

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ **A2112093**

din
от **14.07.2021**

1. Destinația / Назначение

Pentru participarea la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

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

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat/

Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

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

4. Valabil pînă la / Действителен до 29.07.2021

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



Sef DDF Rîșcani
a DCAF mun. Chișinău

Funcția/ Должность

Clandia GOJAN

Execuțor

Nume și prenume/ Фамилия и имя


Semnătura/ Подпись

Viorica CĂUȘ

Numele și prenumele/ Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 14.07.2021 ora 15:14:25
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (3,52)



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

Republica Moldova, MD-2068
mun. Chişinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDM2X329

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

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московей, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDM2X329

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 MOLDM2X329.

Director

Nina Turcan

Director financiar



Nina Balmuș

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





I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS din Registrul de stat al persoanelor juridice

nr. 8506 din 28.04.2021

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.**

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,

Asociați:

- 1. POIATA VITALIE 33,40 %**
- 2. NASEDCHIN ALEXANDR 33,30 %**
- 3. KOJEVNIKOV DMITRII 33,30 %.**

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: 28.04.2021.

Specialist coordonator
tel. 022-207-840



Lazari Aliona



EB 0358735

Lista fondatorilor Biosistem-mld SRL

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

Scrisoare de informare

Prin prezenta, SRL „Biosistem mld”, va informeaza ca conform “*legii Nr. 160 din 22-07-2011 privind reglementarea prin autorizare a activității de întreprinzător*”, cu modificarile ulterior adoptate de parlamentul RM, **Importul, comercializarea, asistența tehnică si reparația dispozitivelor medicale** nu mai este activitate licentiata. Respectiv nu mai sunt eliberate licente pentru acest gen de activitate, iar licentele cu termenul de valabilitate expirat nu mai sunt prelungite.



Vitalie Poiata

L.Ș.

Data predostavlenia 11.05.2021 10:00:47

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

SITUATIILE FINANCIARE
pentru perioada 01.01.2020 - 31.12.2020

Entitatea: BIOSISTEM MLD S.R.L.
Cod CUIO: 40717392
Cod IDNO: 1010600028048

Sediul:
MD:
Rajonul(municipiul): 106, DOF RISCANI
Cod CUATM: 0150, SEC RISCANI
Strada: SECTORUL RISCANI STR Albisoara nr.16 bl.1 of.7

Activitatea principala: 08666, Comerț cu ridicata al produselor farmaceutice
Forma de proprietate: 16, Proprietate colectivă
Forma organizatorico-juridică: 530, Societate cu răspundere limitată

Date de contact:
Telefon: +37322808719
WEB:

E-mail: zml13@mail.ru
Numele și coordonatele al contabilului-șef: DI (dna) Tel.
Numărul mediu al salariaților în perioada de gestiune: 3 persoane.

Persoanele responsabile de semnarea situațiilor financiare* Nasedchin Alexandr

Unitatea de măsură: leu

BILANȚUL

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
A C T I V				
ACTIVE IMOBILIZATE				
I. Imobilizări necorporale				
1.	Imobilizări necorporale în curs de execuție	010		
2.	Imobilizări necorporale în exploatare, total	020	487	
din care:				
2.1.	concesiunile, licențe și mărci	021	487	
2.2.	drepturi de autor și titluri de protecție	022		
2.3.	programe informatice	023		
2.4.	alte imobilizări necorporale	024		
3.	Fond comercial	030		
4.	Avansuri acordate pentru imobilizări necorporale	040		
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050	487	
II. Imobilizări corporale				
1.	Imobilizări corporale în curs de execuție	060		
2.	Terenuri	070		
3.	Mijloace fixe, total	080	2208593	2793637
din care:				
3.1.	căldiri	081		
3.2.	construcții speciale	082		
3.3.	mașini, utilaje și instalații tehnice	083	2204135	2791637
3.4.	mijloace de transport	084		

A.	3.5. inventar și mobilier	085			
	3.6. alte mijloace fixe	086	4458	2000	
	4. Resurse minerale	090			
	5. Active biologice imobilizate	100			
	6. Investiții imobiliare	110			
	7. Avansuri acordate pentru imobilizări corporale	120			
	Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	2208593	2793637	
	III. Investiții financiare pe termen lung				
	1. Investiții financiare pe termen lung în părți nefiliate	140			
	2. Investiții financiare pe termen lung în părți afiliate, total	150			
din care:					
2.1. acțiuni și cote de participație deținute în părțile afiliate	151				
2.2. împrumuturi acordate părților afiliate	152				
2.3. împrumuturi acordate aferente intereselor de participație	153				
2.4. alte investiții financiare	154				
Total investiții financiare pe termen lung (rd.140 + rd.150)	160				
IV. Creanțe pe termen lung și alte active imobilizate					
1. Creanțe comerciale pe termen lung	170				
2. Creanțe ale părților afiliate pe termen lung	180				
Inclusiv: creanțe aferente intereselor de participație	181				
3. Alte creanțe pe termen lung	190				
4. Cheltuieli anticipate pe termen lung	200				
5. Alte active imobilizate	210				
Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220				
TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	2209080	2793637		
ACTIVE CIRCULANTE					
I. Stocuri					
1.	Materiale și obiecte de mică valoare și scurtă durată	240	54051	51978	
2.	Active biologice circulante	250			
3.	Producția în curs de execuție	260			
4.	Produse și mărfuri	270	5710647	7221203	
5.	Avansuri acordate pentru stocuri	280			
Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	5764698	7273181		
II. Creanțe curente și alte active circulante					
1.	Creanțe comerciale curente	300	4337729	3912218	
2.	Creanțe ale părților afiliate curente	310			
Inclusiv: creanțe aferente intereselor de participație	311				
3.	Creanțe ale bugetului	320	166486	74631	
4.	Creanțele ale personalului	330			
5.	Alte creanțe curente	340			
6.	Cheltuieli anticipate curente	350	4	2	
7.	Alte active circulante	360	1647908	5756117	
Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	6152127	9742968		
III. Investiții financiare curente					
1.	Investiții financiare curente în părți nefiliate	380			
2.	Investiții financiare curente în părți afiliate, total	390			
din care:					
2.1.	acțiuni și cote de participație deținute în părțile afiliate	391			
2.2.	împrumuturi acordate părților afiliate	392			
2.3.	împrumuturi acordate aferente intereselor de participație	393			

