

FORMULARUL OFERTEI (F3.1)

Data: **15 dec 2018, 11:00 - 26 dec 2018, 11:30**
Licităția nr.: **21002449**
Invitație la licitația nr.:
Alternativa nr.:
Către: **IMSP Dispensarul Municipal Dermato-Venerologic Chișinău**

Biosistem-mld SRL declară că:

a) Au fost examinate și nu există rezervări față de documentele de licitație, inclusiv modificările nr.

b) Biosistem-mld SRL se angajează să furnizeze, în conformitate cu documentele de licitație și condițiile stipulate în specificațiile tehnice și de formare a prețurilor, următoarele bunuri și/sau servicii

Reactive și consumabile de laborator

c) Suma totală a ofertei fără TVA constituie:

151.060,00 lei

d) Suma totală a ofertei cu TVA constituie:

167.200,00 lei

e) Prezenta ofertă va rămâne valabilă pentru perioada de timp specificată în FDA4.8., începînd cu data-limită pentru depunerea ofertei, în conformitate cu FDA5.2., va rămîne obligatorie și va putea fi acceptată în orice moment pînă la expirarea acestei perioade;

f) În cazul acceptării prezentei oferte, Biosistem-mld SRL se angajează să obțină o Garanție de bună execuție în conformitate cu FDA7, pentru executarea corespunzătoare a contractului de achiziție publică.

g) Nu sîntem în nici un conflict de interese, în conformitate cu punctul IPO5.4.

h) Compania semnatară, afiliații sau sucursalele sale, inclusiv fiecare partener sau subcontractor ce fac parte din contract, nu au fost declarate neeligibile în baza prevederilor legislației în vigoare sau a regulamentelor cu incidență în domeniul achizițiilor publice, în conformitate cu punctul IPO5.5.

Semnat: _____

Nume: **Poiana Vitalie**

În calitate de: **Director**

Ofertantul: **Biosistem-mld SRL**

Adresa: **mun.Chisinau, Albisoara 16/1 of.7**

Data: **15 dec 2018, 11:00 - 26 dec 2018, 11:30**



FORMULAR INFORMATIV DESPRE OFERTANT (F3.3)

15 dec 2018, 11:00 - 26 dec 2018,

Data: 11:30

Licitația

nr.: 21002449

pag.1 din 2

A. Ofertanți individuali

1. Informații generale		
1.1.	Numele juridic al ofertantului	Biosistem-mld SRL
1.2.	Adresa juridică a ofertantului în țara înregistrării	mun.Chisinau, Albisoara 16/1 of.7
1.3.	Statutul juridic al ofertantului	
	Proprietate	Privata
	Formă de organizare juridică	SRL
	Altele	
1.4.	Anul înregistrării ofertantului	2010
1.5.	Statutul de afaceri al ofertantului	Antreprenor
	Producător	
	Agent local/Distribuitor al producătorului străin	Da
	Intermediar	
	Companie de antrepozit	
	Altele	
1.6.	Informația despre reprezentantul autorizat al ofertantului	
	Numele	Poiata Vitalie
	Locul de muncă și funcția	Director
	Adresa	mun.Chisinau, Albisoara 16/1 of.7
	Telefon / Fax	+ 37322 808517/ 808719
	E-mail	info@biosistem-mld.com
1.7.	Numărul de înregistrare pentru TVA	0607490
1.8.	Numărul de identitate al ofertantului pentru impozitul pe venit (pentru ofertanții străini)	
1.9.	Ofertantul va anexa copiile/originalele	Documente obligatorii:
2. Informații de calificare		
2.1.	Numărul de ani de experiență generală a ofertantului în livrări de bunuri și servicii	7
2.2.	Numărul de ani de experiență specifică a ofertantului în livrarea bunurilor similare	7
2.3.	Valoarea monetară anuală a livrărilor de bunuri similare în fiecare din ultimii 5 ani	"Nu se aplică"
2.4.	Disponibilitate de resurse financiare (bani lichizi sau capital circulant, sau de resurse creditare, extras din cont bancar etc.). Enumerați și anexați copiile documentelor justificative	"Nu se aplică",

2.5.	Detalii privind capacitatea de producere / echipamente disponibile	“Nu se aplică”,
2.6.	Livrări majore de bunuri similare pe parcursul ultimilor 5 ani de activitate. Indicați detaliile livrărilor respective, inclusiv cele în proces de efectuare sau abia angajate, sau așteptate, cu datele preconizate de livrare	Nu se aplică
3. Informații financiare		
3.1.	Rapoarte financiare sau extrase din bilanțul financiar, sau declarații de profit / pierderi, sau rapoartele auditorilor pentru ultimul an de activitate. Enumerați mai jos și anexați copii: Raportul financiar 2017	
3.2.	Denumirea, adresa, numerele de telefon, telex și fax ale băncilor care pot oferi caracteristici despre ofertant în cazul contactării de către autoritatea contractantă 2038, mun. Chișinău, bd. Moscovei, 14/1 Banca: BC Moldincombank SA fil. Invest	
3.3.	Informație privind litigiile în care ofertantul este sau a fost implicat:	
	a) Orice proces pe parcursul ultimilor 5 ani: nu sunt	
	Cauza litigiului	Rezultatul sau sentința și suma implicată
	nu-s	
	b) Procese curente, pe parcursul anului fiscal curent: nu sunt	
	Cauza litigiului	Situația curentă a procesului

Semnat:

Nume:

Funcția în cadrul firmei:

Denumirea firmei și sigiliu:

Poiata Vitalie

Director

Biosistem-mld SRL

**DECLARAȚIA PRIVIND CONDUITA ETICĂ ȘI NEIMPLICAREA ÎN PRACTICI FRAUDULOASE ȘI
DE CORUPERE (F3.4)**

Data: 15 dec 2018, 11:00 - 26 dec 2018, 11:30
Licităția nr.: 21002449
Către: IMSP Dispensarul Municipal Dermato-Venerologic Chișinău

Biosistem-mld SRL confirmă prin prezenta că:

1. Nici unul dintre angajații, companionii, agenții, acționarii, consultanții, partenerii noștri sau rudele sau asociații ai lor nu este în relații care ar fi putut considerate ca un conflict de interese, conform prevederilor din documentele de licitație, punctul IPO4.
2. În cazul în care vom afla despre faptul unui conflict potențial, vom raporta imediat informația respectivă către autoritatea contractantă.
3. Nici unul dintre angajații, companionii, agenții, acționarii, consultanții, partenerii noștri sau rudele sau asociații ai lor nu a fost angajat în practici de corupere, escrocherie, complotare, constrângere sau alte practici anticoncurențiale în procesul pregătirii ofertei din cadrul prezentei licitații, conform prevederilor din documentele de licitație, punctul IPO8.
4. În legătură cu procedura respectivă de licitație și cu orice contract care, eventual, ne va fi adjudecat ca rezultat al acesteia, nu au fost, nici nu vor fi efectuate nici un fel de plăți către angajații, companionii, agenții, acționarii, consultanții, partenerii noștri sau rudele lor, care sînt implicați în achiziția publică, implementarea contractului și aprobarea plăților contractuale în numele autorității contractante.

