



REPUBLICA MOLDOVA

LICENȚĂ

Seria A MMII

Nr. 044322

Denumirea autorității de licențiere

Camera de Licențiere

Denumirea, forma juridică de organizare, sediul (adresa juridică) a titularului de licență

**Societatea cu Răspundere Limitată
"BIOSISTEM MLD"**

mun. Chișinău, str. Albișoara, 16/1, ap. 7

Data și numărul certificatului de înregistrare de stat a titularului de licență

12.08.2010 MD 0101250

Numărul de înregistrare a întreprinderii sau IDNO

1010600028048

Codul fiscal

Genul de activitate, integral sau parțial, pentru a cărui desfășurare se eliberează licența

*** Importul, comercializarea, asistența tehnică și reparația dispozitivelor medicale ***

Data eliberării licenței

4 octombrie 2010

Reperfectată: 1)19.10.2012; 2)14.05.2014

Valabilă pînă la

4 octombrie 2015

Prelungită pînă la: 03.10.2020

**Semnătura conducătorului
autorității de licențiere**

Director al Camerei de Licențiere

Valentin GUZNAC



Notă: Licența este valabilă numai cu anexa autenticată de autoritatea de licențiere, în care sînt indicate condițiile de licențiere pentru genul de activitate specificat în licență.



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

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

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

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московской, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent
in moneda nationala al “BIOSISTEM MLD” S.R.L. (c/f 1010600028048), cu
IBAN MD95ML000000002251429243.

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

L. Svirepova
semnătura

MD 0101250





„CAMERA ÎNREGISTRĂRII DE STAT” Î.S.
Secția fonduri speciale și informații curente

EXTRAS
din Registrul de stat al persoanelor juridice

nr. 14419 din 11.07.2016

Denumirea completă: **Societatea cu Răspundere Limitată «BIOSISTEM MLD».**

Denumirea prescurtată: «BIOSISTEM MLD» S.R.L.

Forma juridică de organizare: **Societate cu Răspundere Limitată.**

Numărul de identificare de stat și codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

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

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

- 1 Activitatea farmaceutică;**
- 2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;**
- 3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;**
- 4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;**
- 5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;**
- 6 Consultații în domeniul sistemelor de calcul.**

Capitalul social: **5400 lei.**

Administrator: POIATA VITALIE, IDNP 0983103892591,

Asociați:

- 1. POIATA VITALIE , IDNP 0983103892591**
cota 1803.60 lei, ce constituie 33,4 %
- 2. NASEDCHIN ALEXANDR , IDNP 2002001070747**
cota 1798.20 lei, ce constituie 33,3 %
- 3. KOJEVNIKOV DMITRII , IDNP 0972305012362**
cota 1798.20 lei, ce constituie 33,3 %.

Prezentul extras este eliberat în temeiul art. 34 al Legii nr. 220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: 11.07.2016.

Specialist principal
tel. 022-266-252


Lazari Aliona



Lista fondatorilor Biosistem-mld SRL

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

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ **A2011484**

din
от **20.05.2020**

1. Destinația / Назначение

Pentru proceduri de achiziții 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 04.06.2020

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

**Șef DDF Rîșcani
a DGAF mun.Chișinău**

Funcția/Doljnost

L.S/ М.П.
Svetlana SLONOVSCAIA
Executor:

Numele și prenumele/Фамилия и имя



Семіатура/Подпись

Ana STOICOV

Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 20.05.2020 ora 12:01:21
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,37)

