ORDIN DE PLATA NR.: 873 TIP.DOC. 1

DATA EMITERII:19 august 2021

PLATITI: 7000-00 LEI: Sapte Mii lei 00 bani

PLATITOR: (R) "BIOSISTEM MLD" S.R.L.
CONTUL DE PLATI/CODUL IBAN
MD95ML0000000002251429243
CODUL FISCAL :1010600028048 /

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

BENEFICIAR (R) Centrul pentru achizitii publice centralizate in sanatate
CONTUL DE PLATI/CODUL IBAN
MD23TRPCCC518430B01859AA
CODUL FISCAL :1016601000212 /

PRESTATORUL BENEFICIAR
Ministerul Finantelor - Trezoreria de Stat
CODUL BANCII:
:TREZMD2X :

DESTINATIA PLATII:/P102/7000,00 Pentru garantia pentru oferta la procedura de achizi?ie publica nr. ocds-b3wdp1-MD-16258 19712090 din 21.08.2021

TIPUL TRANSFERULUI
NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:101:
DATA PRIMIRII:19/08/2021
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSqGSIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4XDTIxMDEyODExMzgwNVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRAwDgYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqGSIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4XDTIxMDEyODExMzkxOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAwDgYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

L.S. (semnatura electronica)

CONDUCATOR: (semnatura manuala)

CONTABIL-SEF: (semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

Digitally signed by Poiata Vitalie
Date: 2021.08.19 13:55:21 EEST
Reason: MoldSign Signature
Location: Moldova

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

CC 04 AE

CERTIFICAT
privind lipsa sau existenţa restanţelor faţă de bugetul public naţional

Nr. / № A2114136 **din** / от 18.08.2021

1. Destinaţia / Назначение

Pentru participare 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 localităţii** Код - Наименование населенного пункта
Albisoara nr.16 bl.1 of.7	0150-SEC.RISCANI

3. Atestarea lipsei sau existenţei restanţelor conform datelor Sistemului Informaţional Automatizat / Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

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

4. Valabil pînă la / Действителен до 02.09.2021

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

Şef DDF Rîşcani a DGAF mun.Chişinău
Funcţia/Должность

Semnătura/Подпись

Viorica CĂUŞ
Numele şi prenumele/Фамилия и имя

L.Ş/ М.П.

Executor: *Svetlana Slonovscaia*
Numele şi prenumele/Фамилия и имя

Este extras din Sistemul Informaţional al SFS SIA „Contul curent al contribuabilului"// 18.08.2021 ora 14:54:53
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: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 – 19/23

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

Filiala „Invest" BC „Moldindconbank" SA confirmă existența contului curent in moneda nationala al **"BIOSISTEM MLD" S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML0000000022514292 43**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării **12.08.2010**

Data eliberării **12.08.2010**

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

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

MD 0101250

I.P. "AGENŢIA SERVICII PUBLICE"

Departamentul înregistrare şi licenţiere a unităţilor 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 şi codul fiscal: **1010600028048.**

Data înregistrării de stat: **12.08.2010.**

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

Obiectul principal de activitate:

1 Activitatea farmaceutică;

2 Importul, fabricarea, comercializarea, asistenţa tehnică şi (sau) reparaţia dispozitivelor medicale şi (sau) a opticii;

3 Acordarea asistenţei medicale de către instituţiile medico-sanitare private;

4 Comerţul cu ridicata al calculatoarelor, echipamentelor periferice şi software-ului;

5 Întreţinerea şi repararea maşinilor de birou şi a tehnicii de calcul;

6 Consultaţii în domeniul sistemelor de calcul.

Capitalul social: **5400** lei.

Administrator: POIATA VITALIE,

Asociaţi:

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 şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de: 28.04.2021.

Specialist coordonator
tel. 022-207-840

Lazari Aliona

"AGENŢIA SERVICII PUBLICE" IDNO 1002600024700 REPUBLICA MOLDOVA CHIŞINĂU 003

EB 0358735

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

Lista fondatorilor Biosistem-mld SRL

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

BIOSISTEM-MLD S.R.L.
c/f 1010600028048; adresa: str. Albișoara 16/1 of.7, or. Chișinău
tel.+373-22-808517, +373-22-808719, fax +373-22-808519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

Către Grupul de lucru pentru evaluarea
Procedurii de achiziție nr. ocds-b3wdp1-MD-1625819712090
Din 30 iul 2021, 9:21 - 21 aug 2021, 9:21
din cadrul CAPCS

Declarație

Prin prezenta, SRL „Biosistem-mld", declara ca :