C.	2.4. alte investiții financiare în părți afiliate	394			
	Total investiții financiare curente (rd.380 + rd.390)	400			
	IV. Numerar și documente bănești	410	8911899	3942779	
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	20828724	20958928	
	TOTAL ACTIVE (rd.230 + rd.420)	430	23037804	23752565	
	P A S I V				
	CAPITAL PROPRIU				
	I. Capital social și neînregistrat				
	1.	Capital social	440	5400	5400
	2.	Capital nevărsat	450	()	()
3.	Capital neînregistrat	460			
4.	Capital retras	470	()	()	
5.	Patrimoniul primit de la stat cu drept de proprietate	480			
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	5400	
II. Prime de capital					
III. Rezerve					
1.	Capital de rezervă	510			
2.	Rezerve statutare	520			
3.	Alte rezerve	530			
	Total rezerve (rd.510 + rd.520 + rd.530)	540			
IV. Profit (pierdere)					
1.	Corecții ale rezultatelor anilor precedenți	550	X		
2.	Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	21021465	12085295	
3.	Profit net (pierdere netă) al perioadei de gestiune	570	X	7974831	
4.	Profit utilizat al perioadei de gestiune	580	X	()	
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	21021465	20060126	
V. Rezerve din reevaluare					
VI. Alte elemente de capital propriu					
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	21028865	20065526	
DATORII PE TERMEN LUNG					
1.	Credite bancare pe termen lung	630			
2.	Împrumuturi pe termen lung	640			
din care:					
2.1.	Împrumuturi din emisiunea de obligațiuni	641			
Inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642				
2.2.	alte împrumuturi pe termen lung	643			
3.	Datorii comerciale pe termen lung	650			
4.	Datorii față de părțile afiliate pe termen lung	660			
Inclusiv: datorii aferente intereselor de participație	661				
5.	Avansuri primite pe termen lung	670			
6.	Venituri anticipate pe termen lung	680			
7.	Alte datorii pe termen lung	690			
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700			
DATORII CURENTE					
1.	Credite bancare pe termen scurt	710			
2.	Împrumuturi pe termen scurt, total	720			

E.	din care:	721			
	2.1. împrumuturi din emisiunea de obligațiuni	722			
	Inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	723			
	2.2. alte împrumuturi pe termen scurt	730	1331928	3252667	
	3.	Datorii comerciale curente	740		
	4.	Datorii față de părțile afiliate curente	741		
	Inclusiv: datorii aferente intereselor de participație	742			
	5.	Avansuri primite curente	750	159545	188105
	6.	Datorii față de personal	760	2913	50
	7.	Datorii privind asigurările sociale și medicale	770		
8.	Datorii față de buget	780	434590	187676	
9.	Datorii față de proprietari	790			
10.	Venituri anticipate curente	800			
11.	Alte datorii curente	810	81963	58541	
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	2010939	3687039	
PROVIZIOANE					
1.	Provizioane pentru beneficiile angajaților	830			
2.	Provizioane pentru garanții acordate cumpărătorilor/clientilor	840			
3.	Provizioane pentru impozite	850			
4.	Alte provizioane	860			
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870			
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	23037804	23752565	

SITUAȚIA DE PROFIT ȘI PIERDERE

de la pină la

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	27319617	25963175
din care:			
venituri din vânzarea produselor și mărfurilor	011	26856566	25044358
venituri din prestarea serviciilor și executarea lucrărilor	012	463051	918817
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016		
Costul vânzării, total	020	15672962	15186814
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	15672962	15186814
costul serviciilor prestate și lucrărilor executate terților	022		
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzării	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	11646655	10776361
Alte venituri din activitatea operațională	040	28586	247603
Cheltuieli de distribuție	050	16306	19740
Cheltuieli administrative	060	964136	1259776
Alte cheltuieli din activitatea operațională	070	417394	640169
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	10277405	9104279

Venituri financiare, total	090	490609	519239
din care:			
venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093		25612
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	490609	493627
Cheltuieli financiare, total	100	686605	597528
din care:			
cheltuieli privind dobânzile	101		
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	686605	597528
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	-195996	-78289
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	-195996	-78289
Profit (pierdere) până la impozitare (rd.080 + rd.150)	160	10081409	9025990
Cheltuieli privind impozitul pe venit	170	1178993	1051159
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	8902416	7974831

SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU
de la până la

Anexa 3

Nr. dno	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfârșitul perioadei de gestiune
1	2	3	4	5	6	7
	Capital social și nelregistrat					
	1. Capital social	010				
	2. Capital nevărsat	020	()	()	()	()
	3. Capital nelregistrat	030				
I.	4. Capital retras	040	()	()	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și nelregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
II.	Prime de capital	070				
	Rezerve					
	1. Capital de rezervă	080				
III.	2. Rezerve statutare	090				
	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			

IV.	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130				
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X			
	4. Profit utilizat al perioadei de gestiune	150	X	()	()	()
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160				
V.	Rezerve din reevaluare	170				
VI.	Alte elemente de capital propriu	180				
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190				

SITUAȚIA FLUXURILOR DE NUMERAR
de la până la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vânzări	010		
Plăți pentru stocuri și servicii procurate	020		
Plăți către angajați și organe de asigurare socială și medicală	030		
Dobânzi plătite	040		
Plata impozitului pe venit	050		
Alte încasări	060		
Alte plăți	070		
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080		
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		
inclusiv: dividende încasate din străinătate	121		
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		
inclusiv: dividende plătite rezidenților	171		
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		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210		
Diferențe de curs valutar favorabile (nefavorabile)	220		
Sold de numerar la începutul perioadei de gestiune	230		
Sold de numerar la sfârșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

Версия для печати
Сохранить

Расписка 2

Респондент
Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.
Предоставил отчет: RSE1_21
На фискальный период: A/2020
Дата предоставления: 11.05.2021
Временная метка отчета зарегистрированного в Информационной Системе НБС : 11.05.2021 12:26:31

National Bureau of Statistics (NBS) received the electronic version of the report, sent by you. The data provided is verified by NBS.

Версия для печати
Сохранить

Расписка

Респондент
Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.
Предоставил отчет: RSE1_21
На фискальный период: A/2020
Дата предоставления: 11.05.2021
Временная метка отчета зарегистрированного в Системе Электронной Отчетности и отправленного в Информационную Систему БНС : 11.05.2021 10:00:47

EC DECLARATION OF CONFORMITY

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

Hereby DECLARES

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

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

under the specifications declared by BioSystems S.A.

It means that the products:

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

Barcelona, November 6th, 2012




Dr. Antonio Elduque
Managing director
BioSystems S.A.



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



CLINICAL CHEMISTRY – BIOCHEMISTRY:

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

CLINICAL CHEMISTRY – TURBIDIMETRY:

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

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

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



CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

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

CLINICAL CHEMISTRY – INSTRUMENTS:

A15	BA400
A25	BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

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



CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

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

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

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

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

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



AUTOIMMUNITY – ELISA:

ANA Screening
Anti-Annexin V IgG/IgM (ANX)
Anti-b2-Glycoprotein 1 IgG/IgM
(b2GP1)
Anti-Cardiolipin Antibodies (ACA-
IgG/IgM)
Anti-Centromere B Antibodies (CENP-
B)
Anti-Citrullinated Protein Antibodies
(ACPA)
Anti-Deamidated Gliadin Peptides IgA
(DGP IgA)
Anti-Deamidated Gliadin Peptides IgG
(DGP IgG)
Anti-dsDNA Antibodies
Anti-GBM Antibodies - EIA (GBM)
Anti-Gliadin Antibodies (AGA-IgG/IgA)
Anti-Histones Antibodies (HIST)
Anti-Insulin Antibodies (INS)
Anti-Jo1 Antibodies
Anti-M2 Antibodies (M2)

Anti-MPO Antibodies
Anti-Nucleosome Antibodies (NCL)
Anti-Phospholipid IgG/IgM (APLA)
Anti-PR3 Antibodies
Anti-Ribosomal P Antibodies (Rib P)
Anti-Scl70 Antibodies
Anti-Sm Antibodies
Anti-Sm/RNP Antibodies
Anti-SSA (Ro) Antibodies
Anti-SSB (La) Antibodies
Anti-Thyroglobulin Antibodies (Anti-Tg)
Anti-Thyroid Peroxidase Antibodies
(Anti-TPO)
Anti-tTransglutaminase IgA Antibodies
(Anti- tTG IgA)
Anti-tTransglutaminase IgG Antibodies
(Anti- tTG IgG)
ASCA-IgG/IgA (ASCA)
ENA 4-Profile
ENA 6-Screening

AUTOINMUNIDAD – INSTRUMENTOS:

AUTOIMMUNITY – INSTRUMENTS:

iPRO



RAPID TESTS – LATEX AGGLUTINATION:

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

Rheumatoid factors (RF) - Slide

INFECTIOUS IMMUNOLOGY – SYPHILIS:

RPR-Carbon

TPHA

INFECTIOUS IMMUNOLOGY – FEBRILE ANTIGENS:

Febrile Serodiagnostics Multiscreening

Febrile Serodiagnostics Salmonella

Brucella abortus

Brucella abortus, Rose Bengal

Proteus Ox19

Salmonella paratyphi AH

Salmonella paratyphi AO

Salmonella paratyphi BH

Salmonella paratyphi BO

Salmonella paratyphi CH

Salmonella paratyphi CO

Salmonella typhi H

Salmonella typhi O

Brucella Positive Control

Proteus Positive Control

Salmonella Positive Control

Serology Negative Control

Certificate

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 sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

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

Effective Date: 2020-01-08
Certificate Registration No.: SX 60145545 0001
An audit was performed. Report No.: 28300434 004
This Certificate is valid until: 2022-12-12