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-----:
ORDIN DE PLATA NR.: 226                                TIP.DOC. 1 :
                                DATA EMITERII:26 mai 2020 :
=====:
PLATITI: 1500-00                                LEI: Una Mie Cinci Sute lei 00 bani :
:
:
=====:
PLATITOR: (R) "BIOSISTEM                                CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L.                                MD95ML000000002251429243 :
                                CODUL FISCAL :1010600028048 / :
:
:
=====:
PRESTATORUL PLATITOR                                CODUL BANCII:
BC"Moldindconbank"S.A. suc."Invest" Chisinau                                :MOLDMD2X329:
=====:
BENEFICIAR (R)USMF "Nicola                                CONTUL DE PLATI/CODUL IBAN :
e Testemitanu" IP                                MD19AG0000000022512015544 :
                                CODUL FISCAL :1007600000794 / :
:
:
=====:
PRESTATORUL BENEFICIAR                                CODUL BANCII:
BC"MOLDOVA-AGROINDBANK"S.A.                                :AGRNMD2X :
=====:
DESTINATIA PLATII: Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la „procedura de achizi?ie publi: NORMAL/URGENT :N:
ca nr. ocds-b3wdp1-MD-1587029359985 din : :
28.05.2020 : :
: :
: L.S. :
=====:
                                CODUL TRANZACTIEI:001: :
DATA PRIMIRII:26/05/2020 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
:-----:
CONDUCTOR:Web Poiata Vitalie :
MIIGQQYJKoZiIhvcNAQcCoIIGMjCCBi4CAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB :
DQEHAaCCBEowggRGMIIIDLqADAgECAhNHAABcVycdZVmKkP29AAAAAFxXMA0GCSq :
SIB3DQEBcWUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4 :
DTE5MDEyODEwMTYyOFoXDTIxMDEyODEwMjYyOFowfjELMAkGA1UEBhMCTUQxGjA :
gNVBAoTEUJpb3Npc3RlbSBNTEQgU1JMMRIwEAYDVQQLEwkwNjkyMDAzMTQxZjZA :
:
: (semnatura electronica) :
CONTABIL-SEF:Web Nasedchin Alexandr :
MIIGUgYJKoZiIhvcNAQcCoIIGQzCCBj8CAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3 :
DQEHAaCCBFswggRXMIIDP6ADAgECAhNHAABcVpWe/gMeSmneAAAAAFxWMA0GCSqG :
SIB3DQEBcWUAMCIxIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X :
DTE5MDEyODEwMTQwNFoXDTIxMDEyODEwMjYyOFowfjY4xCzAJBgNVBAYTAk1EMScw :
YDVQQKEEx5NzWR1Y29yIFNSTCwgQmlvc2lzdGVtIE1MRCBTUkwxEjAQBGNVBAsT :
:
: L.S. (semnatura electronica) :
CONDUCTOR: :
: (semnatura manuala) :
CONTABIL-SEF: :
: (semnatura manuala) :
SEMNATURA PRESTATORUL L.S. :
:-----:
MOTIVUL REFUZULUI : L.S. :
-----:

```

**Către Grupul de lucru pentru evaluarea
licitației publice Nr. ocds-b3wdp1-MD-1587029359985
din 28.05.2020
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
- are experiență specifică în livrarea bunurilor similare minim 3 ani
- 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

_____ Poiata Vitalie

L.Ș.

Nr. cpt.	ACTIV	Cod rd.	Sold la	
			inceputul perioadei de gestiune	Sfirsitul perioadei de gestiune
1	2	3	4	5
	Total capital propriu (rd.320 + rd.330 + rd.340 + rd.350 + rd.360 - rd.370 + rd.380)	390	18188279	21026865
	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		
	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 asigurările sociale și 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

pina la

Показатели	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vinzari	010	27523075	27319617
Costul vinzariilor	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
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	10772	-135996
Profit (pierdere) pina la impozitare (rd.080 + rd.090)	100	10664171	10081409
Cheltuieli privind impozitul pe venit	110	1281160	1178993
Profit net (pierdere neta) al perioadei de gestiune (rd.100 - rd.110)	120	9373011	8902416

SITUATIA MODIFICARILOR CAPITALULUI PROPRIU

pina la

№ n/n	Показатели	Cod rd	Sold la			
			inceputul perioadei de gestiune	Majorari	Diminuari	Sold la sfirsitul perioadei de gestiune
1	2	3	4	5	6	7
	Capital social si suplimentar					
	Уставный капитал	010				
	Добавочный капитал	020				
	Capital nevarsat	030	0	0	0	0
	Capital neinregistrat	040				
	Изъятый капитал	050	0	0	0	0
	Total capital social si suplimentar (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
	Резервы					
	Capital de rezerva	070				
	Rezerve statutare	080				
	Alte rezerve	090				
	Total reserve (rd.070 + rd.080 + rd.090)	100				
	Profit nerepartizat (pierdere neacoperita)					
	Contestiile 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				
	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

pina la

Показатели	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		
Dobanzi plătite	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		

Дата предоставления 21.05.2020 10:13:29 SITUATIILE FINANCIARE

2019 pentru perioada 01.01.2019 - 31.12.2019 de lichidare
НАЦИОНАЛЬНОЕ БЮРО СТАТИСТИКИ

Entitatea: BIOSISTEM MLD S.R.L.
Sediul: SEC BISCANI, STR ALBISOARA NR.16 BL.1 OF.7
Район: Муниципальный 126, ГОР. BISCANI
Село (коммуна): Улица SEC BISCANI, STR ALBISOARA NR.16 BL.1 OF.7
Cod postal: 2001
Cod CUATM: 0150, SEC BISCANI
Activitatea principala: 6464, Comerț cu ridicata al produselor farmaceutice
Forma proprietății: 16, Proprietate colectivă
Forma organizatorico-juridică: 330, Societate cu răspundere limitată
Cod OKPD: 40717392
Фискальный код: 3010600028048
WEB:
Numele și coordonatele al contabilului-șef: Nasedchin Alexandr
Телефон: +37322898719
Numărul mediu scriptic al personalului în perioada precedentă: 6 лиц

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

Unitatea de masura: lei

Notă informativă privind veniturile și cheltuielile clasificate după natură

Показатели	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		
Variata stocurilor	050		
Costul vinzariilor marfurilor vandute	060		
Cheltuieli privind stocurile	070		
Cheltuieli cu personalul privind remunerarea muncii	080		
Contributiile de asigurari sociale de stat obligatorii si prime de asigurare obligatorie de asistenta medicala	090		
Cheltuieli cu amortizarea si deprecierea activelor imobilizate	100		
Другие расходы	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.	ACTIV	Cod rd.	Sold la	
			inceputul perioadei de gestiune	Sfirsitul perioadei de gestiune
1	2	3	4	5
	Active imobilizate			
	Imobilizari necorporale	010	1137	487
	Imobilizari corporale in curs de executie	020		
	Земля	030		
	Основные средства	040	938614	2208593
	Минеральные ресурсы	050		
	Долгосрочные биологические активы	060		
	Investitii financiare pe termen lung in parti neafiliate	070		
	Investitii financiare pe termen lung in parti afiliate	080		
	Investitii imobilizabile	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			
	Материалы	140		6209
	Оборотные биологические активы	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
	Capital propriu			
	Capital social si suplimentar	320	5400	5400
	Резервы	330		
	Contestiile ale rezultatelor anilor precedenti	340		
	Profit nerepartizat (pierdere neacoperita) al anilor precedenti	350	18182879	12119049
	Profit net (pierdere neta) al perioadei de gestiune	360		8902416
	Profit utilizat al perioadei de gestiune	370		
	Прочие элементы собственного капитала	380		

1	2	3	4	5	6	7
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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

Показатели	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune		Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune
		Intrari / majorari	lesiri / 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	
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

Показатели	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	Bcero	Transferari din active si datorii pe termen lung in active si datorii curente	lesiri / diminuari	Diferente de curs valutar	La care termenul de plata nu a sosit sau este expirat pina la un an
1	2	3	4	5	6	7	8	9
Creante si investitii financiare curente - total	010							
Creante comerciale, inclusiv pe tari:	020							