- Va instala și instrui personalului beneficiarului cu privire la utilizarea echipamentelor livrate, organizate la sediul beneficiarului de către personalul autorizat al furnizorului.
- Termenul de garanție pentru echipamentul oferit nu este mai mic de 24 de luni de la data livrării/instalării acestuia.
- Perioada de reacție: jumătate de oră sau mai puțin la telefon și 24 ore sau mai puțin la locul beneficiarului în cazul apariției defecțiunilor tehnice.
- Va organiza inspecțiile planificate / întreținerea profilactică și calibrarea conform programului stabilit și mentenanța dispozitivului medical pe durata perioadei de garanție, efectuat de către un inginer calificat al ofertantului.
- Anul producerii echipamentului nu este mai vechi de anul 2020.
- Va înregistra în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale bunurile contractate pînă la momentul livrării acestora.

- Pînă la momentul livrării va prezenta numărul de înregistrare din Lista producătorilor, conform prevederilor HG 212/2018 privind gestionarea Echipamentelor Electrice si Electronice (EEE).

_____Vitalie Poiata

L.Ș.

Дата предоставления 11.05.2021 10:00:47

Anexe la SNC
"Prezentarea situațiilor financiare"
Aprobat de Ministerul Finanțelor
al Republicii Moldova

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2020 - 31.12.2020

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

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

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice
Forma de proprietate: 16, Proprietate colectivă
Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:
Telefon: +37322808719
WEB:
E-mail: zmii13@mail.ru
Numele și coordonatele al contabilului-șef: Dl (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

la

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrșitul 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. concesiuni, 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. clădiri	081		
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	2204135	2791637
	3.4. mijloace de transport	084		
	3.5. inventar și mobilier	085		
	3.6. alte mijloace fixe	086	4458	2000
A.	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 neafiliate	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 participare	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 participare	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 participare	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
B.	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 neafiliate	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 participare	393		
	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 nelnregistrat	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	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
C.	**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	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	21026865	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		
D.	3. Datorii comerciale pe termen lung	650		
	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	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		
	din care: 2.1. Împrumuturi din emisiunea de obligațiuni	721		
	inclusiv: Împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	1331928	3252667
	4. Datorii față de părțile afiliate curente	740		
E.	inclusiv: datorii aferente intereselor de participare	741		
	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/clienților	840		
F.	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 pînă la

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	27319617	25963175
din care: venituri din vînzarea 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 vînzări	016		
Costul vînzărilor, total	020	15672962	15186814
din care: valoarea contabilă a produselor și mărfurilor vîndute	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 vînzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	11646655	10776361
Alte venituri din activitatea operațională	040	28586	247603
Cheltuieli de distribuire	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 dobînzi	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 dobînzile	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) pînă 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 pînă la

Anexa 3

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

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vînzări	010		
Plăți pentru stocuri și servicii procurate	020		
Plăți către angajați și organe de asigurare socială și medicală	030		
Dobînzi 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 vînzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobînzi 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 nerezidenților	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 sfîrșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

Расписка 2

Респондент
Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.
Предоставил отчёт: RSF1_21
На фискальный период: A/2020
Дата предоставления: 11.05.2021
Временная метка отчёта 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.

Расписка

Респондент
Фискальный код: 1010600028048, наименование: BIOSISTEM MLD S.R.L.
Предоставил отчёт: RSF1_21
На фискальный период: A/2020
Дата предоставления: 11.05.2021
Временная метка отчёта зарегистрированного в Системе Электронной Отчётности и отправленного в Информационную Систему БНС : 11.05.2021 10:00:47

Better Usability

Minimum size with the footprint similar to that of a 17 inch laptop, with space saving design that allows internal storage of lyse giving small labs more space.
10.4 inch TFT touch screen together with our powerful software enhances user operations and experience.

New technology that eliminates the need for cleanser and rinse, reducing the number of reagents needed while at the same time lowering overall reagent consumption.
Flexible packaging of reagents, with normal and small sizes to better cater to the needs of different daily sample volumes.

Enhanced Performance

Higher throughput at 70 tests per hour.

Micro sample volume at 9.0uL for whole blood mode with capillary whole blood samples supported, perfect for pediatric samples.