Semnat: _____
Nume: Poiata Vitalie
Funcția în cadrul firmei: Director
Denumirea firmei și sigiliu: Biosistem-mld SRL

DECLARAȚIE
Privind Situația Personală A Operatorului Economic (F3.5)

Operator economic
Biosistem-mld SRL
(denumirea/numele)

Subsemnatul, Poiata Vitalie reprezentant împuternicit al Biosistem-mld SRL (denumirea operatorului economic) în calitate de ofertant/ofertant asociat declar pe propria răspundere, sub sancțiunea excluderii din procedura de achiziție publică și sub sancțiunile aplicabile faptei de fals în acte publice, că nu mă aflu în situația prevăzută la art. 18 din Legea privind achizițiile publice nr. 131 din 03.07.2015, respectiv în ultimii 5 ani nu am fost condamnat prin hotărâre definitivă a unei instanțe judecătorești pentru participarea la activități ale unei organizații criminale, pentru corupție, fraudă și/sau spălare de bani.

Subsemnatul declar că informațiile furnizate sunt complete și corecte în fiecare detaliu și înțeleg că autoritatea contractantă are dreptul de a solicita, în scopul verificării și confirmării declarațiilor, orice documente doveditoare de care dispun.

Subsemnatul, Poiata Vitalie reprezentant împuternicit al Biosistem-mld SRL (denumirea operatorului economic), în calitate de ofertant/ofertant asociat, la procedura de 21002449 (se menționează procedura) pentru atribuirea contractului de achiziție publică având ca obiect Cerere a ofertelor de prețuri (denumirea produsului, serviciului sau lucrării), codul CPV 33696200-7, la data de 15 dec 2018, 11:00 - 26 dec 2018, 11:30 (zi/luna/an), organizată de IMSP Dispensarul Municipal Dermato-Venerologic Chișinău (denumirea autorității contractante), declar pe propria răspundere că:

- a) nu am intrat în faliment ca urmare a hotărârii judecătorești;
- b) mi-am îndeplinit obligațiile de plată a impozitelor, taxelor și contribuțiilor de asigurări sociale;
- c) nu am fost condamnat, în ultimii 3 ani, prin hotărârea definitivă a unei instanțe judecătorești, pentru o faptă care a adus atingere eticii profesionale sau pentru comiterea unei greșeli în materie profesională;
- d) toate informațiile și documentele prezentate pentru procedura de achiziție menționată mai sus sunt veridice și autentice;
- e) nu suntem incluși în Lista de interdicție a operatorilor economici.

Subsemnatul declar că informațiile furnizate în scopul demonstrării îndeplinirii criteriilor de calificare și selecție sunt complete și corecte în fiecare detaliu și înțeleg ca autoritatea contractantă are dreptul de a solicita, în scopul verificării și confirmării declarațiilor, orice documente doveditoare de care dispun.

Înțeleg ca în cazul în care această declarație nu este conformă cu realitatea sunt pasibil de încălcarea prevederilor legislației penale privind falsul în declarații.

Data completării: 15 dec 2018, 11:00 - 26 dec 2018, 11:30

Operator economic,
Biosistem-mld SRL

L.Ș.

Specificații tehnice (F4.1)

Numărul licitației:			21002449			Data: 15 dec 2018, 11:00 - 26 dec 2018, 11:30			Alternativa nr.:
Denumirea licitației:			Reactive și consumabile de laborator			Lot:			Pagina 1 din
Nr. Lot	Denumire Lot	Cod CPV	Denumirea bunurilor și/sau a serviciilor	Modelul articolului	Țara de origine	Producătorul	Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină propusă de către ofertant	Standarde de referință
1	2	3	4	5	6	7	8	9	10
10,1	TPHA 200 teste	33696200-7	TPHA 200 teste	TPHA	Spania	Biosystems	Conform anexei 2 al ordinului MS RM nr.701 din 18.10.2010	Conform anexei 2 al ordinului MS RM nr.701 din 18.10.2010	ISO, CE
14,1	RPR - 10,0 ml /500 teste	33696200-7	RPR - 10,0 ml /500 teste	RPR-CARBON	Spania	Biosystems	Conform anexei 2 al ordinului MS RM nr.701 din 18.10.2010	Conform anexei 2 al ordinului MS RM nr.701 din 18.10.2010	ISO, CE
17,1	Teste HIV 1/2 imunocromatice material biologic sânge, ser, plasmă	33696200-7	Teste HIV 1/2 imunocromatice material biologic sânge, ser, plasmă CARD	Anti-HIV 1/2 Test, WB/S/P (Cassette WB/S/P)	Turcia	Turklab	Conform anexei 2 al ordinului MS RM nr.701 din 18.10.2010	Conform anexei 2 al ordinului MS RM nr.701 din 18.10.2010	ISO, CE
44,1	Ansa microbiologică, vol. 10 ul PS sterilă, ambalat câte 20 buc	33696200-7	Ansa microbiologică, vol. 10 ul PS sterilă, ambalat câte 20 buc	LOOP 10UL B/20 PEEL. FLOW	Spania	Deltalab	Conform anexei 3 al ordinului MS RM nr.701 din 18.10.2010	Conform anexei 3 al ordinului MS RM nr.701 din 18.10.2010	ISO, CE
47,1	Lamele 24x24 mm	33696200-7	Lamele 24x24 mm	COVER SLIDE 24X24	Spania	Deltalab	Conform anexei 3 al ordinului MS RM nr.701 din 18.10.2010	Conform anexei 3 al ordinului MS RM nr.701 din 18.10.2010	ISO, CE

Semnat: _____ Numele, prenumele: Poiata Vitalie

Ofertantul: Biosistem-mlD SRL

În calitate de: Director

Adresa: mun.Chisinau, Albisoara 16/1 of.7

Specificații de preț (F4.2)

Numărul licitației:		21002449						Data:	15 dec 2018, 11:00 - 26 dec 2018, 11:30	Alternativa nr.:
Denumirea licitației:		Reactive și consumabile de laborator						Lot:		Pagina 1 din
Nr. Lot	Denumire Lot	Denumirea bunurilor și/sau a serviciilor	Cod CPV	Cantitatea	Unitatea de măsură	Preț unitar (fără TVA)	Preț unitar (cu TVA)	Suma fără TVA	Suma cu TVA	Termenul de livrare/ prestare
<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>	<u>11</u>
10,1	TPHA 200 teste	TPHA 200 teste	33696200-7	2000	teste	3,72	4,02	7.440,00	8.040,00	01.01.2019 - 31.12.2019
14,1	RPR - 10,0 ml /500 teste	RPR - 10,0 ml /500 teste	33696200-7	2000	ml	35,02	37,82	70.040,00	75.640,00	01.01.2019 - 31.12.2019
17,1	Teste HIV 1/2 imunocromatice material biologic sânge, ser, plasmă	Teste HIV 1/2 imunocromatice material biologic sânge, ser, plasmă CARD	33696200-7	4000	teste	10,77	11,63	43.080,00	46.520,00	01.01.2019 - 31.12.2019
44,1	Ansa microbiologică, vol, 10 ul PS sterilă, ambalat câte 20 buc	Ansa microbiologică, vol, 10 ul PS sterilă, ambalat câte 20 buc	33696200-7	50000	buc	0,56	0,68	28.000,00	34.000,00	01.01.2019 - 31.12.2019
47,1	Lamele 24x24 mm	Lamele 24x24 mm	33696200-7	10000	buc	0,25	0,30	2.500,00	3.000,00	01.01.2019 - 31.12.2019
							TOTAL Oferta	151.060,00	167.200,00	