1	2	3	4	5	6	7	8	9
Avansuri acordate, inclusiv pe tari:	030							
1	2	3	4	5	6	7	8	9
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040							
1	2	3	4	5	6	7	8	9
Alte creante si investitii financiare, inclusiv pe tari:	050							
1	2	3	4	5	6	7	8	9
Datorii curente - total	060							
Datorii comerciale, inclusiv pe tari:	070							
1	2	3	4	5	6	7	8	9
Avansuri primite, inclusiv pe tari:	080							
1	2	3	4	5	6	7	8	9
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	090							
1	2	3	4	5	6	7	8	9
Datorii privind dividendele calculate, inclusiv pe tari:	100							
1	2	3	4	5	6	7	8	9
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

Показатели	Cod rd	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Fluxuri de numerar din activitatea de investitii			
Incasari din vnzarea activelor imobilizate	090		
Plati aferente intrarilor de active imobilizate	100		
Dobziri incasate	110		
Dividende incasate	120		
Alte incasari (plati)	130		
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		

Anexa 6

Date generale

- Certificat de inregistrare a entitatii, eliberat de Camera Inregistrarii de Stat.
Numar de inregistrare Data inregistrarii Seria Numar
- Capital social inregistrat de Camera Inregistrarii de Stat:
Asta - suma lei, inclusiv:
1) cota statului neș,
2) cota detinatorilor a cel puțin 20% increase neș.
Modificari ulterioare:
a) suma lei, inclusiv cota statului neș,
b) suma lei, inclusiv cota statului neș.
- Entitatele, activitatea carora necesita licenta, indica:
Licenta in vigoare:
Nr. Ord. neș / Data eliberarii / Valabilitate / Tipul de activitate / Organul care a eliberat licenta
- Numarul mediu scrisic pe personalului in perioada de gestiune ș persoane, inclusiv pe categorii:
1) personal administrativ ș persoane ș,
2) muncitori ș persoane ș.
- Numarul personalului la 31 decembrie 2019 ș persoane ș.
- Remunerarea personalului entitatii in perioada de gestiune ș26523 neș.
- Remunerarea membrilor organelor de administrare, de conducere si supraveghere si alte angajamente aparute sau asumate in legatura cu pensile membrilor actuali sau ale fostilor membri ai acestor organe, pe categorii neș.
- Avansurile si creditele acordate membrilor organelor specificate la pct.7 lei, inclusiv rambursate neș.
- Valoarea activelor imobilizate si circulante, inregistrate in calitate de gaj
1) valoarea de gaj neș,
2) valoarea contabila neș.
- Numarul actiunilor ordinare la finele perioadei de gestiune unitati.
- Profit net (pierdere neta) a perioadei de gestiune pentru o actiune ordinara:
1) profit neș,
2) pierdere neș.

Anexa 9

**NOTA INFORMATIVA
privind relatiile cu nerezidentii**

Tabelul 1

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

Показатели	Cod rd./ cod tara	Sold la inceputul perioadei de gestiune		Modificari in perioada de gestiune			Sold la sfirsitul perioadei de gestiune
		Intrari / majorari	lesiri / 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	
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						

1	2	3	4
Venituri din dividende si participatii in alte entitati, inclusiv pe tari:	040		
1	2	3	4
Venituri din decontarea datorilor cu termenul de prescriptie expirat, inclusiv pe tari:	050		
1	2	3	4
Другие доходы, inclusiv pe tari:	060		
1	2	3	4
Cheltuieli - total			
Cheltuieli aferente bunurilor procurate si vindute peste hotare fara trecerea frontierei de stat a Republicii Moldova, inclusiv pe tari:	070		
	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
Другие расходы, 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

**NOTA INFORMATIVA
privind relatiile cu nerezidentii**

Bunuri ale nerezidentilor inregistrate in conturi extrabilantiere

Показатели	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				
Bunuri primite spre prelucrare, inclusiv pe tari:	020				
Bunuri obtinute din materialele prelucrate, inclusiv pe tari:	030				

Anexa 9

Tabelul 7

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

Informatiile privind activele imobilizate

Показатели	Nr. строки	Existenta la inceputul perioadei (la costul de intrare)	Amortizarea acumulata la inceputul perioadei	Deprecierea acumulata la inceputul perioadei	Intrarea in cursul perioadei (la costul de intrare)	Iesirea in cursul perioadei (la costul de intrare)	Existenta la sfirsitul perioadei (la costul de intrare)	Amortizarea acumulata la sfirsitul perioadei	Deprecierea acumulata la sfirsitul perioadei
A	1	2	3	4	5	6	7	8	9
1. Imobilizari necorporale in curs de executie	100								
2. Imobilizari necorporale in utilizare, total inclusiv:	200								
2.1. brevete si mārci	210								
2.2. licențe de activitate	220								
2.3. programe informatice	230								
3. Imobilizari corporale in curs de executie	300								
4. Terenuri	400		x						
5. Mijloace fixe, total din care:	500							x	
5.1. cladiri	510								
5.2. constructii speciale	520								
5.3. masini, utilaje, instalatii de transmisie inclusiv: tehnică de calcul	530								
5.4. mijloace de transport	540								
5.5. instrumente si inventar	550								
5.6. costuri ulterioare aferente obiectelor neinregistrate in bilanț	560								
5.7. mijloace fixe primite in leasing financiar	570								
5.8. mijloace fixe primite in gestiune economică	580								
5.9. alte mijloace fixe	590								
6. Resurse minerale	600								
7. Investitii imobiliare, total	700								

Persoanele responsabile de semnarea rapoartelor financiare ale entitatii*
* conform art.36 din Legea contabilitatii.

Documente atasate - Notă explicativă (fișierul pdf)

Biosistem 2019.pdf

Anexa 7

Anexa 9

Tabelul 5

Col.(9+10) = col.(3+4) + col.5 - col.7 ± col.8

**NOTA INFORMATIVA
privind relatiile cu nerezidentii**

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

Показатели	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 pînă la un an	Termenul expirat mai mult de un an	Всего	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 pînă 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									
Avansuri acordate, inclusiv pe tari:	030									
Imprumuturi acordate si creante privind leasingul financiar, inclusiv pe tari:	040									
Depozite, inclusiv pe tari:	050									
Alte creante si investitii financiare, inclusiv pe tari:	060									
Datoriile curente - total	070									
Datorii comerciale, inclusiv pe tari:	080									
Avansuri primite, inclusiv pe tari:	090									
Credite bancare, imprumuturi si datorii privind leasingul financiar, inclusiv pe tari:	100									
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

**NOTA INFORMATIVA
privind relatiile cu nerezidentii**

Investitii financiare in strainatate si participarea nerezidentilor in capitalul social

Показатели	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 pînă la 10% inclusiv, in capitalul social al entitatilor nerezidente, inclusiv pe tari:	020				
Cote de participatie si actiuni de peste 10% in capitalul social al entitatilor nerezidente, inclusiv pe tari:	030				
Уставный капитал	040				
Cote de participatie si actiuni de pînă la 10% inclusiv, inclusiv pe tari:	050				
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

**NOTA INFORMATIVA
privind relatiile cu nerezidentii**

Venituri si cheltuieli aferente tranzactiilor cu nerezidentii

Показатели	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		
Venituri din dobinzi aferente activitatii operationale si altor activitati, inclusiv pe tari:	030		

Anexa 9

Tabelul 6

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

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

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

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

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

THE HEAD OF THE DEPARTMENT OF SANITARY PRODUCTS

[Illegible signature]

M^a del Carmen Abad Luna

EMAIL
mpizarro@aemps.es