BC-30s
Auto Hematology Analyzer

Technical Specifications

Principles
Impedance method for WBC, RBC and PLT counting
Cyanide free reagent for hemoglobin test

Performance

Parameter	Linearity Range	Precision (CV %)	Carryover
WBC(10^9/L)	0-200	≤3.5% (4.0-6.9) ≤2.0% (7.0 -15.0)	≤0.5%
RBC(10^{12}/L)	0-8.00	≤1.5% (3.5-6.5)	≤0.5%
HGB(g/L)	0-280	≤1.5% (100 -180)	≤0.5%
MCV(fL)		≤1.0% (70 -110)	
PLT(109/L)	0-4000	≤5.0% (100 -149) ≤4.0% (150 -500)	≤1.0%

Parameters
21 parameters: WBC, Lymph#, Mid#, Gran#, Lymph%, Mid%, Gran%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT, P-LCR,P-LCC
3 histograms for WBC, RBC and PLT

Reagent
M-30D DILUENT
M-30CFL LYSE
PROBE CLEANSER

Sample Volume
Prediluted mode 20μL
Whole blood mode 9 μL

Throughput
70 samples per hour

Display
10.4 inch TFT Touch Screen

Multi-language
Chinese, English, Spanish, Portuguese, Russian, French, Bahasa Indonesia

Data Storage Capacity
Up to 500,000 results including numeric and graphical information

Communication
LAN Port supports HL7 protocol
Support bi-directional LIS

Interface
4 USB port (for external printer, software upgrade, barcode reader, WIFI adapter,keyboard and mouse), LAN port (1)

Printout
Thermal recorder, 50 mm wide paper, various printouts formats
External printer optional

Operating Environment
Temperature: 10°C~40°C
Humidity: 10%~90%
Air pressure: 70kPa ~ 106kPa

Power Requirement
100V-240V
≤300VA
50Hz/60Hz

Dimension and Weight
Dimension: Depth(410 mm) x width(300 mm) x height(400 mm)
Weight: ≤20Kg

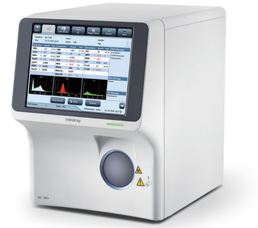
Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan, Shenzhen 518057, P.R. China
Tel: +86 755 8188 8998 Fax: +86 755 26582680
E-mail: intl-market@mindray.com www.mindray.com
Mindray is listed on the NYSE under the symbol "MR"

P/N: ENG-BC-30s-210285x6-20150623

mindray

BC-30s
Auto Hematology Analyzer

Minimum Size,
Maximum Capability



mindray
healthcare within reach

BC-30s

Auto Hematology Analyzer

What a 3-part should be

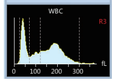
At Mindray we pride ourselves in our dedication and experience in developing better solutions for small labs. Our new line of 3-part hematology analyzers is the culmination of that effort. Compact yet powerful, full featured yet affordable, the BC-30s is what a 3-part analyzer should be.

Exclusive Feature

Detailed flag information never before seen on a 3-part analyzer. Provides information useful for diagnosis including WBC flag, RBC flag and PLT flag.

Different flag information provided according to parameter results together with histograms.

Parameter	Result	Unit
WBC	L 2.4	10^9/L
Lym#	L 0.7	10^9/L
Mid#	R 0.3	10^9/L
Gran#	RL 1.4	10^9/L
Lym%	0.305	
Mid%	R 0.130	
Gran%	R 0.565	

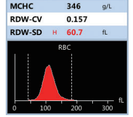


Leucopenia
Lymph decreased
Pancytopenia

Sample 1 : BC-30s shows flags "Leucopenia", "Lymph decreased", "Pancytopenia" which mean white blood cell decreased, the low number of Lymphocyte and decreased of leukocyte, erythrocyte and plate count. Meanwhile "R3" flag is also displayed. Two kinds of flag messages are both supported to ensure clinicians have better understanding of sample results.

Sample 2 : Flag "Anemia" means that the sample has the possibility of anemia.

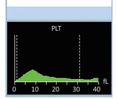
Parameter	Result	Unit
RBC	L 1.86	10^12/L
HGB	L 67	g/L
HCT	L 0.193	
MCV	H 103.5	fL
MCH	H 35.8	pg
MCHC	346	g/L
RDW-CV	0.157	
RDW-SD	H 60.7	fL