Semnat: _____ Numele, prenumele: Poiata Vitalie

Ofertantul: Biosistem-mld SRL

În calitate de: Director

Adresa: mun.Chisinau, Albisoara 16/1 of.7

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ORDIN DE PLATA NR.: 22                                TIP.DOC. 1 :
                                DATA EMITERII:26 decembrie 2018 :
=====:
PLATITI: 1600-00                                LEI: Una Mie Sase 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)  IMSP Dispe          CONTUL DE PLATI/CODUL IBAN :
nsarul  Municipal Dermato Ve MD16EC0000000225137161572 :
nerologic                                CODUL FISCAL :1003600153337 / :
:
:
=====:
PRESTATORUL BENEFICIAR                                CODUL BANCII:
BC"EuroCreditBank"S.A.                                :ECBMD2X :
=====:
DESTINATIA PLATII: Pentru garantia de bun:  TIPUL TRANSFERULUI :
a execu?ie la licitatie publica nr. ocds:  NORMAL/URGENT :N:
-b3wdpl-MD-1542018292401 din 26 dec 2018: :
: :
: :
: L.S. :
=====:
                                CODUL TRANZACTIEI:001: :
DATA PRIMIRII:26/12/2018 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
:-----:
CONDUCTATOR:Web "BIOSISTEM MLD" SRL Director :
MIIGdgYJKoZIhvcNAQcCoIIIGZzCCBmMCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB:

DQEHAaCCBH8wggR7MIIDY6ADAgECAhNHAAAegBMk4hdmW0YgAAAAAB6AMA0GCSq:

SIB3DQEBcUAMCIXIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4:

DTE3MDEyNzA5MjM0N1oXDTE5MDEyNzA5MzM0NlowgbIXCzAJBgNVBAYTAk1EMRA:
gYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEWhDaGlzaW5hdTEfMB0GA1UECgwWIkJ :
:
(semnatura electronica) :
CONTABIL-SEF:Web "BIOSISTEM MLD" SRLContabil :
MIIGfwYJKoZIhvcNAQcCoIIIGcDCCBmwCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBIIgwgSEMIIIDbKADAgECAhNHAAAefpGRMCmMAwZ5AAAAAB5+MA0GCSqG:
SIB3DQEBcUAMCIXIDAeBgNVBAMTF0NFU1QxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTE3MDEyNzA5MjM0N1oXDTE5MDEyNzA5MzM0NlowgbsxCzAJBgNVBAYTAk1EMRAw:
YDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEWhDaGlzaW5hdTEtMCsGA1UEChMkTUVE :
:
L.S. (semnatura electronica) :
CONDUCTATOR: :
(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMNATURA PRESTATORUL L.S. :
:
MOTIVUL REFUZULUI : L.S. :
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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. Chișinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

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

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

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

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei
care a eliberat certificatul

L. Svirepova
semnătura

MD 0101250





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

EXTRAS
din Registrul de stat al persoanelor juridice

nr. 14419 din 11.07.2016

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

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

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

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

Data înregistrării de stat: **12.08.2010.**

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

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

1 Activitatea farmaceutică;

2 Importul, fabricarea, comercializarea, asistența tehnică și (sau) reparația dispozitivelor medicale și (sau) a opticii;

3 Acordarea asistenței medicale de către instituțiile medico-sanitare private;

4 Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului;

5 Întreținerea și repararea mașinilor de birou și a tehnicii de calcul;

6 Consultații în domeniul sistemelor de calcul.

Capitalul social: **5400 lei.**

Administrator: POIATA VITALIE, IDNP 0983103892591,

Asociați:

1. POIATA VITALIE , IDNP 0983103892591

cota 1803.60 lei, ce constituie 33,4 %

2. NASEDCHIN ALEXANDR , IDNP 2002001070747

cota 1798.20 lei, ce constituie 33,3 %

3. KOJEVNIKOV DMITRII , IDNP 0972305012362

cota 1798.20 lei, ce constituie 33,3 %.

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

Specialist principal
tel. 022-266-252


Lazari Aliona



Lista fondatorilor Biosistem-mld SRL

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

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2017 31.12.2017

Entitatea BIOSISTEM MLD SRL

(Denumirea completă)

407173921010600028048

(Cod CUIIO)(Cod IDNO)

Sediul: MD MD-2001MUN.CHIȘINĂU; MUN.CHIȘINĂU SEC.RÎȘCANI150

(Cod poștal)Raionul (municipiul, UTA); LocalitateaCod CUATM

Albisoara, 16, 1, of.7

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

G4646

Cod CAEM, rev.2

Forma de proprietate: Proprietate privată15

Cod CFP

Forma organizatorico-juridică: SOCIETATI CU RASPUNDERE LIMITATA530

Cod CFOJ

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

WEB:

Numele și coordonatele al contabilului-șef: Dl (dna) +37322808719

Unitatea de măsură: leu

Tel. +37369463619

Anexa 8

Notă informativă privind veniturile și cheltuielile clasificate după natură

Indicatori	Cod rd.	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Venituri din vânzări	010	15.623.709	20.497.176
Alte venituri din activitatea operațională	020		500
Venituri din alte activități	030	368.943	361.872
Total venituri (rd.010 + rd.020 + rd.030)	040	15.992.652	20.859.548
Variația stocurilor	050		
Costul vânzărilor	060	9.960.221	11.372.168
Cheltuieli privind stocurile	070	306.856	118.975
Cheltuieli cu personalul privind remunerarea muncii	080	129.850	169.200
Contribuții de asigurări sociale de stat obligatorii și prime de asigurare obligatorie de asistență medicală	090	35.709	46.530
Cheltuieli cu amortizarea și deprecierea activelor imobilizate	100	7.389	90.494
Alte cheltuieli	110	306.855	548.183
Cheltuieli din alte activități	120	289.432	558.776
Total cheltuieli (rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	11.036.312	12.904.326
Profit (pierdere) până la impozitare (rd.040 – rd.130)	140	4.956.340	7.955.222
Cheltuieli privind impozitul pe venit	150	595.238	959.194
Profit (pierdere) net al perioadei de gestiune (rd.140 – rd.150)	160	4.361.102	6.996.028