[Seal: Spanish State Agency of
Medication and Sanitary Products]
Page 1/1

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

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

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

MARTA CASANOVA HERNANDEZ
Traductora-Intérprete Jurada de INGLÉS

Marta Casanova

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

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

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

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

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


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

- | | |
|--|---|
| • K3E/EDTA 3K (anticoagulante) | • K3E/EDTA 3K (anticoagulant) |
| • K2E/EDTA 2K (anticoagulante) | • K2E/EDTA 2K (anticoagulant) |
| • 4NC/CITRATO 3Na (anticoagulante) | • 4NC/Citrate 3Na (anticoagulant) |
| • 9NC/CITRATO 3Na (anticoagulante) | • 9NC/Citrate 3Na (anticoagulant) |
| • LH/Heparina LI (anticoagulante) | • LH/LI Heparin (anticoagulant) |
| • LH/Heparina LI - Gel (anticoagulante) | • LH/LI Heparin + Gel (anticoagulant) |
| • MonoiodoAcetato LI + Gránulos PS activador (antiglicolítico) | • IodoAcetate LI + Granules activator (antiglycolitic) |
| • LH/Heparina LI + MonoiodoAcetato LI (anticoagulante + antiglicolítico) | • LH/LI Heparin + IodoAcetate LI (anticoagulant + antiglycolitic) |
| • FX/Fluoruro Na + Oxalato K (antiglicolítico + anticoagulante) | • FX/Na Fluoride + K Oxalate (antiglycolitic + anticoagulant) |
| • Z/Vacio (sin aditivos) | • Z/Empty (non additive) |
| • Z/ Tubo tratado (para suero) | • Z/ Treatment Tube (for serum) |
| • Z/ Tubo tratado con Gel separador (para suero) | • Z/ Treatment Tube with Separator Gel (for serum) |
| • Z/ Tubo tratado con Gránulos PS (para suero) | • Z/ Treatment Tube with Granules PS (for serum) |
| • Z/ Tubo con activador de la coagulación (para suero) | • Z/ Tube with clotting activator (for serum) |
| • Z/ Tubo con activador + Gel separador (para suero) | • Z/ Tube with clotting activator + Separator Gel (for serum) |
| • Z/ Tubo con activador + Gránulos PS (para suero) | • Z/ Tube with clotting activator + Granules PS (for serum) |

Accesorios

- | | |
|--|--|
| • CAP-GALET (Embudo para muestras de sangre) | • CAP-GALET (Funnels for Blood Sampling) |
|--|--|

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

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

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

file:TF-1004_F_10-2014



DECLARACIÓN DE CONFORMIDAD CE CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

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

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

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

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

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

Código GMDN / GMDN Code: 33722

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

ESCOBILLON - Swab

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

Clasificación: Clase IIa
Classification: Class IIa

INFORMACIÓN ADICIONAL

En referencia a los escobillones, este documento tiene su apoyo en el Certificado CE número 2005_06_0474_CP
Epi-graph 1, de Garantía de Calidad de la Producción de suero con los Anexos V y VII de la Directiva 93/42/CEE,
emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Organismo Notificado número
0318.

OTHER INFORMATION:

Regarding the swabs, this documentation is supported by the CE Certificate number 2005_06_0474_CP Epi-graph 1,
Production Quality Assurance according to Annexes V and VII of Directive 93/42/EEC issued by the Agencia Española
de Medicamentos y Productos Sanitarios (AEMPS), Notified Body number 0318.



TUBO CON MEDIO DE TRANSPORTE - Tube with transport medium

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


José Saez
Director General / Managing Director: 0300. F. +34 93

Anna Mir
Responsable Técnico / Technical Director

ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

REF	DESCRIPCIÓN	DESCRIPTION
300200	ESCOBILLON MAD.+ALGODON PEEL/1	SWAB IWV PEEL/1 WOOD+COTTON
300201	ESCOBILLON PS+ALGODON PEEL/1	SWAB IWV PEEL/1 PS+COTTON
300202	ESCOBILLON PS+VISCOSA PEEL/1	SWAB IWV PEEL/1 PS+VISCOSSE
300203	ESCOBILLON ALU+ALGODON PEEL	SWAB IWV PEEL ALUM+COTTON
300210	ESCOBILLON MAD.+ALGOD. B/2 PEEL	SWAB B/2 PEEL/2 WOOD+COTTON
300250	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300251	ESCOBILLON ALU.+ALGODON TUBO	SWAB IN TUBE ALUM+COTTON
300252	ESCOBILLON PS+VISCOSA TUBO	SWAB IN TUBE PS+VISCOSSE
300253	ESCOBILLON ALU.+VISCOSA TUBO	SWAB IN TUBE ALUM+VISCOSSE
300254	ESC.ALUM.TRENZADO+VISCOSA TUBO	SWAB TWISTED ALUM+VISCOSSE TUBE
300259	ESCOBILLON MAD.+VISCOSA TUBO	SWAB IN TUBE WOOD+VISCOSSE
300261	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PP+COTTON
300263	ESCOBILLÓN 13X165MM PS C/POLIÉSTER	SWAB 13X165MM PS W/POLYESTER
300280	CARY BLAIR MADERA+ALGODON	CARY BLAIR SWAB WOOD+COTTON
300281	AMIES ALUMINIO+VISCOSA	AMIES SWAB ALUMINIUM+VISCOSSE
300284	AMIES LIQUIDO PS+VISCOSA	AMIES SWAB LIQUID PS+VISCOSSE
300285	AMIES CARBON PS+VISCOSA	AMIES+CHARCOAL SWAB PS+VISCOSSE
300287	AMIES PS+VISCOSA	AMIES SWAB PS+VISCOSSE
300290	STUART MADERA+ALGODÓN	STUART SWAB WOOD+COTTON
300291	STUART ALUMINIO+ALGODÓN	STUART SWAB ALUM+COTTON
300292	STUART ALUMIN.TRENZADO+VISCOSA	STUART SWAB TWISTED ALU + VISC
300294	VIRUS ALUMINIO + POLIESTER	VIRUS SWAB ALUMINIUM POLYESTER
300295	STUART 13X165MM PS C/VISCOSA	STUART 13X165MM PS W/VISCOSSE
300296	H. VIRUS ALUM. ALGODÓN	SWAB FOR VIRUS WIRE+COTTON TIP
300297	VIRUS PS+POLIESTER	VIRUS SWAB PS POLYESTER
300299	CHLAMYDIA PS+POLIESTER	CHLAMYDIA SWAB PS+POLYESTER
310200	ESCOBILLON MAD.+ALGODON FLOW	WOOD+COTTON SWAB FLOW
310202	ESCOBILLON PS+VISCOSA FLOW	PS+VISCOSSE SWAB FLOW

Fecha / Date: 20/05/2016
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CDCE-54 Rev.14

REF	DESCRIPCIÓN	DESCRIPTION
300211.1	ESCOBILLÓN PS+ALG. PACK PEEL/2	SWAB B/2 PS+COTTON PEEL/2
300212.1	ESCOBILLON PS+VISCOSA PEEL/2	SWAB PEEL/2 PS+VISCOSSE
300250.1	ESCOBILLON MAD.+ALGOD. PURO TU	SWAB IN TUBE WOOD+PURE COTTON
300250.M	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300261.M	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PS+COTTON
300268.B	ESCOBILLON PS+POLIESTER PEEL PACK	SWAB PS+POLIESTER IND.WRAPPED
300280.2	CARY BLAIR PS+VISCOSA	CARY BLAIR SWAB PS+VISCOSSE
300281/1	ESC. AMIES+CARBON ALUM.VISCOSA	AMIES CHARCOAL SWAB WIRE+VISCOSSE
300281T	AMIES ALUMINIO TRENZADO+ VISCOS	AMIES SWAB TWIST.WIRE+VISCOSSE
300281TC	AMIES+CARBON ALU.TRENZADO+ VISC	AMIES+CHARCOAL TWIS.WIRE+VISCOS
300285.M	AMIES CARBON PS VISCOSA 6x100	AMIES CHARCOAL PS RAYON 6X100
300287.5	AMIES PS VISCOSA CAJAS 6x100	AMIES PS VISCOSSE CASES 6X100
300287.A	ESCOB.AMIES PS+VISCOSA	AMIES SWAB PS+VISCOSSE
300295C	STUART CARBÓN PS + VISCOSA	STUART+CHARCOAL SWAB PS+VISCOSSE
310253.1	ESCOB. ALUM+VISCOSA FLOW	ALUM+VISCOSSE SWAB FLOW
310211.1	ESCOBILLON PS+ALGODON B/2 FLOW	PS+COTTON SWAB B/2 FLOW
300250.MY	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300211.10	ESCOBILLÓN PS+ALG. PACK PEEL/10	SWAB PS+COTTON PEEL/10
300281AV	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PS+COTTON

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DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

DELTALAB S.L.
Plaza de la Verneda, nº 1
Pol. Ind. La Lliana
08191 Rubí (Barcelona) – España

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

SISTEMA INVASIVO ESTÉRIL, CON PUNTA ABSORBENTE, PARA TOMA DE MUESTRAS CON Y SIN MEDIO DE TRANSPORTE.
INVASIVE STERILE COLLECTION SWAB, WITH ABSORBENT TIPPED, FOR SAMPLE COLLECTION WITH AND WITHOUT TRANSPORT MEDIUM
(Códigos según Anexo 1 / Codes in Annex 1)

Tipo: Escobillón estéril con punta absorbente para la recogida de muestras.