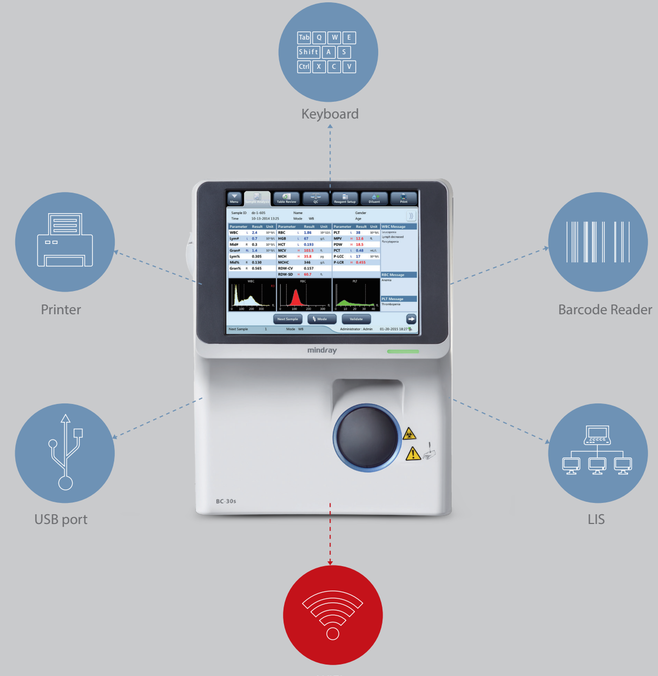
Anemia

Sample 3 : Flag "Thrombopenia" indicator is shown together with Platelets low flag.

Parameter	Result	Unit
PLT	L 38	10^9/L
MPV	H 12.6	fL
PDW	H 18.5	
PCT	L 0.48	mL/L
P-LCC	L 17	10^9/L
P-LCR	H 0.455	



Thrombopenia



WIFI capability provides you an added option for data communication together with bi-directional LIS, USB port and LAN port, barcode reader, printer and keyboard.

PRECIL
A Mindray Company

www.precil.com.cn

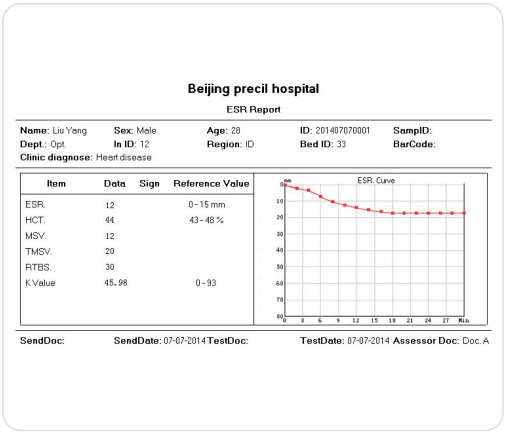
LBY-XC40B/ LBY-XC20B

Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor

Dynamic Scan， Easy Operation

LBY-XC40B/ LBY-XC20B

Auto Dynamic Erythrocyte Sedimentation Rate (ESR) Monitor



Beijing precil hospital

ESR Report

Name: Liu Yang **Sex:** Male **Age:** 28 **ID:** 201407070001 **SampID:**
Dept.: Opt. **In ID:** 12 **Region:** ID **Bed ID:** 33 **BarCode:**
Clinic diagnose: Heart disease

Item	Data	Sign	Reference Value
ESR.	12		0 - 15 mm
HCT.	44		43 - 48 %
MSV.	12		
TMSV.	20		
RTBS.	30		
K Value	45. 98		0 - 93

ESR. Curve

SendDoc: **SendDate:** 07-07-2014 **TestDoc:** **TestDate:** 07-07-2014 **Assessor Doc:** Doc.A

Technical specifications

Testing Channel	40/20
Testing Time	60min/30min
Scanning Interval	2.5min
Accuracy	±5%
Channel Consistency	5%
Repeatability Error	≤3%
Report Unit	mm/h

Features

- Dynamic scanning of erythrocyte sedimentation process
- Automatically calibration to the test result at 25℃
- Auto induction of sample loading and auto testing
- Extremely easy operation: load and testing

PRECIL
A Mindray Company

Beijing Precil Instrument Co., Ltd.

Building No5,Shangdi Qunying Technology and Science Park, Haidian District ,Beijing, P.R.China(100085)
TEL: 0086-10-62971818 62987758 FAX: 0086-10-62987761 http://www.precil.com.cn

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-20s** Including reagents as following: **M-30D DILUENT** **M-30CFL LYSE** **PROBE CLEANSER**
Classification:	The device not in IVDD annex II and not for self testing/performance evaluation

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

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

Standards Applied:

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

Start of CE-Marking: 2015-3-31

Place, Date of Issue: Shenzhen, 2015-3-31

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Declaration of Conformity CE

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80 20537 Hamburg, Germany
Product:	**Auto Hematology Analyzer**
Model:	**BC-30s** Including reagents as following: **M-30D DILUENT** **M-30CFL LYSE** **PROBE CLEANSER**
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Place, Date of Issue: Shenzhen, 2015-3-31

Signature: .....