Certification Body



Date 2020-01-08



D. Swiatko

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

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60145545 0001
Report No.: 28300434 004

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
Spain

Activity: Labelling and assembling of reagents,
warehousing and shipment of instruments
and reagents for clinical diagnostic

Certification Body



Date: 2020-01-08

D. Swiatko

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

Certificate Holder: **BIOSYSTEMS S.A.**
Costa Brava 30
08030 Barcelona
Spain

Scope: Design, development, manufacture, distribution, servicing of:
-Instruments and reagents for clinical diagnostic.
-Instruments and reagents for agro-alimentary analysis.
Distribution and service of reagents and instruments for veterinary diagnosis.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2019-12-19 until 2022-12-18.
First certification 1996

2019-12-20



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

www.tuv.com



Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 6696**

No.	Location	Scope
/02	BIOSYSTEMS S.A. Pol. Ind. Can Tapioles naus 7-12-13 08110 Montcada i Reixac Spain	Labeling and assembly of reagent. Storage, and shipping of: - Instruments and reagents for diagnosis and reagents for clinical diagnosis.- Instruments and reagents for agri-food analysis.- Instruments and reagents for veterinary diagnosis.

2019-12-20



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Page 1 of 1

Klicken Sie hier, um Text einzugeben.

www.tuv.com

 **TÜVRheinland**[®]
Precisely Right.

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.

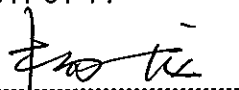
Standards Applied:

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



America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

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: See Page 2 for Overall Scope Statement.

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.: SH2005501

Effective Date: 2020-08-12

Expiry Date: 2023-06-30

Page 1 of 4

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services



America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Overall Scope Statement

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, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and 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

Page 2 of 4

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services



America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

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

Facility Scopes: 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, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and 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

Page 3 of 4

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services



America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Facility(ies)

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

Facility Scopes:

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, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and 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

Page 4 of 4

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services



America

CERTIFICATE

No. QS6 044751 0135 Rev. 01

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: See Page 2 for Overall Scope Statement.

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: 65-467-1304

Effective Date: 2019-08-26

Expiry Date: 2021-10-23

Page 1 of 4

Date of Issue: 2019-11-25

(Dawn M. Tibodeau)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com



ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

CERTIFICATE

No. QS6 044751 0135 Rev. 01

Regulatory Requirements: Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Overall Scope Statement:

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls; Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Page 2 of 4

Date of Issue: 2019-11-25



(Dawn M. Tibodeau)
Manager, Certification Body MHS

CERTIFICATE

No. QS6 044751 0135 Rev. 01

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.
1203 Nanhuan Avenue, Guangming District, 518106 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Facility Scopes:

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 (NIBP House, NIBP Cuff, Sensor Cables including
SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG
Cables and Leadsets, Temperature Probe, Probe Cover),
Vital Signs Monitor, Center Monitoring System, Telemetry
Monitoring System, Pulse Oximeter, Defibrillator / Monitor
and Accessories, Electrocardiograph, Anesthesia Machine
and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic
Equipment, Ultrasonic Transducer, Hematology Analyzer,
Clinical Chemistry Analyzer, Microplate Reader, Microplate
Washer for In-Vitro Diagnostic Use, Chemiluminescence
Immunossay Analyzer, Flow Cytometer, Auto Sample
Processing System, Auto Slide Maker and Stainer;) Reagents
for Hematology Analyzer, Reagents for Clinical Chemistry
Analyzer, Chemiluminescence Immunoassay Reagents,
Chemiluminescence Immunoassav Calibrators and Controls;
Disposable Anesthesia Mask, Reusable Anesthesia Mask,
Respiratory Mask, Disposable Breathing Circuit, Reusable
Breathing Circuit, Heat and Moisture Exchanger, Filter,
Breathing Bag
DUNS No: 65-467-1304

Page 3 of 4

Date of Issue: 2019-11-25



(Dawn M. Tibodeau)
Manager, Certification Body MHS



America

CERTIFICATE

No. QS6 044751 0135 Rev. 01

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

Production of Medical Electronic Equipment (including Patient Monitor and Accessories (NIBP House, NIBP Cuff, Sensor Cables including SPO2 Cable and Temperature Cable, SPO2 Sensor, ECG Cables and Leadsets, Temperature Probe, Probe Cover), Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories (Vaporizer), Ventilator, Ultrasonic Diagnostic Equipment, Ultrasonic Transducer, Hematology Analyzer, Clinical Chemistry Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, Auto Sample Processing System, Auto Slide Maker and Stainer;) Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassav Calibrators and Controls; Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag
DUNS No: 54-459-5743

Page 4 of 4
Date of Issue: 2019-11-25

(Dawn M. Tibodeau)
Manager, Certification Body MHS

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



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 H10-800 |
| DIRUI H13-Cr | DIRUI H12-800MA | |
| DIRUI H13-Cr (H-800) | DIRUI H14-Ca | |
| | DIRUI H14-Ca (H-800) | |

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

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

Valid Since
May 9th, 2012
Changchun, China

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

(place and date of issue)

(name and signature or equivalent marking of authorized person)

认证证书

标准 **ISO 9001:2015**

证书登记号码 **01 100 1832306**

证书持有者:

迪瑞医疗科技股份有限公司

统一社会信用代码: 91220101605902656F

注册地址: 中华人民共和国吉林省长春市

高新技术产业开发区云河街 95 号

邮编: 130012

经营地址: 同上述地址

认证范围:

体外诊断医疗器械的设计开发、生产和销售

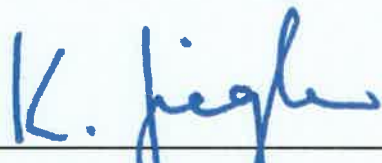
证明完成了审核并满足了 ISO 9001:2015 标准的要求。

有效期:

证书有效期从 2018-05-03 至 2021-05-02。

此证书须经过符合要求的监督审核保持有效。

2018-05-03


TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1832306**

Certificate Holder: **Dirui Industrial Co., Ltd.**
Unified Social Credit Code: 91220101605902656F
Registration Address: 95 Yunhe Street,
New & High Tech. Development Zone,
Changchun City, Jilin Province 130012, P. R. China
Operation Address: same as above

Scope: **Design and Development, Manufacture and Distribution of in Vitro
Diagnostic Medical Test Systems**

Proof has been furnished by means of an audit that the
requirements of ISO 9001:2015 are met.

Validity: **The certificate is valid from 2018-05-03 until 2021-05-02.
It remains valid subject to satisfactory surveillance audits.**

2018-05-03



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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 and additional site included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

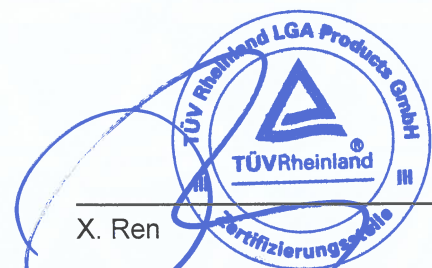
are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-06-26
Certificate Registration No.: SX 60127937 0001
An audit was performed. Report No.: 15047317 007
This Certificate is valid until: 2020-03-01

Certification Body



Date 2018-06-26



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 60127937 0001
Report No.: 15047317 007

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

Scope:

Products:

- Urine Test Systems (Reagents, Analyzers, Controls)
- Hematology Test Systems (Reagents, Analyzers, Controls)
- Clinical Chemistry Test Systems (Reagents, Analyzers, Controls)
- Immunochemistry Test Systems (Reagents, Analyzers, Controls)
- Vaginal Infections Test Systems (Reagents, Analyzers, Controls)

Site included:

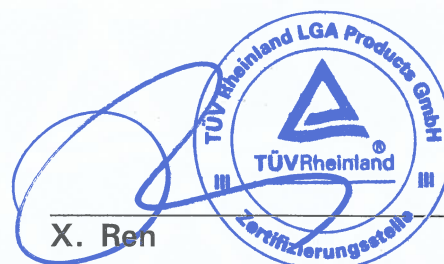
3333 Yiju Street, New & High Tech. Development Zone,
Changchun, 130103 Jilin, China

Design and Development, Manufacture and Distribution of
Urine Test Analyzers, Hematology Test Analyzers, Clinical
Chemistry Test Analyzers, Immunochemistry Test Analyzers,
Vaginal Infections Test Analyzers

Certification Body



Date: 2018-06-26



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

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

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

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

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

THE HEAD OF THE DEPARTMENT OF SANITARY PRODUCTS

[Illegible signature]

M^a del Carmen Abad Luna

EMAIL
mpizarro@aemps.es

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

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

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

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

MARTA CASANOVA HERNANDEZ
Traductora-Intérprete Jurada de INGLÉS

Marta Casanova

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

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

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

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

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


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

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

Accesorios

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

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

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

AQUISEL, S.L.

08630 ABRERA (Barcelona) España

Tf: (93) 770 39 00 Fax: (93) 770 39 15

file:TF-1004_F_10-2014



DECLARACIÓN DE CONFORMIDAD CE CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

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

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

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

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

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

Código GMDN / GMDN Code: 33722

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

ESCOBILLON - Swab

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

Clasificación: Clase IIa
Classification: Class IIa

INFORMACIÓN ADICIONAL

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



OTHER INFORMATION:

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



TUBO CON MEDIO DE TRANSPORTE - Tube with transport medium

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


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

Anna Mir
Responsable Técnico / Technical Director

ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

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

Fecha / Date: 20/05/2016
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REF	DESCRIPCIÓN	DESCRIPTION
300211.1	ESCOBILLÓN PS+ALG. PACK PEEL/2	SWAB B/2 PS+COTTON PEEL/2
300212.1	ESCOBILLON PS+VISCOSA PEEL/2	SWAB PEEL/2 PS+VISCOSSE
300250.1	ESCOBILLON MAD.+ALGOD. PURO TU	SWAB IN TUBE WOOD+PURE COTTON
300250.M	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300261.M	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PS+COTTON
300268.B	ESCOBILLON PS+POLIESTER PEEL PACK	SWAB PS+POLIESTER IND.WRAPPED
300280.2	CARY BLAIR PS+VISCOSA	CARY BLAIR SWAB PS+VISCOSSE
300281/1	ESC. AMIES+CARBON ALUM.VISCOSA	AMIES CHARCOAL SWAB WIRE+VISCOSSE
300281T	AMIES ALUMINIO TRENZADO+ VISCOS	AMIES SWAB TWIST.WIRE+VISCOSSE
300281TC	AMIES+CARBON ALU.TRENZADO+ VISC	AMIES+CHARCOAL TWIS.WIRE+VISCOS
300285.M	AMIES CARBON PS VISCOSA 6x100	AMIES CHARCOAL PS RAYON 6X100
300287.5	AMIES PS VISCOSA CAJAS 6x100	AMIES PS VISCOSSE CASES 6X100
300287.A	ESCOB.AMIES PS+VISCOSA	AMIES SWAB PS+VISCOSSE
300295C	STUART CARBÓN PS + VISCOSA	STUART+CHARCOAL SWAB PS+VISCOSSE
310253.1	ESCOB. ALUM+VISCOSA FLOW	ALUM+VISCOSSE SWAB FLOW
310211.1	ESCOBILLON PS+ALGODON B/2 FLOW	PS+COTTON SWAB B/2 FLOW
300250.MY	ESCOBILLON MAD.+ALGODON TUBO	SWAB IN TUBE WOOD+COTTON
300211.10	ESCOBILLÓN PS+ALG. PACK PEEL/10	SWAB PS+COTTON PEEL/10
300281AV	ESCOBILLON PS+ALGODON TUBO	SWAB IN TUBE PS+COTTON