Type: Absorbent tipped sterile swab for samples collection.

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

Código GMDN / GMDN Code: 33722

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

ESCOBILLON - Swab

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

Clasificación: Clase I Estéril
Classification: Class I Sterile

INFORMACIÓN ADICIONAL

En referencia a los escobillones, este documento tiene su apoyo en el Certificado CE número **2005.06.0475 CP Epigraph 6**, de Garantía de Calidad de la Producción de acuerdo con los Anexos VII punto 5 y V punto 3 de la Directiva 93/42/CEE, emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Organismo Notificado número 0318.

OTHER INFORMATION:

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

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TUBO CON MEDIO DE TRANSPORTE – Tube with transport medium

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




José Saez
Director General / Managing Director



Anna Mir
Responsable Técnico / Technical Director

Fecha / Date: 20/05/2016
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ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS/ANNEX 1 – ARTICLES DESCRIPTION

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

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

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

El fabricante / The manufacturer:

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

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

**CONTENEDORES PARA MUESTRAS NO ESTÉRILES
GENERAL SPECIMEN CONTAINER NON-STERILE**
(Códigos según Anexo 1 / Codes in Annex 1)

Finalidad Prevista: Recogida y conservación y/o transporte, de cualquier tipo de muestra para diagnóstico (por ejemplo, orina, heces, esputo, mucosa, tejido) para análisis y/u otra investigación.

Intended Use: Collection and preservation and/or transport, of any type of diagnostic specimen (e.g. urine, faeces, sputum, mucous, tissue) for analysis and/or other investigation.

Código GMDN / GMDN Code: 47775

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

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

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

José Saez
Director General / Managing Director

Anna Mir
Responsable Técnico / Technical Director



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

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

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

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

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REF	DESCRIPCIÓN	DESCRIPTION
409852	FRASCO 50ML PP CON ESPATULA	50ML CONTAINER WITH SPOON PP
409902	FRASCO 200ML PP	200ML CONTAINER PP
409905	FRASCO 200ML PP AZUL TRANS. ETI	CONTAINER 200 ML PP BLUE-PLAIN LBL
409915	FRASCO 200ML PP AZUL TRANS S/E	CONTAINER 200 ML PP BLUE
409926	FRASCO 200ML PP B/U	200ML CONTAINER PP I/W
410046	FRASCO 50 ML PP T/PRECINTO	TAMPER EVIDENT CONT. 50ml H80mm
410047	FRASCO T/BISAGRA 50ml H=80mm	HINGED LID CONT. 50ml H=80mm
410056	FRASCO PRECINTO 50ml H80mm B/U	HINGED LID CONT. 50ml H80mm I/B
419802	FRASCO 50ML PP T/PRECINTO	50ML CONT SEALED CAP PP
419805	FRASCO 50ML PP T/PREC/ AZUL	PP 50 ML CONT. SEALED CAP BLUE
419825	FRASCO 50ML PP T/PREC. AZUL B/U	50ML CONT SEAL BLUE CAP I/W PP
419826	FRASCO 50ML PP T/PRECINTO B/U	50ML CONT SEALED CAP I/W PP
429900	TUBO CONICO 50 ML PP TAPADO	50ML CONICAL TUBE PP
429901	TUBO CONICO 50ML PP FALDON TAPADO	50ML CONICAL TUBE SKIRT PP
429903	TUBO 50ML PP CON.FALDON S/TAP	50ML CON.TUBE SKIRTE PP NO CAP
429910	TUBO CONICO 15ML PP TAPADO	15ML CONICAL TUBE PP
444602801	FRASCO DE SEG. 60ML T/AZUL	CHILD PROOF CONT 60ML BLUE LID
444602802	ANTI-CHILD. SIN TAPON	CHILD PROOF CONT. 60ML NO CAP
444602901	FRASCO SEGURIDAD 60ML T/AZUL	CHILDPROOF CONT 60ML BLUE LID
444602903	ANTI-CHILD BLANCO T/BLANCO 60	CHILD PROOF WHITE CONTAINER 60
444603202	FRASCO DE SEG. 30ML T/BLAN PRECINTO	SECURITY CONT. 30ML WHITE CAP
444603204	F.SEGURIDAD BLANCO 30ML T/BLANCO	CHILDPROOF WH. CONT 30ML B/CAP
444603300	FRASCO SEGURIDAD 60ML T/BLANCO	CHILDPROOF CONT 60ML WHITE LID
444603305	ANTI-CHILD AZUL TAPON BLANCO	CHILD PROOF BLUE CONT. WHITE CAP
444603306	ANTI-CHILD. VERDE TAPON BLANCO	CHILD PROOF GREEN CONT. WHITE CAP
444603308	ANTI-CHILD. ROJO TAPON BLANCO	CHILD PROOF RED CONT. WHITE CAP
444603402	F. SEGURIDAD 125ML T/BLANCO	CHILDPROOF CONT 125ML WHITE LID
202845N	TARRO HISTOLOGIA 250ML NEGRO	HISTOLOGY CONTAINER 250ML BLACK
202846/T	FRASCO DE SEGURIDAD 500ML TAPADO	SECURITY CONTAINER 500ML CAPPED
202847/T	FRASCO DE SEGURIDAD 1000ML TAPADO	SECURITY CONTAINER 1000ML CAPPED

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

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REF	DESCRIPCIÓN	DESCRIPTION
409502.G.4	FR.60 GRAD.S/ROSCAR TAP.SEPARA	CONT.60 GRAD.UNCAPPED SEP.CAP
409507.G	FRASCO 60ml PP GRAD.T/VERDE	60ml CONT.PP GRAD.GREEN CAP
409511.4	FR.60ML AZUL CLARO S/ETIQUETA	60ML LIGHT BLUE CONTAINER
409511.5	FR.60ML AZUL TRANS.L. ETIQ. BLANC	60ML CONTAINER TRANS.BLUE LBL
409552.Y	FRASCO 60ml PP C/ESPÁTULA T/AM	60ml CONTAINER W/SPOON YEL/LID
409552.G	FRASCO 60ML PP GRADUADO C/ESPA	60ML CONTAINER W/SPOON GRADUAT
409552.TA	FRASCO 60ML PP C/ESPATULA T.AZUL	60ML CONTAINER PP W/SPOON BLUE CAP
409702.3	FRASCO 150ml PP TAPÓN BLANCO	PP CONTAINER 150ml WHITE CAP
409702.P	FRASCO 150ML PP ROSCADO	150ML PP CUPPED CONTAINER
409702.PB	FRASCO 150ML PP ROSCADO T.BLA	150ML PP CUPPED CONT.WHITE C.
409703.5	FRASCO 150 ML. T/AZUL S/ROSCAR	150ML CONT SEPARATED BLUE CAP
409703WC	FRASCO 150ML PP SIN ROSCAR T/BLANCO	150ML PP CONT.SEPAR.CAP WHITE
409711.4	FR.150ML AZUL CLARO S/ETIQUETA	150ML LIGHT BLUE CONTAINER
409711.5	FR.150ML AZUL TRANS. ETIQ. BLANC	150ML CONTAINER BLUE TRANS.LB
409805.6	FRASCO 50ML PP T/ROJO SEPARADO	50ML PP CONTAINER SEP. RED CAP
410046.5	FRASCO T/PREC.50ml H80mm C/500	HINGED LID CONT.50ml H80 C/500
410046A.5	FRASCO T/PREC.50ml 500UD AZUL	HINGED LID CONT.500U BLUE
410046R.5	FRASCO T/PREC.50ml 500UD ROSA	HINGED LID CONT.500U PINK
420900.E	TUBO 12ML PP S/TAPON C/FALDON	PP 12ML TUBE W/SKIRT W/OUT CAP
429900.25	TUBO CONICO 50ml PP B/25	50ml CONICAL TUBE PP B/25
429900SP	TUBO 50ML PP CONICO SIN ROSCAR	50ML CONICAL TUBE PP SEP.CAP
429901.25	TUBO CON.50ml PP C/FALDON B/2	50ml CONICAL TUBE W/SKIRT B/25
429910SP	TUBO 15ml PP CONICO SIN ROSCAR	15ml CONICAL TUBE PP SEP.CAP
429927S/E	TUBO CONICO 50ML C/FALDON B/U	50ML CONICAL TUBE SKIRT I/W PP
44462903M	ANTI-CHILD BLANCO T/BLANCO 60	CHILDPROOF WHIE CONT.60ML WC
309202.O	FRASCO 30ML PS ST. EO	CONTAINER 30ML PS ST.EO
429930	TUBO 50ML PP CONICO IMPRESO B/25	50ML TUBE PP CONICAL PRINT 25/B
429940	TUBO 15 ML PP CONICO IMPRESO GRANEL	15ML TUBE PP CONICAL PRINTED IN BULK
429945	TUBO 15 ML PP CONICO IMPRESO B/25	15ML TUBE PP CONICAL PRINT 25/B

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

DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

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

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

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

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

Código GMDN / GMDN Code: 58139

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

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

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

José Saez
Director General / Managing Director

Anna Mir
Responsable Técnico / Technical Director

ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

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

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

El fabricante / The manufacturer:

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

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

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

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