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity V 1.0

Applied Standards List

Product: **Auto Hematology Analyzer**

BC-20s、BC-30s

Including reagents as following:

M-30D DILUENT

M-30CFL LYSE

PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2011	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
ENISO 18113-2:2011	I In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1：2003+A1：2003	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61010-2-010：2005	Safety requirements for electrical equipment for measurement, control and

Declaration of Conformity V 1.0

	laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2006	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices
EN ISO13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes

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

SCC Accredited CB-MS
OCSM Accrédité CCN

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:

TÜV SÜD ISO 9001

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**

Date of Issue: 2020-08-20

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

SCC Accredited CB-MS
OCSM Accrédité CCN

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

Date of Issue: 2020-08-20

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

SCC Accredited CB-MS
OCSM Accrédité CCN

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 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

Date of Issue: 2020-08-20

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

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

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 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

Date of Issue: 2020-08-20

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD 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:

TÜV SÜD ISO 13485

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**

Date of Issue: 2019-11-25

Dawn Tibodeau

(Dawn M. Tibodeau)
Manager, Certification Body MHS
TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

TÜV®

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

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 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

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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

Date of Issue: 2019-11-25

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD 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

Date of Issue: 2019-11-25

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TÜV®

Roller Mixer

Roller mixer is used for mixing blood samples, viscous substances and liquid-solid suspensions, prevention of blood coagulation and immune precipitation etc.

MX-T6-S

MX-T6-Pro

Features:

* LCD display indicates the speed and time for MX-T6-Pro.
* Gentle and highly efficient rocking and rolling motion.

Technical Parameters:

Model	MX-T6-S	MX-T6-Pro
Mixing Mode	Rocking & Rolling	
Speed Range	0~70rpm	10~70 rpm
Rocking Amplitude	24mm	
Number of Roller	6 pcs	
Roller Length	280mm	
Max. Loading Weight	4kg	
Timing Range	/	1~1199min
Operation Mode	Continuous	Continuous or timing
Display	/	LCD
Motor Type	DC motor	
Consumption	25W	30W
Power Supply	AC110/220V±10%, 50/60Hz	
External Size(W*D*H) mm	260*450*120mm	
Package Size(W*D*H) mm	400*600*260mm	
Gross Weight(kg)	6.5kg	8kg

BIOBASE

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TEL: +86-531-81219803 FAX: +86-531-81219804
E-MAIL: export@biobase.cn WEBSITE: www.biobase.cc / www.meihuatrade.com

DECLARATION OF CONFORMITY

Technical file of the company mentioned below has been inspected and audit has been completed successfully

Low Voltage Directive 2014/35/EU and Electromagnetic Compatibility Directive 2014/30/EU have been taken as reference for these processes

Manufacturer:	**Jinan Biobase Biotech Co., Ltd.** No. 51 South Gongye Road, Jinan, Shandong Province, China
Related Directives:	**2014/35/EU Low Voltage Directive (LVD)** **2014/30/EU Electromagnetic compatibility (EMC)**
Harmonised Standards:	**EN 61010-1:2010; EN 61326-1:2013**
Product(s):	Roller Mixer
Type(s)/Model(s):	MX-T6-S, MX-T6-Pro
Classification:	Laboratory Equipment
Examination Period:	July 30, 2018
Date of Expiry:	July 29, 2023
Review Result:	We, Jinan Biobase Biotech Co., Ltd, declare that during the self-testing and performance evaluation, no non-compliance according to the requirements of the Low Voltage Directive 2014/35/EU and Electromagnetic Compatibility Directive 2014/30/EU was detected.

Year of DOC marking: **2018**

Signed for and on behalf of Company: **Jinan Biobase Biotech Co., Ltd.**

General Manager: Robert Wang

Document No: BKSD-180730

CE

Myr

AUTOMATED
SLIDE STAINER

SS-30

Flexible and versatile design for
optimized staining results

Devoted to Histology

AUTOMATED SLIDE STAINER

SS-30

FOR ROUTINE AND SPECIAL STAINING PROTOCOLS IN HISTOLOGY AND CYTOLOGY LABS

Flexible, optimized and user-friendly

MULTISTAINING CAPABILITY

More staining flexibility allowing simultaneous and automatic staining of various 30-slide racks with identical or different staining protocols. Continuous loading to maximize efficiency and productivity in labs.

Up to 5 slide racks can be run simultaneously depending on protocols, load frequency and instrument configuration, enabling up to 150 slides to be stained simultaneously. The instrument calculates the most efficient route for each rack/ protocol.

FLEXIBLE STAINING

The agitation system can be individually programmed for each station: it is available in 4 different preset dip modes with 3 configurable parameters: number, speed and amplitude of the dips. A special programming for the washing stations is also available.

Several adaptors are available for the most popular coverslipper racks in the market.

COMPACT FOOTPRINT

Ideal for labs with shallow benches to optimize valuable space. Smartly designed to occupy less space without compromising slide staining productivity.