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

CDCE-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 Lliana
08191 Rubí (Barcelona) – España

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

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

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

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

Código GMDN / GMDN Code: 33722

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

ESCOBILLON - Swab

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

Clasificación: Clase I Estéril
Classification: Class I Sterile

INFORMACIÓN ADICIONAL

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

OTHER INFORMATION:

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

Fecha / Date: 20/05/2016
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CDCE-86 Rev.4

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.**



DELTALAB S.L.
 Plaza de la Verneda 1, Pol. Ind. La Lliana
 08191 Rubí - Barcelona
 T. +34 936 995 000
 José Saez
 Director General / Managing Director
 Anna Mir
 Responsable Técnico / Technical Director

Fecha / Date: 20/05/2016
Pag. 2/4

CDCE-86 Rev.4

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

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

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

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

El fabricante / The manufacturer:

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

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

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

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

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

Código GMDN / GMDN Code: 47775

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

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

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

José Saez
Director General / Managing Director

Anna Mir
Responsable Técnico / Technical Director



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

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

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

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

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

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

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

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

DECLARACIÓN DE CONFORMIDAD CE
CE DECLARATION OF CONFORMITY

El fabricante / The manufacturer:

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

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

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

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

Código GMDN / GMDN Code: 58139

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

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

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

José Saez
Director General / Managing Director

Anna Mir
Responsable Técnico / Technical Director

ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION

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

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

El fabricante / The manufacturer:

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

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

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

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

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

Código GMDN / GMDN Code: 58143

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

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

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

José Saez
Director General / Managing Director

Anna Mir
Responsable Técnico / Technical Director

Fecha / Date: 22/11/2013
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**ANEXO 1 – DESCRIPCIÓN DE ARTÍCULOS
ANNEX 1 – ARTICLES DESCRIPTION**

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

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

CDCE-77 Rev.2.2

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

El fabricante / The manufacturer:

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

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

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

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

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

Código GMDN / GMDN Code: 58138

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

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

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

José Saez
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 ES16/20725

The management system of

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

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

has been assessed and certified as meeting the requirements of

ISO 9001:2015

For the following activities

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

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

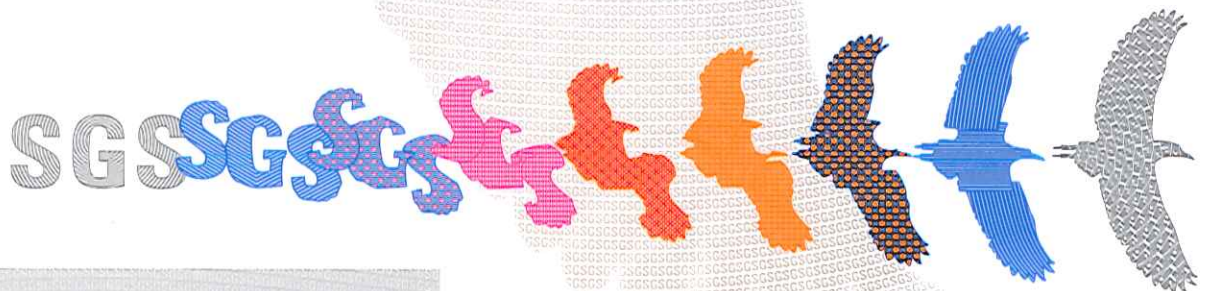
This is a multisite certification. See following page(s).

Authorised by

Certification Management

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

Page 1 of 2



This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <http://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

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

ISO 9001:2015

Issue 4



Sites where these activities are totally or partially carried out

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

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

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

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

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

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

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

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

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

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



Certificate ES16/20725.01



DELTALAB, S.L.