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

Código GMDN / GMDN Code: 58143

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

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

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

José Sáez
Director General / Managing Director

Anna Mir
Responsable Técnico / Technical Director

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

CDCE-77 Rev.2

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

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

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

CDCE-77 Rev.2.2

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

El fabricante / The manufacturer:

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

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

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

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

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

Código GMDN / GMDN Code: 58138

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

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

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

José Sáez
Director General / Managing Director

Anna Mir
Responsable Técnico / Technical Director

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

CDCE-45 Rev. 10

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

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

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

CDCE-45 Rev. 10

Certificado ES10/81672

The management system of

DELTALAB, S.L.

Pol. Ind. La Llana, Plaza De La Verneda, 1
08191 Rubí (Barcelona)

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

Design, manufacture and sale of laboratory material for the collection, transport and conservation of samples for microbiological, molecular biology, haematology, biochemistry, histology, microscopy and colorimetric analysis.
Commercialization of equipment for the storage of prepared samples, cryogenic stored samples, general labware and industrial packages.

Diseño, fabricación y comercialización de material de laboratorio para la toma, transporte y conservación de muestras para análisis de microbiología, biología molecular, hematología, bioquímica, histología, microscopía y coloración.
Comercialización de equipos para el almacenamiento de muestras preparadas, almacenamiento de muestras para criogenización, material general de laboratorio y envases industriales.

in/ from the following sites

Pol. Ind. La Llana, Plaza De La Verneda 1 - 08191 Rubí (Barcelona)

This certificate is valid from
29 November 2017 until 11 October 2019.
Issue 7. Certified since October 2010.

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

Authorized by

Dirección de Certificación

SGS ICS Ibérica, S.A. (Unipersonal)
C/Trespaderne, 29. 28042 Madrid. España.
t 34 91 313 8115 f 34 91 313 8102 www.sgs.com

Page 1 of 1



Certificate ES10/81671

The management system of

DELTALAB, S.L.

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

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016



For the following activities

Design, manufacture and sale of sterile and non sterile medical devices for the collection, transport and conservation of biological samples for clinical and IVD analysis.

Diseño, fabricación y comercialización de productos sanitarios estériles y no estériles para la toma, transporte y conservación de muestras biológicas para análisis clínicos y de IVD.

This certificate is valid from 18 September 2017 until 11 October 2019 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 10 September 2019
Issue 7. Certified since 12 October 2010

Authorised by

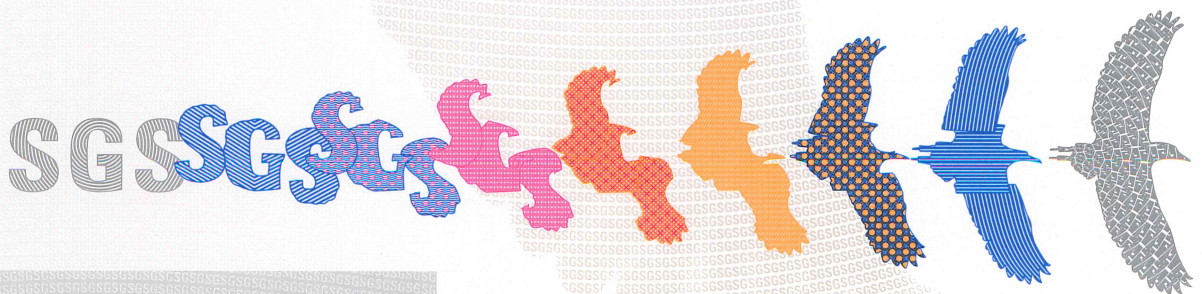
SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485 2016 0417

Page 1 of 1



0005



DECLARATION OF CONFORMITY

Manufacturer Grena Limited
1000 Great West Road
Brentford, Middlesex, TW8 9HH
United Kingdom

Product(s)

Disposable circular staplers with related surgical instruments (class IIb, rule 8)
Disposable linear staplers and cartridges for linear staplers (class IIb, rule 8)
Disposable bone marrow aspiration needles (class IIa, rule 6)
Disposable bone marrow biopsy needles (class IIa, rule 6)
Disposable staples cartridges for reusable linear staplers (class IIb, rule 8)
Disposable staples cartridges for reusable circular staplers (class IIb, rule 8)
Disposable endoscopic linear cutting staplers (class IIa, rule 6)
Cartridges for disposable endoscopic linear cutting staplers (class IIb, rule 8)
Surgical meshes (class IIb, rule 8)
Disposable automatic clip appliers with clips (class IIb, rule 8)
LigaV® – Titanium ligating clips (class IIb, rule 8)
VClip® – Titanium ligating clips (class IIb, rule 8)
Click'a-V® – Polymer ligating clips (class IIb, rule 8)
Disposable endoscopic instruments:
Disposable grasper with ratchet atraumatic fenestrated (class IIb, rule 9)
Disposable grasper with ratchet-Allis (class IIb, rule 9)
Disposable grasper with ratchet-Maxi Grip (class IIb, rule 9)
Disposable toothed grasper with ratchet (class IIb, rule 9)
Disposable grasper with ratchet –Babcock (class IIb, rule 9)
Disposable Metzenbaum scissors-curved (class IIb, rule 9)
Disposable scissors-straight (class IIb, rule 9)
Disposable scissors-hook (class IIb, rule 9)
Disposable dissector-Maryland (class IIb, rule 9)
Disposable dissector with ratchet- Maryland (class IIb, rule 9)
Disposable endoscopic dissector 3mm – Maryland, non-ratcheted
Disposable endoscopic dissector 3mm – Maryland, ratcheted
Disposable endoscopic grasper 3mm – atraumatic fenestrated
Disposable endoscopic scissors 3mm – curved
Limited use endoscopic instruments:
Limited use dissector- Maryland (class IIb, rule 9)
Limited use dissector with ratchet- Maryland (class IIb, rule 9)
Limited use Metzenbaum scissors- curved (class IIb, rule 9)
Limited use scissors-straight (class IIb, rule 9)
Limited use scissors-hook (class IIb, rule 9)
Limited use grasper with ratchet atraumatic fenestrated (class IIb, rule 9)
Limited use disposable grasper with ratchet-Allis (class IIb, rule 9)
Limited use grasper with ratchet-Maxi Grip (class IIb, rule 9)
Limited use toothed grasper with ratchet (class IIb, rule 9)
Limited use grasper with ratchet –Babcock (class IIb, rule 9)
Reusable endoscopic surgical instruments (class IIb, rule 9)
Disposable linear cutting staplers and cartridges for cutting staplers (class IIb, rule 8)
Disposable trocars with accessories (class IIa, rule 7)
Sterile disposable skin staplers (class IIa, rule 7)
Thoracentesis/paracentesis sets (class IIa, rule 6)
Suction cannulas and suction sets (class IIa, rule 7)
Suction-irrigation sets (class IIa, rule 6)
Disposable skin staples removers (class I sterile, rule 1)
Chest drainage systems (class I sterile, rule 1)
Connecting tubes (class I sterile, rule 1)
Retrieval bags (class IIa, rule 6)
Veress needles (class IIa, rule 6)
Silicone slings (class IIa, rule 6)
Arida® absorbing pads (class I, rule 1)
Arida® absorbing pads – sterile (class I sterile, rule 1)
Solidifying agent (class I, rule 1)
Open surgery and endoscopic clip appliers (class I, rule 6)
Vomit bags (class I, rule 1)

Classification According to Annex IX of Directive 93/42/EEC

We herewith declare under our sole responsibility that the above mentioned products meet the provisions of the directive 93/42/EEC concerning medical devices which apply to them. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied

All applicable harmonized standards required by the Directive 93/42/EEC. The detailed list in the Technical Files.

Notified Body

CE 0197

TÜV Rheinland LGA Products GmbH
Lillystrasse 2
90431 Nürnberg
Germany

EC Certificate(s)

HD 60040590 0001
DD 60040589 0001

Brentford, 09.05.2014