REAL-TIME DISPLAY

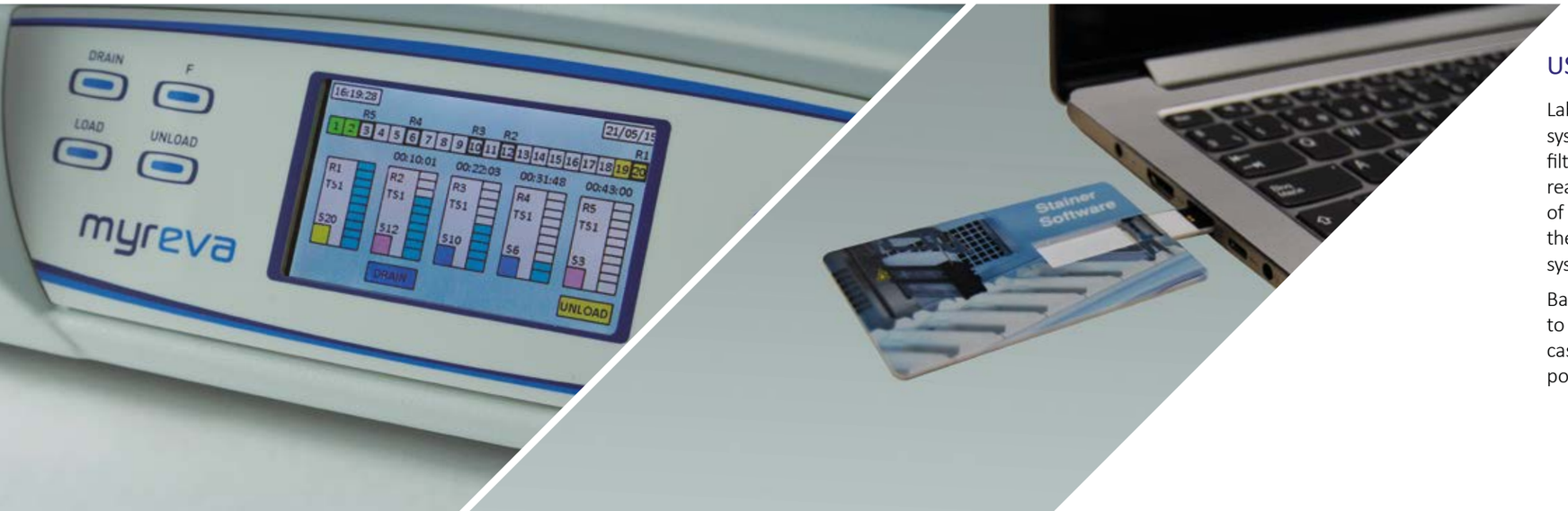
SS-30 displays in real time the status of each staining protocol. It can store up to 20 programmed protocols in memory with 50 steps each maximum as well as up to 52 reagents (32 pre-programmed).

The drain function minimizes the reagent carryover and helps reducing reagent consumption to optimize costs.

DEDICATED SOFTWARE

SS-30 stainer is supplied with a PC dedicated software that offers the option to define protocols and modify the list of saved reagents from the convenience of a PC.

It has also reporting capabilities through a USB plug to acquire data, displaying real status of the running protocols and managing reports and errors.



USER AND SPECIMEN SAFETY

Lab-friendly integrated filtration system equipped with a charcoal filter and individual lids for the reagent stations to avoid evaporation of reagents. Optional adaptor for the laboratory general extraction system.

Back-up battery with 2h autonomy to finish the staining protocols in case of power failure. External 12V power supply.

The transparent hood is equipped with two hinged doors (loading/ unloading stations) to reduce the exposure to reagents.

Water overflowing in the stainer is secured thanks to an innovative two water level sensors system.

The Reagent Management System (RMS) keeps track of reagent usage and ensures an optimal staining quality (available only in version SS-30H).

SPECIFICATIONS

Specimens	Histological and/or cytological
Staining capacity	Up to 5 racks simultaneously
Slide rack capacity	30 slides
Number of programs	Up to 20 programs with max. 50 steps each
Immersion time	From 1 s to 59 m 59 s per step
Agitation system	Independently programmable for each station
Selectable parameters	Number, speed and amplitude of dips
Drain function	Minimizes reagent carryover
Total stations	20 vessels with individual lid
Reagent stations	Up to 19
Reagent stations capacity	300 ml
Water stations	Up to 3
Load stations	Up to 2
Unloading stations	Up to 3 (2 if drying station is available)
Drying station	1 (available only in SS-30H)
Drying station temperature	30 to 70° C
Fume extraction system	Charcoal filter

Power requirements

SS-30	100-240VAC	50-60Hz	0,17A
SS-30H	100-240VAC	50-60Hz	0,76A

Backup battery capacity	2 h
Dimensions (l x w x h)	1.200 x 440 x 368 mm
Weight	55 kg