BILANȚUL

Anexa 1

la 31.12.2017				
Nr. crt.	ACTIV	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
1.	Active imobilizate			
	Imobilizări necorporale	010	2.437	1.787
	Imobilizări corporale în curs de execuție	020		
	Terenuri	030		
	Mijloace fixe	040	195.525	904.703
	Resurse minerale	050		
	Active biologice imobilizate	060		
	Investiții financiare pe termen lung în părți neafiliate	070		
	Investiții financiare pe termen lung în părți afiliate	080		
	Investiții imobiliare	090		
	Creanțe pe termen lung	100		
	Avansuri acordate pe termen lung	110		
	Alte active imobilizate	120		
	Total active imobilizate (rd.010 + rd.020 + rd.030 + rd.040 + rd.050 + rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	197.962	906.490
2.	Active circulante			
	Materiale	140	2.329	457
	Active biologice circulante	150		
	Obiecte de mică valoare și scurtă durată	160	49.454	63.968
	Producția în curs de execuție și produse	170		
	Mărfuri	180	3.435.875	4.430.031
	Creanțe comerciale	190	5.303.786	3.157.174
	Creanțe ale părților afiliate	200		
	Avansuri acordate curente	210	793.582	1.097.547
	Creanțe ale bugetului	220	35.037	4.973
	Creanțe ale personalului	230		
	Alte creanțe curente	240		
	Numerar în casierie și la conturi curente	250	747.829	4.742.040
	Alte elemente de numerar	260		
	Investiții financiare curente în părți neafiliate	270		
	Investiții financiare curente în părți afiliate	280		
	Alte active circulante	290	8.004	5.373
	Total active circulante (rd.140 + rd.150 + rd.160 + rd.170 + rd.180 + rd.190 + rd.200 + rd.210 + rd.220 + rd.230 + rd.240 + rd.250 + rd.260 + rd.270 + rd.280 + rd.290)	300	10.375.896	13.501.563
	Total active (rd.130 + rd.300)	310	10.573.858	14.408.053

Nr. crt.	PASIV	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
3.	Capital propriu			
	Capital social și suplimentar	320	5.400	5.400
	Rezerve	330		
	Corecții ale rezultatelor anilor precedenți	340	X	
	Profit nerepartizat (pierdere neacoperită) al anilor precedenți	350	8.952.137	5.643.627
	Profit net (pierdere netă) al perioadei de gestiune	360	X	6.996.028
	Profit utilizat al perioadei de gestiune	370	X	
	Alte elemente de capital propriu	380		
	Total capital propriu (rd.320 + rd.330 + rd.340 + rd.350 + rd.360 - rd.370 + rd.380)	390	8.957.537	12.645.055
4.	Datorii pe termen lung			
	Credite bancare pe termen lung	400		
	Împrumuturi pe termen lung	410		
	Datorii pe termen lung privind leasingul financiar	420		
	Alte datorii pe termen lung	430		
	Total datorii pe termen lung (rd.400 + rd.410 + rd.420 + rd.430)	440		
5.	Datorii curente			
	Credite bancare pe termen scurt	450		
	Împrumuturi pe termen scurt	460		
	Datorii comerciale	470	1.084.518	1.595.609
	Datorii față de părțile afiliate	480		
	Avansuri primite curente	490	186.214	7.303
	Datorii față de personal	500	7.343	45.149
	Datorii privind asigurările sociale și medicale	510		
	Datorii față de buget	520	318.484	39.698
	Venituri anticipate curente	530		
	Datorii față de proprietari	540		
	Finanțări și încasări cu destinație specială curente	550		
	Provizioane curente	560		
	Alte datorii curente	570	19.762	75.239
	Total datorii curente (rd.450 + rd.460 + rd.470 + rd.480 + rd.490 + rd.500 + rd.510 + rd.520 + rd.530 + rd.540 + rd.550 + rd.560 + rd.570)	580	1.616.321	1.762.998
	Total pasive (rd.390 + rd.440 + rd.580)	590	10.573.858	14.408.053

SITUAȚIA DE PROFIT ȘI PIERDERE

Anexa 2

de la 01.01.2017 până la 31.12.2017

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

SITUAȚIA MODIFICĂRIILOR CAPITALULUI PROPRIU

Anexa 3

de la 01.01.2017 până la 31.12.2017

Nr. 3/o	Indicatori	Cod rd.	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfârșitul perioadei de gestiune
1	2	3	4	5	6	7
1	Capital social și suplimentar					
	Capital social	010	5.400			5.400
	Capital suplimentar	020				
	Capital nevârsat	030	0	0	0	0
	Capital netregistrat	040				
	Capital retras	050	0	0	0	0
	Total capital social și suplimentar (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060	5.400			5.400
2	Rezerve					
	Capital de rezervă	070				
	Rezerve statutare	080				
	Alte rezerve	090				
	Total rezerve (rd.070 + rd.080 + rd.090)	100				
3	Profit nerepartizat (pierdere neacoperită)					
	Corecții ale rezultatelor anilor precedenți	110				
	Profit nerepartizat (pierdere neacoperită) al anilor precedenți	120	8.952.137	4.361.103	7.669.613	5.643.627
	Profit net (pierdere netă) al perioadei de gestiune	130	X	5.996.028		6.996.028
	Profit utilizat al perioadei de gestiune	140	X	0	0	0
	Rezultatul din tranziția la noile reglementări contabile	150				
	Total profit nerepartizat (pierdere neacoperită) (rd.110 + rd.120 + rd.130 + rd.140 + rd.150)	160	8.952.137	11.357.131	7.669.613	12.639.655
4	Alte elemente de capital propriu, din care					
	Diferențe din reevaluare	171				
	Subvenții entităților cu proprietate publică	172				

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

Anexa 4

de la 01.01.2017 până la 31.12.2017

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

1. Certificat de înregistrare a entității, eliberat de Camera Înscriștrării a Statului
 Număr de înregistrare MD0101250 Data înregistrării 12.08.2014 Seria MD Număr 0101250

2. Capital social înregistrat de Camera Înscriștrării de Stat:
 data 21.08.2010 suma 5.400 lei, inclusiv:
 1) cota statului _____ lei,
 2) cota deținătorilor a cel puțin 20% _____ lei,
 Modificări ulterioare:
 a) _____ suma _____ lei, inclusiv cota statului _____ lei,
 b) _____ suma _____ lei, inclusiv cota statului _____ lei.

3. Entitățile, activitatea cărora necesită licență, indică:
 Licența în vigoare:
 1) Număr 044322 data eliberării 2010-10-04 00:00:00
 Termen de valabilitate 03.10.2020
 Tipul de activitate _____
 Organul care a eliberat licența _____

4. Numărul mediu scrisorilor la personalului în perioada de gestiune _____ persoane, inclusiv pe categorii:
 1) personal administrativ _____ persoane,
 2) muncitori _____ persoane.