Wiesław Brodaczewski
Director



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

**Design and development, production and distribution
of disposable and reusable medical devices for surgical and
patient care procedures. Servicing of suction devices.
(see attachment for site included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date: 2018-06-29
Certificate Registration No.: SX 60130220 0001
An audit was performed. Report No.: 26300270 007
This Certificate is valid until: 2021-04-13

Certification Body



Date 2018-06-29

Maciej Sciera
Maciej Sciera



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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60130220 0001
Report No.: 26300270 007

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

Scope:

Site included:

Grena Ltd.
Chelsea House
Chelsea Street
Nottingham NG7 7HP
United Kingdom

Activity: Design and development, production and distribution of disposable and reusable medical devices for surgical and patient care procedures. Especially: production, purchasing, logistics and distribution of disposable and reusable medical devices.

Certification Body



Date: 2018-06-29

Maciej Sciera



EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 84868
Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

In respect of:

The design, development and manufacture of sterile Endoluminal Stent Grafts, sterile Securement Devices and Delivery Systems for Endovascular Indications, sterile Vascular Introducer Sheaths, sterile Stent Graft Balloon Catheters, sterile Coronary Stents and Delivery Systems, Sterile Intravascular Catheters and sterile/non-sterile Catheter Systems for Renal Denervation.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2004-08-24**

Date: **2019-08-22**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 1 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Number	Device Name	Intended purpose per IFU
Class III products under the scope of CE 84868		
N/A	Attain Clarity Venogram Balloon Catheter	See CE 593123
N/A	Driver Sprint Rapid Exchange Coronary Stent System	See CE 545439
N/A	Endeavor Resolute Zotarolimus-Eluting Coronary Stent System Resolute Integrity Zotarolimus-Eluting Coronary Stent System	See CE 514336
N/A	Endeavor Sprint Zotarolimus-Eluting RX Coronary Stent System	See CE 86406
N/A	Endurant™ Stent Graft System Endurant™ II Stent Graft System Endurant™ IIs Stent Graft System	See CE 559659
N/A	Euphora Rapid Exchange Balloon Dilatation Catheter	See CE 622066
N/A	Heli-FX™ EndoAnchor™ Systems	See CE 669930
N/A	IN.PACT Admiral (Paclitaxel-coated PTA Balloon Catheter)	See CE 570280

First Issued: **2004-08-24**

Date: **2019-08-22**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 2 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Number	Device Name	Intended purpose per IFU
Class III products under the scope of CE 84868		
N/A	IN.PACT Falcon (Paclitaxel-eluting PTCA Balloon Catheter)	See CE 570282
N/A	IN.PACT Pacific (Paclitaxel-eluting PTA Balloon Catheter)	See CE 570281
N/A	Integrity Rapid Exchange Coronary Stent System	See CE 91271
N/A	Micra™ Introducer Sheath with Hydrophilic Coating	See CE 599898
N/A	NC Euphora Rapid Exchange Balloon Dilatation Catheter	See CE 612356
N/A	NC Solarice Rapid Exchange Balloon Dilatation Catheter	See CE 630635
N/A	NC Sprinter Rapid Exchange Balloon Dilatation Catheter	See CE 506473
N/A	Reliant Stent Graft Balloon Catheter	See CE 635936
N/A	Resolute Onyx Zotarolimus-Eluting Coronary Stent System	See CE 618060
N/A	Sentrant Introducer Sheath with Hydrophilic Coating	See CE 595294
N/A	Solarice Rapid Exchange Balloon Dilatation Catheter	See CE 630580
N/A	Sprinter Legend OTW Balloon Dilatation Catheter	See CE 547584

First Issued: **2004-08-24**

Date: **2019-08-22**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 3 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Number	Device Name	Intended purpose per IFU
Class III products under the scope of CE 84868		
N/A	Sprinter Legend RX Balloon Dilatation Catheter	See CE 525652
N/A	Sprinter Over-the-Wire Balloon Dilatation Catheter	See CE 92065
N/A	Telescope Guide Extension Catheter	See CE 701802
N/A	Valiant Navion™ Thoracic Stent Graft System	See CE 702496
N/A	Valiant Thoracic Stent Graft with the Captivia Delivery System	See CE 554030

First Issued: **2004-08-24**

Date: **2019-08-22**

Expiry Date: **2024-05-26**

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Page 4 of 7

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

**Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA**

Class IIb products under the scope of CE 84868		
GMDN #	Device or Generic Device Group	Intended Purpose per IFU
58893 (Catheter) 35156 (Generator)	Symlicity Spyral™ Multi-Electrode Renal Denervation Catheter & Symlicity G3™ Renal Denervation RF Generator	The Symlicity G3™ Renal Denervation RF Generator when used with the Symlicity Spyral™ Multi-Electrode Renal Denervation Catheter is intended to deliver low-level radio frequency (RF) energy through the wall of the renal artery to denervate the human kidney.

First Issued: **2004-08-24**

Date: **2019-08-22**

Expiry Date: **2024-05-26**

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Page 5 of 7

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Class IIb products under the scope of CE 84868		
GMDN #	Device or Generic Device Group	Intended Purpose per IFU
46777	Talent Endoluminal Occluder System	The Talent Endoluminal Occluder System is intended for endoluminal occlusion of the contralateral iliac artery in cases where an abdominal aortic aneurysm is treated with an aorto-uni-iliac stent graft and subsequent femoral-to-femoral bypass procedure

First Issued: **2004-08-24**

Date: **2019-08-22**

Expiry Date: **2024-05-26**

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 84868

Issued To:

**Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA**

Class IIa products under the scope of CE 84868		
NBOG code	Device or Generic Device Group	Intended Purpose per IFU
MD0106	Confida™ Expandable Sheath	The Confida™ Expandable Sheath is intended to be inserted into the femoral artery, over a guidewire, and once expanded, to provide a guide for catheters or devices introduced into the femoral iliac arteries.

First Issued: **2004-08-24**

Date: **2019-08-22**

Expiry Date: **2024-05-26**

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Page 7 of 7

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This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 84868**
 Date: **2019-08-22**
 Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Subcontractor:	Service(s) supplied
Invatec S.p.A. Via Martiri della Libertà 7 25030 Roncadelle (BS) Italy	Manufacture
Medistri SA Rte de L'Industrie 96 1564 Domdidier Switzerland	ETO Sterilization
Medtronic B.V. / E.O.C. Earl Bakkenstraat 10 6422 PJ Heerlen The Netherlands	EU Representative
Medtronic CoreValve LLC 1851 E. Deere Ave Santa Ana, CA 92705 USA	Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 84868**
 Date: **2019-08-22**
 Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Subcontractor:	Service(s) supplied
Medtronic Ireland Parkmore Business Park West Galway Ireland	Design EU Representative Manufacture
Medtronic Mexico EG Carret. Int. Km. 1969 Guad-Nogales Km. 2 85340 Empalme Sonora Mexico	Manufacture
Medtronic Mexico S. de R.L. de CV Av. Paseo Cucapah 10510 El Lago C.P. 22210 Tijuana, Baja California Mexico	Manufacture
Medtronic Vascular 3576 Unocal Place Santa Rosa California 95403 USA	Design

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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 Date: **2019-08-22**
 Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Subcontractor:	Service(s) supplied