ORDERING INFORMATION

SS-30	Automated slide stainer	100-240v / 50-60 Hz
SS-30H	Automated slide stainer with drying station	100-240v / 50-60 Hz

OPTIONAL ACCESSORIES

SS30-059	Adapter for THERMO-MICROM rack (30 slides)
SS30-200	Load station LEICA racks
SS30-200B	Lid for load station LEICA rack
SS30-201	Adapter for LEICA plastic rack (30 slides)
SS30-201B	Adapter for LEICA metal rack (30 slides)
SS30-202	Adapter for SAKURA rack (20 slides)
SS30-204	Adapter for MEDITE rack (20 slides)
SS30-205	Adapter for MEDITE rack (30 slides)
SS30-210	Megaslides adapter

Especialidades Médicas Myr S.L

ISO 9001 / 13485 certified company

Lleida, 17-23

43712 Llorenç del Penedès - Spain

Tel. +34 977 66 8020

Fax. +34 977 66 8030

esp.medicas@myr.com.es

www.myr.com.es

Local Distributor. Contact information.

Especialidades Médicas Myr, S.L.

Specification & Data Sheet

AUTOMATED SLIDE STAINER SS-30 & SS-30H SPECIFICATIONS

MULTISTAINING CAPABILITY

- Up to 5 racks can be run simultaneously depending on protocols (identical and/or different), load frequency and instrument configuration.
- 20 stations in total distributed in:
  - Up to 2 loading stations.
  - Up to 3 unloading stations (2 only if drying station available).
  - Up to 3 wash stations with running water.
  - 1 drying station (only in model SS-30H).
- 30 slides per Rack.
- Reagent stations capacity: 300 ml.
- Up to 20 programs in memory with 50 steps each maximum.

The Reagent Management System (RMS) keeps track of reagent usage and ensures an optimal staining quality (only available in version SS-30H).

DEDICATED SOFTWARE

- Individually programmable agitation system for each station.
  - Available in 4 different modes with 3 configurable parameters: number, speed and amplitude of dips.
  - Special programming for washing stations.
- Programmable immersion time between 1s to 59m 59s per step.
- Up to 52 reagents in the memory (32 programmed and 20 defined by user).
- Real time display of staining protocol status.
- Drain function: it minimizes reagent carryover and helps reducing reagent consumption to optimize costs.
- Reporting capabilities through a USB plug to acquire data, displaying real status of the running protocols and managing reports and errors.

SPECIFICATIONS

- Back-up battery with 2h autonomy to finish the staining protocols in case of power failure.
- Integrated filtration system equipped with a charcoal filter.
- Drying station temperature: 30-70ºC (only for SS-30H).
- Several adaptors are available for the most popular coverslipper racks in the market.
- Water overflowing in the stainer is secured thanks to an innovative two water level sensors system.
- Optional adaptor for the laboratory general extraction system.
- External power supply 12V.

TECHNICAL DATA

Specifications

Power requirements	Input: 100-240V – 1,5A/50-60 Hz Output: 12V, SS-30: 5,5A – SS-30H: 12,5A
Dimensions	1.200 x 440 x 368 mm (W x D x H)
Weight when unloaded and without packaging	55 kg
Total weight with packaging	92 kg
Transportation and packaging conditions	Temperature -20 to +50ºC
Water supply	Supply: Running water Maximum pressure: 4 bar Water temperature: less than 30º (86ºF) without freezing Fitting: Standard ¾” Drainage: By gravity Pipe diameter 20mm
Classification in accordance with IEC 1010	Protection class 1 Pollution degree 2 Overvoltage category II
Operating conditions	Operating temperature range: 10-40ºC Relative air humidity: 10-80% non-condensing **FOR INDOOR USE ONLY**
Suggested value for UPS	500 VA

Operating capacity

Processing capacity	Up to 5 racks at a time, depending on the programs, load frequency and device configuration Simultaneous performance of up to 5 different staining protocols
Load capacity per rack	30 slides
No. of programs in the memory	Stores up to 20 programs, each with up to 50 steps
No. of reagents in the memory	Maximum 52 (32 programmed and 20 user-configurable)
Immersion time	1 s - 59 m 59 s per step
Number of stations	20 stations with individual cover
Reagent stations	Maximum 18
Reagent station volume	300 ml
Rinsing stations	Up to 3
Loading stations	Up to 2
Unloading stations	Up to 2
Drying station	1

Drying station temperature	30 – 70ºC
Fume extraction	Active charcoal filter
Accumulator life	2 hours (lithium-ion batteries) Only batteries approved by the manufacturer are permitted to be used