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

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

ISO 9001:2015

For the following activities



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

in / from the following sites

Pol. Ind. La Llana, Plaza de la Verdeda, 1 - 08191 Rubí (Barcelona)

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

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

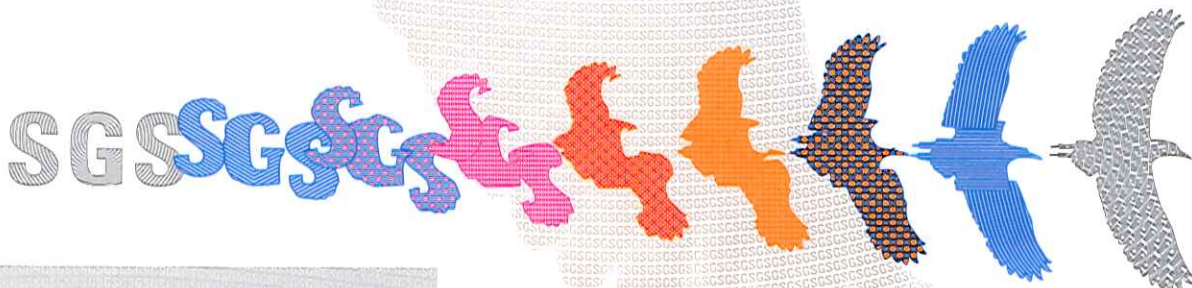


Authorized by

Certification Management

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

Page 1 of 1



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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 13485:2016 EN ISO 13485:2016



For the following activities

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

Distribution of non-active medical devices and in vitro diagnostic medical devices.

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

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

This certificate is valid from 11 October 2019 until 11 October 2022 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 10 September 2022

Issue 9. Certified since 12 October 2010

Authorised by



0005

SGS United Kingdom Ltd

Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK

t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

HC SGS 13485 2016 0118

Page 1 of 1



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EU Declaration of Conformity

OSRAM

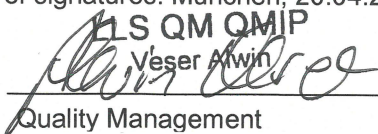
Document number: 2016 / 9C1-3364256-EN-00
Manufacturer or representative: OSRAM GmbH
Address: Marcel-Breuer-Str. 6
80807 München
Germany
Brand name or trade mark: OSRAM
Product type: Lamp controlgear
Product designation: QUICKTRONIC
 See attached list

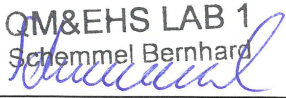
The designated product(s) is (are) in conformity with the relevant Union harmonisation legislation:

- Low Voltage Directive:** 2006/95/EC: Directive of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (until 19.04.2016)
2014/35/EU: Directive of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits; Official Journal of the EU L96, 29/03/2014, p. 357-374 (from 20.4.2016)
- EMC Directive:** 2004/108/EC: Directive of the European Parliament and of the Council of 15 September 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility (until 19.04.2016)
2014/30/EU: Directive of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility; Official Journal of the EU L96, 29/03/2014, p. 79-106 (from 20.4.2016)
- 2009/125/EC**
and amendments
Directive of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products
- 244/2009**
and amendments
Commission Regulation (EC) implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for non-directional household lamps
- 245/2009**
and amendments
Commission Regulation (EC) implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for fluorescent lamps without integrated ballast, for high intensity discharge lamps, and for ballasts and luminaires able to operate such lamps, and repealing Directive 2000/55/EC of the European Parliament and of the Council
- 1194/2012**
and amendments
Commission Regulation (EU) No 1194/2012 of 12 December 2012 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for directional lamps, light emitting diode lamps and related equipment
- 2011/65/EU**
and amendments
Directive of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment; Official Journal of the EU L174, 1/07/2011, p. 88-110
- 1999/5/EC**
and amendments
Directive of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity

Last two digits of the year in which the CE marking was affixed: 16

Place and date of signatures: München, 20.04.2016

Signatures: 
Quality Management


Quality Assurance

Names: Mr. Alwin Vesper

Mr. Bernhard Schemmel

Customer service contact: OSRAM GmbH, Steinerne Furt 62, 86167 Augsburg, Deutschland

This declaration of conformity is issued under the sole responsibility of the manufacturer or representative. It certifies compliance with the indicated Directives, but implies no warranty of properties.

EU Declaration of Conformity

Annex

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

The conformity of the designated product(s) with the provisions of the European **Low Voltage Directive** is given by the compliance with the following European Standard(s) or other specifications. If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

- | | | |
|-------------------------------------|--|--|
| <input checked="" type="checkbox"/> | EN 61347-1:
2008 + A1:2011 + A2:2013 | Lamp controlgear — Part 1: General and safety requirements |
| <input checked="" type="checkbox"/> | EN 61347-2-3:
2011 + Corr. 2011 | Lamp controlgear — Part 2-3: Particular requirements for a. c. and/or d. c. supplied electronic ballasts for fluorescent lamps |

The conformity of the designated product(s) with the provisions of the European **EMC Directive** is given by the compliance with the following European Standard(s) or other specifications. If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

- | | | |
|-------------------------------------|------------------------------|--|
| <input checked="" type="checkbox"/> | EN 55015:
2013 | Limits and methods of measurement of radio disturbance characteristics of electrical lighting and similar equipment |
| <input checked="" type="checkbox"/> | EN 61000-3-2:
2014 | Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) |
| <input checked="" type="checkbox"/> | EN 61000-3-3:
2013 | Electromagnetic compatibility (EMC) — Part 3-3: Limits — Limitation of voltage changes, voltage fluctuations and flicker in public low voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subjected to conditional connection |
| <input checked="" type="checkbox"/> | EN 61547:
2009 | Equipment for general lighting purposes — EMC immunity requirements |

The conformity of the designated product(s) with the provisions of the European Directive **2009/125/EC** is given by the compliance with the following European Standard(s). If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

- | | | |
|-------------------------------------|-------------------------|---|
| <input checked="" type="checkbox"/> | EN 62442-1: 2011 | Energy performance of lamp controlgear - Part 1: Controlgear for fluorescent lamps - Method of measurement to determine the total input power of controlgear circuits and the efficiency of the controlgear |
|-------------------------------------|-------------------------|---|

The conformity of the designated product(s) with the provisions of the European Directive **2011/65/EU** is given by the compliance with the following European Standard(s) or other specifications. If not elsewhere/otherwise indicated the edition/amendment as referenced below applies.