Phoenix DeVentures, Inc. 18655 Madrone Parkway Suite 180 Morgan Hill California 95037 USA	Manufacture
Plexus Corp. Pinnacle Hill Kelso TD5 8XX United Kingdom	Manufacture
Plexus Manufacturing Sdn. Bhd. Bayan Lepas Free Industrial Zone Phase II, 11900 Bayan Lepas Penang Malaysia	Manufacture

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 84868**
Date: **2019-08-22**
Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Subcontractor:	Service(s) supplied
SSP-SiMatrix, Inc. 1131 North US Highway 93 Victor Montana 59875 USA	Manufacture
Sterigenics US, LLC 4900 Gifford Avenue Los Angeles California 90058 USA	ETO Sterilization
Surmodics, Inc. 9924 West 74th Street Eden Prairie Minnesota 55344 USA	Crucial Supplier

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EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 84868**
 Date: **2019-08-22**
 Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Subcontractor:	Service(s) supplied
Synergy Health Ireland Ltd (Synergy Health - AST - Ireland) IDA Business & Technology Park Tullamore, Co. Offaly Ireland	E Beam Sterilization ETO Sterilization
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Daventry) Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	E Beam Sterilization
Teleflex Medical Annacotty Business Park Annacotty Co. Limerick Ireland	Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**
 Date: **2019-08-22**
 Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
24 August 2004		First Issued.
15 November 2004		Transfer of the following certificates from NSAI:- Q252.322, Q252.407, Q252.426, Q252.427, Q252.428, Q252.467, Q252.480, Q252.587, and Q252.611 D252.587 and D252.407, plus incorporation of Medtronic Vascular Ireland as a subcontract manufacturer.
02 December 2004		Carotid and Coronary Stents and Delivery Systems added to the scope (transfer) Medtronic Mexico (manufacture), and Titan Scan Systems, Nutec Corporation, Sterigenics (Queensbury), Steris Corporation-Isomedix Services (Sandy), Rocialle in Health (Mid Glamorgan UK), and EBIS Iotron added as sub-contract sterilizers.
21 December 2004		PTCA Balloon Dilatation Catheters added to the range of products manufactured (transferred from another Notified Body) and Isotron Ireland Ltd added as sub-contract sterilization site.
19 August 2005		Sterilization sub-contractor name change from Titan Scan Systems to Beam One.
03 April 2006		Addition of Sterigenics UK Ltd, as sterilization sub-contractor.
07 August 2006		Addition of AD)MEDES Schuessler GmbH as a sub-contractor for manufacture.

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
 This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 84868**
 Date: **2019-08-22**
 Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
11 January 2008	7149866	Subcontractor name change from EBIS Isotron, Harwell to Isotron Harwell. Addition of Isotron plc, Daventry as a subcontractor for E beam sterilization.
03 October 2008	7279045	Addition of Medtronic Mexico EG, Empalme as a subcontractor for manufacture.
14 April 2009	7341499	Correction of the legal name of the Medtronic Mexico facility and postcode for the Isotron PLC, Daventry facility. Addition of the activity of EU Representative for Medtronic Ireland.
13 August 2009	7432878	Certificate renewal. Addition of Accellant Inc as a manufacturing subcontractor, amendment to company name for Isotron PLC, Daventry, and Steris Corporation, Sandy, Utah. Change to address for the subcontractor, Nutek Corporation. Addition of E Beam Sterilization for Isotron Ireland. Rewording of scope for clarification purposes only.
29 July 2010	7546410	Added C.R. Bard, Inc. to the list of significant subcontractors for manufacturing. Extended the scope to include guidewires.
12 October 2011	7730209	Extension to scope to include Catheter Systems for Renal Denervation. Removal of Carotid Stents and Delivery Systems from the scope. Minor amendments to Isotron Daventry and Isotron Tullamore's addresses.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**
 Date: **2019-08-22**
 Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
26 January 2012	7792125	Amendment to significant subcontractors to reflect Isotron's name change to Synergy Health and removal of Isotron Harwell.
25 May 2012	7842435	Amendment to the address format and zip code for the significant subcontractor Medtronic Mexico (Tijuana).
19 December 2012	7915649	Addition of Medtronic B.V. The Netherlands for EU Representative Activities.
22 January 2013	7945194	Extension to scope to include Superficial Femoral Artery (SFA) and Proximal Popliteal Artery (PPA) Stents and Delivery Systems.
28 February 2013	7960715	Addition of Invatec Technology Center GmbH to the list of significant subcontractors for manufacturing activities.
28 March 2013	7943883	Extension to Scope to include Vascular Introducer Sheaths and the addition of Teleflex Medical for manufacturing activities.
16 December 2013	8082854	Addition of Plexus Manufacturing Sdn Bhd, Malaysia and Plexus Corp, UK to the list of significant subcontractors for manufacturing activities.
13 July 2014	8154862	Certificate Renewal. Various updates and changes to the list of significant subcontractors. Correction of the reference number for the reissue dated 19 th December 2012 on the certificate history page.

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 84868**
 Date: **2019-08-22**
 Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
31 July 2015	8350802	Addition of SSP SiMATrix Inc. as balloon supplier for the Attain Clarity.
01 July 2016	8545838	C. R. Bard, Inc., Medtronic Ardian LLC, Nutek Corporation, Sterigenics NY and Apical Instruments Inc. were removed from the list of significant subcontractors.
09 October 2017	8696759	Certificate scope updated to add the design, development and manufacture of securement devices for endovascular indications.
01 May 2018	8895951	Specify devices covered in this certificate are sterile/non-sterile. Move 'sterile Vascular Introducer Sheaths' up in the scope after securement devices. Remove 'Renal Stents and Delivery Systems' and 'guidewires for diagnostic or interventional procedures' from scope. Correction to certificate history entry #2 from '2014' to '2004'.
06 March 2019	8786554	Traceable to NB 0086.

EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 84868**
 Date: **2019-08-22**
 Issued To: **Medtronic, Inc.**
710 Medtronic Parkway
Minneapolis, MN 55432
USA

Date	Reference Number	Action
Current	9736517	<p>Certificate Renewal.</p> <p>Added product table per MDP4500 Appendix A.</p> <p>Clarified addresses of subcontractors to exactly align with their ISO certificate name and address.</p> <p>Remove "sterile Iliac Stents and Delivery Systems, sterile Superficial Femoral Artery (SFA) and Proximal Popliteal Artery (PPA) Stents and Delivery Systems" from scope as the Complete SE product (iliac and vascular indications) is no longer manufactured nor in the distribution chain.</p> <p>Remove Assurant Cobalt product (iliac product scope) it is no longer manufactured and the last product builds expired in April 2019.</p> <p>Remove subcontractors – Admedes Schuessler GmbH, Germany, Flextronics Medical, Austria, Sterigenics, Corona, CA, Synergy Health, Ireland related to removed products above.</p> <p>Add subcontractors - Phoenix DeVentures, CA, Sterigenics, Los Angeles, CA, SurModics, MN and Medtronic, Santa Ana, CA related to new Class IIa product Confida Expandable Sheath.</p>

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



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
Millennium 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
Cépulet 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
Lentäjätie 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 Herzlyia
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