Optional accessories

SS30-059	Adapter for THERMO-MICROM rack (30 slides)
SS30-200	Load station - LEICA rack
SS30-200A	Load Station – CLEARVUE rack
SS30-200B	Lid for load station LEICA rack
SS30-201	Adapter for LEICA plastic rack (30 slides)
SS30-201B	Adapter for LEICA metal rack (30 slides)
SS30-201C	Adapter for CLEARVUE rack (30 slides)
SS30-202	Adapter for SAKURA rack (20 slides)
SS30-204	Adapter for MEDITE rack (20 slides)
SS30-205	Adapter for MEDITE rack (30 slides)
SS30-210	Megaslides adapter

Especialidades Médicas **Myr** S.L

ES-0031/2014 ES-GS-002/2014

EC Declaration of Conformity / *Declaración de Conformidad CE*

Manufacturer / *Fabricante*

Especialidades Médicas MYR S.L.
C/ Lleida 17-23 - 43712 Llorenç del Penedès - Tarragona - Spain

We declare under our own responsibility that the products / *Declaramos bajo nuestra responsabilidad que los productos*

Slide Stainers SS-30 and SS-30H / *Teñidores de Tejidos SS-30 y SS-30H*

meet all the requirements of the following European Directives that are applicable
cumplen todos los requisitos aplicables de las siguientes Directivas Europeas

98/79/EC:	In Vitro Diagnostic Devices Directive Classification: General IVD (Other), neither listed in Annex II of IVD 98/79/EC nor IVDs for self-testing purpose
2014/30/EU:	Electromagnetic Compatibility (EMC) Directive
2014/35/EU:	Low Voltage Directive
2011/65/EU:	Restriction of the Use of Hazardous Substances in electrical and electronic equipment (RoHS) Directive

The products are designed and manufactured according to the relevant parts of the following International Standards
Los productos están diseñados y fabricados de acuerdo con las partes relevantes de los siguientes estándares

IEC 61010-1: 2010 + A1:2016	**IEC 61010-2-010: 2014**	**IEC 61010-2-081: 2015**
IEC 61010-2-101: 2015	**EN 61326-1: 2013**	**EN 61326-2-6: 2013**
EN ISO 14971: 2012		

The Quality Management System of the company is certified according to the following International Standards:
El Sistema de Gestión de la Calidad de la empresa está certificado de acuerdo con las siguientes normas internacionales:

ISO 9001-2015:	Quality Management system
ISO 13485-2016:	Medical Devices - Quality Management system

Llorenç del Penedès, 03/07/2020

ESPECIALIDADES MÉDICAS MYR S.L.
NIF. B-43202597
C/ Lleida, 17-23, Pol. Ind. L'Empalme
43712 LLORENÇ DEL PENEDÈS - SPAIN
Telf. +34 977 668 020 Fax +34 977 668 030

Francisco Ruiz Robles
Managing Director / *Director General*

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

AENOR *has issued an IQNet recognized certificate that the organization:*

ESPECIALIDADES MEDICAS MYR, S.L.

CL LLEIDA, 17-23.
43712 - LLORENÇ DEL PENEDES
(TARRAGONA)

has implemented and maintains a

Quality Management System

for the following scope:

Design, development and production of machines for pre-treatment before analysis and diagnosis of all types of tissues: human, animal and vegetable.

which fulfills the requirements of the following standard

ISO 9001:2015

First issued on: ***2014-01-24*** *Last issued:* ***2020-03-13*** *Validity date:* ***2023-03-13***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: ***ES-0031/2014***

Alex Stoichitoiu
President of IQNet

Rafael GARCÍA MEIRO
Chief Executive Officer

AENOR

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AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
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IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

Original Electronic Certificate

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

AENOR *has issued an IQNet recognized certificate that the organization:*

ESPECIALIDADES MEDICAS MYR, S.L.

CL LLEIDA, 17-23.
43712 - LLORENÇ DEL PENEDES
(TARRAGONA)

has implemented and maintains a

Medical devices – Quality Management Systems

for the following scope:

Design, development and production of machines for preparation of all types of tissues for in vitro diagnostic.

which fulfills the requirements of the following standard

ISO 13485:2016

First issued on: ***2014-03-28*** *Last issued:* ***2020-03-28*** *Validity date:* ***2023-03-28***

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: ***ES-GS-0002/2014***

Alex Stoichitoiu
President of IQNet

Rafael GARCÍA MEIRO
Chief Executive Officer

AENOR

IQNet Partners*:
AENOR *Spain* AFNOR Certification *France* APCER *Portugal* CCC *Cyprus* CISQ *Italy*
CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* EAGLE Certification Group *USA*
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