5. Numărul personalului la 31.12.2017 _____ persoane

6. Remunerarea personalului entității în perioada de gestiune _____ lei
 7. Remunerarea membrilor organelor de administrare, de conducere și supraveghere și alte angajamente apărute sau asumate în legătură cu pensile membrilor actuali sau ale foștilor membri ai acestor organe, pe categorii _____ lei

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

9. Valoarea activelor imobilizate și circulante, înregistrate în calitate de ga¹
 1) valoarea de ga¹ _____ lei,
 2) valoarea contabilă _____ lei.

10. Numărul acțiunilor ordinare la finele perioadei de gestiune _____ unități.

11. Profit net (pierdere netă) a perioadei de gestiune pentru o acțiune ordinară:
 1) profit _____ lei,
 2) pierdere _____ lei.

12. Dividende calculate pentru o acțiune ordinară pentru perioada de gestiune:
 1) plătute _____ lei,
 2) planificate pentru plată _____ lei.

13. Valută standard disponibilă, calculată în moneda națională a Republicii Moldova – total 849.462 lei,
 inclusiv (lei, denumirea și codul valutei)
 1) 698537 codul valutei Euro
 2) 150925 codul valutei US Dollar

a) la numărător – valoarea de gaj
b) la numitor – valoarea contabilă

Indicatori	Nr. rând	Existența la începutul perioadei (la costul de intrare)	Amortizarea acumulată la începutul perioadei	Deprecierea acumulată la începutul perioadei	Intrarea în cursul perioadei (la costul de intrare)	Ieșirea în cursul perioadei (la costul de intrare)	Existența la sfârșitul perioadei (la costul de intrare)	Amortizarea acumulată la sfârșitul perioadei	Deprecierea acumulată la sfârșitul perioadei
		2	3	4	5	6	7	8	9
1. Imobilizări necorporale în curs de execuție	10C								
2. Imobilizări necorporale în utilizare, total inclusiv:	20C	3.25C	81.3				3.25C	1.463	
2.1 brevete și mărci	21C								
2.2 licențe de activitate	22C	3.25C	81.3				3.25C	1.463	
2.3 programe informatice	23C								
3. Imobilizări corporale în curs de execuție	30C								
4. Trecuți	40C		X					X	
5. Mijloace fixe, total din care:	500	205.204	9.679		796.422	6.100	995.526	90.823	
5.1 clădiri	51C								
5.2 construcții speciale	52C								
5.3 mașini, utilaje, instalații de transmisie	53C	186.815	5.300		796.422	6.100	971.141	83.929	
inclusiv: tehnică de calcul	531								
5.4 mijloace de transport	54C								
5.5 instrumente și inventar	55C								
5.6 costuri ulterioare aferente obiectelor nedreptățite în bilanț	56C								
5.7 mijloace fixe primite în leasing financiar	57C								
5.8 mijloace fixe primite în gestiune economică	58C								
5.9 alte mijloace fixe	59C	18.385	1.379				18.385	6.894	
6. Resurse materiale	600								
7. Investiții imobiliare, total	700								

Recipisa de primire a raportului

ID-ul raportului	289272
Tipul raportului	RSF 1
Tipul perioadei de raportare	Anual
Anul de raportare	2017
Numărul de raportare a perioadei (număr)	10
Numărul de raportare a perioadei (text)	an
Codul statistic al organizației	40717392
Codul fiscal al organizației	1010600028048
IDNO organizației	1010600028048
Denumirea organizației	BIOSISTEM MLD SRL
Statutul raportului	Primit la BNS
Data creării raportului	26.03.2018 11:08:42
Data expedierii raportului	27.03.2018 13:54:13
Subdiviziunea teritorială a BNS	mun. Chișinău
Telefonul subdiviziunii teritoriale a BNS	0-22-739581

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

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

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

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ B1815789

din
OT 14.12.2018

1. Destinatar / Получатель

Pentru participarea la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

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

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

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

4. Valabil pînă la / Действителен до 29.12.2018

5. Autentificarea organului fiscal / Подтверждение налогового органа

Sef Serviciu Riscani
Funcția/Dолжность

[Signature]
Semnătura/Подпись

Ana Stoica
Numele și prenumele/Фамилия и имя

L.Ș/ М.П.

Executor: *[Signature]*
Numele și prenumele/Фамилия и имя



Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 14.12.2018 ora 10:56:39
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)
NOTA (3,06)

EC DECLARATION OF CONFORMITY

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

Hereby DECLARES

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

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

under the specifications declared by BioSystems S.A.

It means that the products:

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

Barcelona, November 6th, 2012



Dr. Antonio Elduque
Managing director
BioSystems S.A.



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



CLINICAL CHEMISTRY – BIOCHEMISTRY:

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

CLINICAL CHEMISTRY – TURBIDIMETRY:

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

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

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



CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

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

CLINICAL CHEMISTRY – INSTRUMENTS:

A15	BA400
A25	BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

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



CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

Albumin (Microalbuminuria)
Anti-Streptolysin O (ASO)
Antithrombin III
Complement Component C3
Complement Component C4
C-Reactive Protein (CRP)
C-Reactive Protein-hs (CRP-hs)

Ferritin
Hemoglobin A1C-Turbi (HbA1C-Turbi)
Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Rheumatoid Factors (RF)
Transferrin

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

ADA Controls
Biochemistry Control Serum (Human) I
Biochemistry Control Serum (Human) II
Biochemistry Control Serum I
Biochemistry Control Serum II
CK-MB Control Serum
Control Urine
Fertility Biochemistry Control
Hemoglobin A1C Control (Elevated)

Hemoglobin A1C Control (Normal)
Hemoglobin A2 Control
Lipid Control Serum I
Lipid Control Serum II
Protein Control Serum I
Protein Control Serum II
Rheumatoid Control Serum I
Rheumatoid Control Serum II

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

Anti-Adrenal Cortex Antibodies (AACA)
Anti-Endomysium Antibodies (AEA)
Anti-Islet Cell Antibodies (AICA)
Anti-Keratin Antibodies (AKA)
Anti-Mitochondrial Antibodies (AMA)
Anti-nDNA antibodies (nDNA)
Anti-Neutrophil Cytoplasmic Antibodies (ANCA)
Anti-Nuclear Antibodies HEp-2 (ANA HEp-2)
Anti-Nuclear Antibodies RL (ANA-RL)
Anti-Skin Antibodies (ASA)
Anti-Smooth Muscle Antibodies (ASMA)
Anti-Striated Muscle Antibodies (AStMA)

Anti-Thyroid Antibodies (ATA)
Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML)
Autoantibodies MsK/MsS (AA-MsK/MsS)
Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS)
Autoantibodies RK/RS (AA-RK/RS)
Autoantibodies RL/RK/RS (AA-RL/RK/RS)
Autoantibodies RL/RKm/RS (AA-RL/RKm/RS)
Glomerular Basement Membrane Antibodies (GBMA)



AUTOIMMUNITY – ELISA:

ANA Screening	Anti-MPO Antibodies
Anti-Annexin V IgG/IgM (ANX)	Anti-Nucleosome Antibodies (NCL)
Anti-b2-Glycoprotein 1 IgG/IgM (b2GP1)	Anti-Phospholipid IgG/IgM (APLA)
Anti-Cardiolipin Antibodies (ACA-IgG/IgM)	Anti-PR3 Antibodies
Anti-Centromere B Antibodies (CENP-B)	Anti-Ribosomal P Antibodies (Rib P)
Anti-Citrullinated Protein Antibodies (ACPA)	Anti-Scl70 Antibodies
Anti-Deamidated Gliadin Peptides IgA (DGP IgA)	Anti-Sm Antibodies
Anti-Deamidated Gliadin Peptides IgG (DGP IgG)	Anti-Sm/RNP Antibodies
Anti-dsDNA Antibodies	Anti-SSA (Ro) Antibodies
Anti-GBM Antibodies - EIA (GBM)	Anti-SSB (La) Antibodies
Anti-Gliadin Antibodies (AGA-IgG/IgA)	Anti-Thyroglobulin Antibodies (Anti-Tg)
Anti-Histones Antibodies (HIST)	Anti-Thyroid Peroxidase Antibodies (Anti-TPO)
Anti-Insulin Antibodies (INS)	Anti-tTransglutaminase IgA Antibodies (Anti- tTG IgA)
Anti-Jo1 Antibodies	Anti-tTransglutaminase IgG Antibodies (Anti- tTG IgG)
Anti-M2 Antibodies (M2)	ASCA-IgG/IgA (ASCA)
	ENA 4-Profile
	ENA 6-Screening

AUTOINMUNIDAD – INSTRUMENTOS:

AUTOIMMUNITY – INSTRUMENTS:

iPRO



RAPID TESTS – LATEX AGGLUTINATION:

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

Rheumatoid factors (RF) - Slide

INFECTIOUS IMMUNOLOGY – SYPHILIS:

RPR-Carbon

TPHA

INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:

Febrile Serodiagnostics Multiscreening
Febrile Serodiagnostics Salmonella
Brucella abortus
Brucella abortus, Rose Bengal
Proteus Ox19
Salmonella paratyphi AH
Salmonella paratyphi AO
Salmonella paratyphi BH
Salmonella paratyphi BO
Salmonella paratyphi CH
Salmonella paratyphi CO
Salmonella typhi H
Salmonella typhi O
Brucella Positive Control
Proteus Positive Control
Salmonella Positive Control
Serology Negative Control

Certificate

Standard **ISO 9001:2008**

Certificate Registr. No. 01 100 6696

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

(With the locations included in the annex)

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

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

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

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

2016-12-16



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Annex to certificate

Standard **ISO 9001:2008**

Certificate Registr. No. 01 100 6696

No.

01 100 6696/02

Location

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

Scope

Labelling and Assembling of
reagents.
Warehousing and Shipment.

2016-12-16



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Page 1 of 1

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

BIOSYSTEMS S.A.
Costa Brava 30
08030 Barcelona
Spain

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

**Design and development, manufacture, distribution and
servicing of instruments and reagents for
clinical diagnostic
(see attachment for site(s) included)**

Proof has been furnished that the requirements specified in

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

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

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

Certification Body



Date 2016-12-13



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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60114603 0001
Report No.: 28300434 001

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

Scope:

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

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

Certification Body



Date: 2016-12-13




Dipl.-Ing. Sven Hoffmann

21.08.2016
İzmir / Turkey

DECLARATION FOR THE ISSUANCE OF QUALITY CERTIFICATES

To Whom It May Concern,

According to IVD 98/79/EC directive,

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

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

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

Cordially,

TURKLAB TIBBİ MALZEMELER SAN TİC A.Ş



EC CERTIFICATE No. 1434-IVDD-56/2016

EC Design-Examination

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

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

HBsAg Test

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

manufactured by:

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

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

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

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

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



Anna Wyroba
Anna Wyroba
Vice President of PCBC

CE 1434

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

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

Module H6



EC CERTIFICATE No. 1434-IVDD-57/2016

Full Quality Assurance System

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

PCBC certifies quality assurance system in company:

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

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

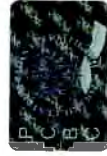
HBsAg Test
Brands: Info®, Toyo®, Rapidan Tester®, Labmen®

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

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

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

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



Anna Wyroba
Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module H7



EC CERTIFICATE No. 1434-IVDD-52/2016

EC Design-Examination

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

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

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

manufactured by:

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

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

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

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

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



Anna Wyroba
Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module H6



EC CERTIFICATE No. 1434-IVDD-53/2016

Full Quality Assurance System

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

PCBC certifies quality assurance system in company:

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

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

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

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

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

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

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



Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module H7



EC CERTIFICATE No. 1434-IVDD-54/2016

EC Design-Examination

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

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

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

manufactured by:

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

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

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

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

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



Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module H6



EC CERTIFICATE No. 1434-IVDD-55/2016

Full Quality Assurance System

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

PCBC certifies quality assurance system in company:

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

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

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

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

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

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

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



Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module H7



EC CERTIFICATE No. 1434-IVDD-58/2016

EC Design-Examination

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

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

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

manufactured by:

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

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

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

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

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



Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module H6



EC CERTIFICATE No. 1434-IVDD-59/2016

Full Quality Assurance System

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

PCBC certifies quality assurance system in company:

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

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

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

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

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

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

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



Anna Wyroba
Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module I17



EC CERTIFICATE No. 1434-IVDD-51/2016

EC Design-Examination

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

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

hCG Pregnancy Test

Brands: Rapidan Nova®, Rapidan Optima®, Info®, Toyo®, Labmen®
Tester®, Rapidan Compact®, Labmen®

manufactured by:

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

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

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

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

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



Anna Wyroba
Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module A1

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

02-699 Warszawa, ul. Kłobucka 23A



CERTIFICATE

No. J - 2670/1/2017

This is to certify that:

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

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

in the following scope of activities:

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

is in conformance with

EN ISO 9001:2008

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

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

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



AC 019
QMS



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

Date of certification decision: 2017-12-05

POLSKIE CENTRUM BADAŃ I CERTYFIKACJI S.A.

02-699 Warszawa, ul. Kłobucka 23A



CERTIFICATE

No. M - 56/1/2017

This is to certify that:

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

in the following scope of activities:

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

is in conformance with

EN ISO 13485:2012

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

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

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



AC 019
QMS



Anna Wyroba
Anna Wyroba, M.Sc.
Vice President

Date of certification decision: 2017-12-05

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

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

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

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

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

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

THE HEAD OF THE DEPARTMENT OF SANITARY PRODUCTS

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

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

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

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

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

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

- | | |
|--|---|
| • K3E/EDTA 3K (anticoagulante) | • K3E/EDTA 2K (anticoagulante) |
| • K2E/EDTA 2K (anticoagulante) | • K2E/EDTA 3K (anticoagulante) |
| • 4NC/Citrato 3Na (anticoagulante) | • 4NC/Citrato 3Na (anticoagulante) |
| • 9NC/Citrato 3Na (anticoagulante) | • 9NC/Citrato 3Na (anticoagulante) |
| • LH/Heparina Li (anticoagulante) | • LH/Heparin (anticoagulante) |
| • LH/Heparina Li - Gel (anticoagulante) | • LH/Li Heparin + Gel (anticoagulante) |
| • 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)

Accesorios

- CAP-GALET (Funnel for Blood Sampling)

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

Firmado/Signed: 
(Gerente / Manager)

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



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

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

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

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

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

Código GMDN / GMDN Code: 33722

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

ESCOBILLON - Swab

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

Clasificación: Clase IIa
Classification: Class IIa

INFORMACIÓN ADICIONAL

En referencia a los escobillones, este documento tiene su apoyo en el Certificado CE número 2005.06.0474 CE
[Logo] de Garantía de Calidad de la Producción de acuerdo con los Anexos V y VII de la Directiva 93/42/CEE
emiso 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. Eupograph 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

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 IW PEEL/1 WOOD+COTTON
300201	ESCOBILLON PS+ALGODON PEEL/1	SWAB IW PEEL/1 PS+COTTON
300202	ESCOBILLON PS+VISCOSA PEEL/1	SWAB IW PEEL/1 PS+VISCOS
300203	ESCOBILLON ALU+ALGODON PEEL	SWAB IW 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+VISCOS
300253	ESCOBILLON ALU.+VISCOSA TUBO	SWAB IN TUBE ALUM+VISCOS
300254	ESC. ALUM. TRENZADO+VISCOSA TUBO	SWAB TWISTED ALUM+VISCOS
300259	ESCOBILLON MAD.+VISCOSA TUBO	SWAB IN TUBE WOOD+VISCOS
300261	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PP+COTTON
300263	ESCOBILLON 13X165MM PS C/POLIESTER	SWAB 13X165MM PS W/POLYESTER
300280	CARY BLAIR MADERA+ALGODON	CARY BLAIR SWAB WOOD+COTTON
300281	AMIES ALUMINIO+VISCOSA	AMIES SWAB ALUMINIUM+VISCOS
300284	AMIES LIQUIDO PS+VISCOSA	AMIES SWAB LIQUID PS+VISCOS
300285	AMIES CARBON PS+VISCOSA	AMIES+CHARCOAL SWAB PS+VISCOS
300287	AMIES PS+VISCOSA	AMIES SWAB PS+VISCOS
300290	STUART MADERA+ALGODON	STUART SWAB WOOD+COTTON
300291	STUART ALUMINIO+ALGODON	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/VISCOS
300296	H. VIRUS ALUM. ALGODON	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+VISCOS SWAB FLOW

Fecha / Date: 20/05/2016
Pag. 3/4

COCE-54 Rev.14

REF	DESCRIPCIÓN	DESCRIPTION
300211.1	ESCOBILLON PS+ALG. PACK PEEL/2	SWAB B/2 PS+COTTON PEEL/2
300212.1	ESCOBILLON PS+VISCOSA PEEL/2	SWAB PEEL/2 PS+VISCOS
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+VISCOS
300281/1	ESC. AMIES+CARBON ALUM.VISCOSA	AMIES CHARCOAL SWAB WIRE+VISCOS
300281T	AMIES ALUMINIO TRENZADO+ VISCOS	AMIES SWAB TWIST WIRE+VISCOS
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 VISCOS CASES 6X100
300287.A	ESCOB.AMIES PS+VISCOSA	AMIES SWAB PS+VISCOS
300295C	STUART CARBÓN PS + VISCOSA	STUART+CHARCOAL SWAB PS+VISCOS
310253.1	ESCOB. ALUM+VISCOSA FLOW	ALUM+VISCOS 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	ESCOBILLON PS+ALG. PACK PEEL/10	SWAB PS+COTTON PEEL/10
300261AV	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PS+COTTON

Fecha / Date: 20/05/2016
Pag. 4/4

COCE-54 Rev.14

DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

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

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

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

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

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

Código GMDN / GMDN Code: 33722

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

ESCOBILLON - Swab

Directiva 93/42/CEE Directiva Productos Sanitarios.
Transposición a la legislación española en **Real Decreto 1591/2009.**
Directive 93/42/EEC 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 2005.05.0475 CP. Epígrafe 6, de Garantía de Calidad de la Producción de acuerdo con los Anexos VII punto 5 y V punto 3 de la Directiva 93/42/CEE, emitido por la Agencia Española de Medicamentos y Productos Sanitarios (AEMPS), Organismo Notificado número 0318.

OTHER INFORMATION:

For the swabs, this documentation is supported by the CE Certificate number 2005.05.0475 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.

Fecha / Date: 20/05/2016
Pag. 3/4

COCE-54 Rev.14

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
Pag. 3/4

COCE-86 Rev.4

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

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

Fecha / Date: 20/05/2016
Pag. 3/4

CDCE-88 Rev 4

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

Fecha / Date: 20/05/2016
Pag. 4/4

CDCE-88 Rev 4

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

Fecha / Date: 20/11/2013
Pag. 1/8

CDCE-14 Rev.13

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

Fecha / Date: 17/01/2017
Pag. 2/8

CDCE-14 Rev.13.15

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

Fecha / Date: 17/01/2017
Pag. 3/8

CDCE-14 Rev.13.15

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

Fecha / Date: 17/01/2017
Pag. 4/8

CDCE-14 Rev.13.15

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/PRECÍ 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.WHYTE CAP
444603306	ANTI-CHILD. VERDE TAPON BLANCO	CHILD PROOF GREEN CONT.WHYTE CAP
444603308	ANTI-CHILD.ROJO TAPON BLANCO	CHILD PROOF RED CONT.WHYTE 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

Fecha / Date: 17/01/2017
Pag. 5/8

CDCE-14 Rev.13.15

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

Fecha / Date: 17/01/2017
Pag. 6/8

CDCE-14 Rev.13.15

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

Fecha / Date: 17/01/2017
Pag. 7/8

CDCE-14 Rev.13.15

REF	DESCRIPCIÓN	DESCRIPTION
429950	TUBO 50 ML PP CONICO IMPRESO C/F B/25	50ML TUBE PP CONICAL PRINT SKIRTED 25/B
300500MI	TUBO 11X55 PS	TUBE 11X55 PS
175723	TUBO 5ML PS 13X75 TAPADO ROJO	TUBE 5ML PS 13X75 CAPPED RED
175724	TUBO 10ML PS 16X95 TAPADO ROJO	10ML TUBE PS 16X95 CAPPED RED
400903	TUBO 10ML PP 16X95 TAPADO ROJO	10ML TUBE PP 16X95 CAPPED RED
661035	TUBO 10ML PS 16X95 TAPADO NATURAL	10ML TUBE PS 16X95 CAPPED NATURAL
408702C	FRASCO VACÍO 120ml LOTE IMPRESO	VACUUM CONT.120ML CML
408726.A	FRASCO P/VACÍO 120ml B/I C/AN.	CUP F/VACUUM 120ml I/B PLAIN/C
400805	TUBO 75X12 PP TAPADO T/AZUL	TUBE 75X12 PP CAPPED C/B/LUE
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

Fecha / Date: 17/01/2017
Pag. 8/8

CDCE-14 Rev.13.15

DECLARACIÓN DE CONFORMIDAD CE CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

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

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

José Sáez
Director General / Managing Director

Anna Mir
Responsable Técnico / Technical Director

Fecha / Date: 21/11/2013
Pag. 1/2

CDCE-79 Rev.1

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

Fecha / Date: 21/11/2013
Pag. 2/2

CDCE-79 Rev.1

DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

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

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

José Sáez
Director General / Managing Director

Anna Mir
Responsable Técnico / Technical Director

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 WRAPP/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 Liana
08191 RUBÍ (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 Diagnóstico "in vitro".
Transposición a la legislación española en Real Decreto 1662/2000.
Directive 98/79/EC: "In-vitro" Diagnostics Medical Devices Directive.
Transposition to Spanish legislation in Real Decreto 1662/2000.

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

José Sáez
Director General / Managing Director

Anna Mir
Responsable Técnico / Technical Director

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

CDCE-45 Rev.10

ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

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

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

CDCE-45 Rev.10

Certificate ES10/81672

The management system of

DELTALAB, S.L.

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

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

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

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

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

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

Re certification audit due before 15 September 2018

Issue 6. Certified since 12 October 2010

Authorised by



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

SGS 9001-8 01 0216

Page 1 of 1



0005



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Certificate ES10/81671

The management system of

DELTALAB, S.L.

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

has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

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

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

This certificate is valid from 11 October 2016 until 31 March 2019
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 31 March 2019

Issue 6. Certified since 12 October 2010

Authorised by



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

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Page 1 of 1



0005



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Declaration of Conformity



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

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

Authorized Representative : Emergo Europe
Molenstraat 15 2513 BH The Hague
The Netherlands

Medical Device : Product Name: Reagent strips for Urinalysis
IVDD-Classification: Professional use

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

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

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

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

Valid Since

May 9th, 2012
Changchun, China

(place and date of issue)

Representative:

Yu Ge

Dirui Industrial Co., Ltd.

于歌

(name and signature or equivalent
marking of authorized person)

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

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

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

Proof has been furnished that the requirements specified in

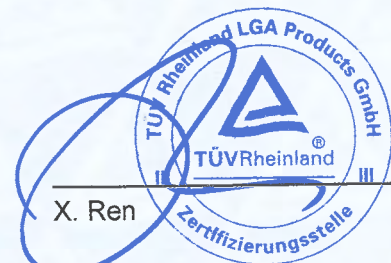
EN ISO 9001:2008

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

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

Certification Body

Date 2017-02-23



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev.0

**Attachment to
Certificate**

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

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

Scope:

Products:

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

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

Date: 2017-02-23

Certification Body



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

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

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

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

Proof has been furnished that the requirements specified in

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

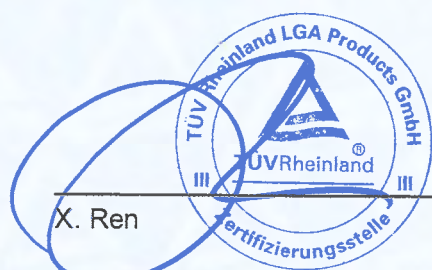
are fulfilled. The quality management system is subject to yearly surveillance.

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

Certification Body



Date 2017-02-23



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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60116875 0001
Report No.: 15047317 006

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

Scope:

Products:

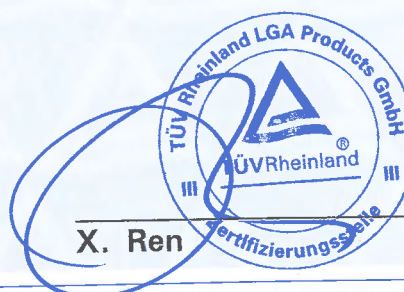
- Urine Analysis Systems (Reagents, Analyzers, Controls)
- Hematology Test Systems (Reagents, Analyzers, Controls)
- Clinical Chemistry Test Systems (Reagents, Analyzers, Controls)
- Fecal Test Systems (Reagents, Analyzers, Controls)

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2017-02-23



Declaration of Conformity **CE**

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

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

Product: Auto Hematology Analyzer
Model: BC-3600

Including reagents as following:

M-30D DILUENT

M-30CFL LYSE

M-30R RINSE

PROBE CLEANSER

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

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

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

Standards Applied:

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

Start of CE-Marking: 2011-01-14

Place, Date of Issue: Shenzhen, 2011-01-14

Signature:

Name of Authorized Signatory: Mr. Yang Long

Position Held in Company: Management Representative

Declaration of Conformity



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

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

Product: Auto Hematology Analyzer

Model: BC-5000

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

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

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

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

Standards Applied:

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

Start of CE-Marking: 2013-9-26

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

Signature:

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity



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

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

Product: Auto Hematology Analyzer

Model: BC-5150

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

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

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

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

Standards Applied:

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

Start of CE-Marking: 2013-9-26

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

Signature: _____

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Applied Standards List

Product: **Auto Hematology Analyzer**

BC-5150、BC-5000

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

Applied Standards:

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

Declaration of Conformity V 1.0

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



Product Service

CERTIFICATE

No. Q5 17 03 44751 089

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

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



Certification Mark:



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

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

Report No.: SH1705528

Valid from: 2017-09-01

Valid until: 2020-08-31

Date, 2017-06-28

Stefan Preiß



Page 1 of 3



Product Service

CERTIFICATE**No. Q5 17 03 44751 089****Applied Standard(s):**

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

Facility(ies):

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

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

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



Product Service

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

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

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

Munich, CRT, 2017-06-28

Stefan Preiß

Page 3 of 3





America

CERTIFICATE

No. QS5 17 07 44751 097

Certificate Holder:

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

Certification Mark:



Scope of Certificate:

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

Standard(s):

ISO 9001:2015

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

Report No.:

M2606

Effective Date:

2017-07-01

Expiry Date:

2020-06-30

Earl Buckmiller

Director, Quality Systems & MS Cert. Body



Page 1 of 3

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

TÜV®





America

CERTIFICATE

No. QS5 17 07 44751 097

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

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

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

Design and Development, Manufacturing of Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator/Monitor and Accessories, Electrocardiograph, Wearable ECG Recorder, Anesthesia Machine, Ventilator, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Magnetic Resonance Imaging System. Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

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

Earl Buckmiller
 Director, Quality Systems & MS Cert. Body

Page 2 of 3

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

TÜV®





America

CERTIFICATE

No. QS5 17 07 44751 097

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
1203 Nanhuan Avenue
Guangming District
518016 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

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

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

Earl Buckmiller
 Director, Quality Systems & MS Cert. Body

Page 3 of 3

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 10 Centennial Drive
 Peabody, MA 01960
 USA

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