body

Date: 2020-02-25

Sebastian Mniszek

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

Attachment to Certificate
Registration No.: **DD 60147049 0001**
Report No.: **26300270 017**

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

Site included:

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

Notified Body

Date: 2020-02-25

Sebastian Mniszek

TÜV Rheinland LGA Products GmbH
TÜVRheinland
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