- | | | |
|-------------------------------------|------------------------|--|
| <input type="checkbox"/> | EN 50581: 2012 | Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances |
| <input checked="" type="checkbox"/> | internal report | |

EU Declaration of Conformity

Attached list

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

QTi 1x14/24/21/39 GII	QTP-OPTIMAL 1x18-40
QTi 1x28/54/35/49 GII	QTP-OPTIMAL 2x18-40
QTi 2x14/24/21/39 GII	QTP-OPTIMAL 1x54-58
QTi 2x28/54/35/49 GII	QTP-OPTIMAL 2x54-58
QTi 1x/35/49/80 GII	
QTi 2x35/49/80 GII	
QTP5 1x49	QTP-FC 1x55
QTP5 1x80	QTP-M 1x26-42
QTP5 1x14-35	QTP-M 2x26-32
QTP5 2x14-35	QT-M 2x26-42/220-240 S
QTP5 2x49	QT-FQ 2x80
QTP5 3x14, 4x14	
QTP-DL 1x18-24	QTP-T/E 1x26-42, 2x26
QTP-DL 1x36-40	QTP-T/E 1x18, 2x18
QTP-DL 2x18-24	
QTP-DL 2x36-40	QT-FIT 5/8 1x18-39
QTP-DL 1x55 GII	QT-FIT 5/8 2x18-39
QTP-DL 2x55 GII	QT-FIT 5/8 1x54-58
QTP-D/E 1x10-13	QT-FIT 5/8 2x54-58
QTP-D/E 2x10-13	

Declaration of Conformity

Attached list

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

QT-FIT5 1x14-35	QT-FIT8 1x18
QT-FIT5 2x14-35	QT-FIT8 1x36
QT-FIT5 3x14, 4x14	QT-FIT8 1x58-70
QT-FIT5 1x49	QT-FIT8 2x18
QT-FIT5 2x49	QT-FIT8 2x36
	QT-FIT8 3x18, 4x18
QT-ECO 1x4-16/220-240 S	QT-FIT8 3x36
QT-ECO 1x4-16/220-240 L	QT-FIT8 2x58
QT-ECO 1x18-21/220-240 S	QT-FIT8 2x58-70
QT-ECO 2x5-11/220-240 S	
QT-ECO 1x18-24/220-240 S	
QT-ECO 1x18-24/220-240 L	
QT-ECO 1x26/220-240 S	
QT-COMBI 1x36/220-240	QT ENDURA 70-100/120-240 S
QT-COMBI 1x58/220-240	QT ENDURA 100-150/120-240 S
QT-ECO 1x18-24/220-240 LI	
QT-ECO 1x4-16/220-240 LI	



Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

OSRAM

Opto Semiconductors

OSRAM Opto Semiconductors GmbH

Leibnizstraße 4
93055 Regensburg
Germany

has established and applies
a Quality Management System for

**Design, development and production of
opto semiconductor wafer,
opto electronic components and displays.**

An audit was performed, Report No. **707056398**.

Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled.

The certificate is valid in conjunction
with the main certificate from **2016-12-21** until **2018-09-14**.

Certificate Registration No.: **12 100 52177/11 TMS**.

Product Compliance Management
Munich, 2016-11-25



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

OSRAM

Opto Semiconductors

OSRAM Opto Semiconductors (Malaysia) SDN. BHD

Bayan Lepas Free Industrial Zone Phase 1
11900 Bayan Lepas, Penang
Malaysia

has established and applies
a Quality Management System for

**Design, development and production of
opto semiconductor wafer,
opto electronic components and displays.**

An audit was performed, Report No. **707056398**.

Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled.

The certificate is valid in conjunction
with the main certificate from **2016-12-21** until **2018-09-14**.

Certificate Registration No.: **12 100 52177/12 TMS**.



Product Compliance Management
Munich, 2016-11-25



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

OSRAM

Opto Semiconductors

OSRAM Opto Semiconductors, Inc.

Kifer Road 1150

Sunnyvale, California, CA 94086

USA

has established and applies
a Quality Management System for

Sales, marketing, customer service and logistics.

An audit was performed, Report No. **707056398**.

Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled.

The certificate is valid in conjunction
with the main certificate from **2016-12-21** until **2018-09-14**.

Certificate Registration No.: **12 100 52177/14 TMS**.

Product Compliance Management
Munich, 2016-11-25



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

OSRAM

Opto Semiconductors

OSRAM Opto Semiconductors (China) Co. Ltd.

No. 57, XiQin Rd

Wuxi New District, Jiangsu, P.R. China

Post Code: 214028

Organisation code: 05524191-X

has established and applies
a Quality Management System for

**Production of
Opto Semiconductor components and displays.**

An audit was performed, Report No. **707056398**.

Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled.

The certificate is valid in conjunction
with the main certificate from **2016-12-21** until **2018-09-14**.

Certificate Registration No.: **12 100 52177/18 TMS**.

Information about this certificate can be inquired at the official website of Certification and
Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

Product Compliance Management
Munich, 2016-11-25



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT