



REPUBLICA MOLDOVA

LICENȚĂ

Seria A MMII

Nr. 044322

Denumirea autorității de licențiere

Camera de Licențiere

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

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

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

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

12.08.2010 MD 0101250

Numărul de înregistrare a întreprinderii sau IDNO

1010600028048

Codul fiscal

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

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

Data eliberării licenței

4 octombrie 2010

Reperfectată: 1)19.10.2012; 2)14.05.2014

Valabilă pînă la

4 octombrie 2015

Prelungită pînă la: 03.10.2020

**Semnătura conducătorului
autorității de licențiere**

Director al Camerei de Licențiere

Valentin GUZNAC



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



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

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

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

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

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

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina 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





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

EXTRAS
din Registrul de stat al persoanelor juridice

nr. 14419 din 11.07.2016

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

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

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

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

Data înregistrării de stat: **12.08.2010.**

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

Modul de constituire: **nou creată.**

Obiectul principal de activitate:

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

Capitalul social: **5400 lei.**

Administrator: POIATA VITALIE, IDNP 0983103892591,

Asociați:

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

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

Specialist principal
tel. 022-266-252


Lazari Aliona



Lista fondatorilor Biosistem-mld SRL

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

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. № **A2016643**

din от **16.07.2020**

1. Destinația / 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 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 31.07.2020

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

Șef DDF Rîșcani
Funcție/Должность
a DGAF mun. Chișinău

L.Ș/ М.П.

Svetlana Slonovscăia
Numele și prenumele/Фамилия и имя



[Signature]
Semnătura/Подпись

Viorica CĂUȘ

Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 16.07.2020 ora 14:09:09
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,10)



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-1593520191124

din 21.07.2020

din cadrul IMSP AMT Centru

Declarație

Prin prezenta, SRL „Biosistem-mlD”, declara că reactivii propuși în ofertă corespund cu Cerințe Generale specificate în Ordinul MS nr.701 din 18.10.2010. Termenul de valabilitate indicat pe ambalaj de producător nu mai mic de 12 luni. Seturile va fi livrate în ambalaj securizat, marcat și etichetat de producător. Date de identitate (denumirea, numărul lotului, seria, termenii de valabilitate, condițiile de păstrare) ale produsului indicate pe ambalaj coincidă în mod obligatoriu cu cele de pe etichetele componentelor incluse în set. Instrucțiunile de utilizare a truselor conțină caracteristicile de performanță și calitate: sensibilitatea, liniaritatea, specificitatea, reproductibilitatea și interferența . Instrucțiunile privind modul de utilizare prezentate în limba de stat sau limba rusă.

_____ Vitalie Poiata

L.Ș.



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. 睿迪瑞医疗科技

于歌 股份有限公司



(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**

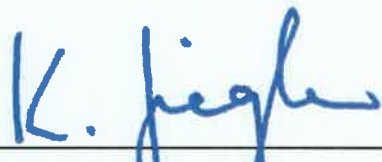
证书持有者：**迪瑞医疗科技股份有限公司**
统一社会信用代码：91220101605902656F
注册地址：中华人民共和国吉林省长春市
高新技术产业开发区云河街 95 号
邮编：130012
经营地址：同上述地址

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

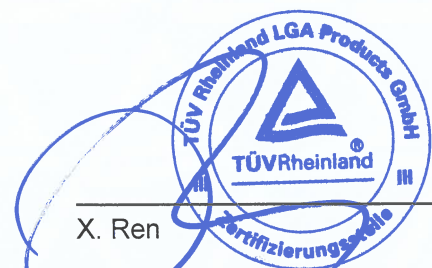
are fulfilled. The quality management system is subject to yearly surveillance.

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:

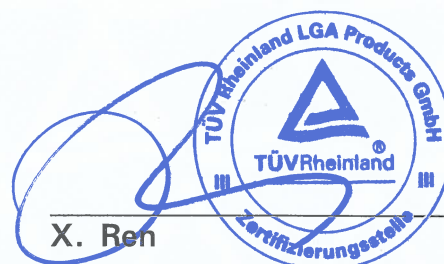
3333 Yiju Street, New & High Tech. Development Zone,
Changchun, 130103 Jilin, China

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





H-500

Urine Analyzer



DIRUI 20th Anniversary

DIRUI

H-500

Urine Analyzer

Product Characteristics:

- Adopting the advanced high luminosity cold light source with 4 -wavelength, which improves the sensitivity, accuracy, specificity, and reduces the interference from ambient light
- Adopting automatic waste handling equipment, which avoids cross-contamination between samples
- Automatically rectify the test results influenced by non-specificity, pH, specific gravity, and color
- Built-in thermal printer with high speed and low noise; External stylus printer
- Connectable with urine sediment analyzer
- Users can set an abnormal value flag by themselves
- International, regular and symbol system units available for option



Technical Specification:

- Test items: urobilinogen, bilirubin, ketone, blood, protein, nitrite, leukocytes, glucose, specific gravity, pH and VC microalbumin creatinine, calcium
- Test wavelength: 525nm, 572nm, 610nm, 660nm
- Test principle: Photoelectric colorimetry
- Suitable strips: DIRUI H8, H10,H11 and H11MA(N) H12,H13-Cr,H14-Ca urinalysis strips
- Test throughput: 514strips/h
- Data memory: 2000 patient results
- Computer interface: RS-232 port; parallel printer interface
- Display: 5.7 " LCD
- Language: Chinese,English,Russian,Polish,Italian,Spanish,Portuguese, Turkish,Hungarian,German,French
- Power supply: 100~240VAC, 50Hz/60Hz
- Power: 40VA
- Dimensions: 380mm×378mm×275mm
- Weight: 6.8kg
- Printer: Built-in thermal printer



Certified to
ISO 9001:2008 and ISO 13485:2003

DIRUI INDUSTRIAL CO.,LTD.

95 Yunhe Street, New & High Tech. Development Zone
Changchun, Jilin 130012 P. R. China

Tel: +86 431 85100409 Fax: +86 431 85172581

E-mail: dirui@dirui.com.cn Http://www.dirui.com.cn

· Specifications subject to change without notice.
20120718

DIRUI



Declaration of Conformity

Manufacturer: Lansion Biotechnology Co., Ltd.
Add: No.2, Qiande Road, Science Park,
Jiangning District, 210000 Nanjing, Jiangsu
Province, PEOPLE'S REPUBLIC OF CHINA
Tel: 025-58577660

Authorized Representative: Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124, Heidelberg,
Germany

We declare under our sole responsibility that:

Product Name: HbA1c Test Kit
(Dry Fluorescence Immunoassay)

Type/Model: 25T

Classification: Others

Conformity Assessment Peocedure: Directive 98/79/EC Annex III

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

DIRECTIVES

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

Nanjing, China March, 12, 2020

Place, Date





Declaration of Conformity

Manufacturer: Lansion Biotechnology Co., Ltd.
Add: No.2, Qiande Road, Science Park,
Jiangning District, 210000 Nanjing, Jiangsu
Province, PEOPLE'S REPUBLIC OF CHINA
Tel: 025-58577660

Authorized Representative: Llins Service & Consulting GmbH
Obere Seegasse 34/2, 69124, Heidelberg,
Germany

We declare under our sole responsibility that:

Product Name: Dry Fluorescence Immunoassay Analyzer
Type/Model: LS-1100
Classification: Others
Conformity Assessment Procedure: Directive 98/79/EC Annex III

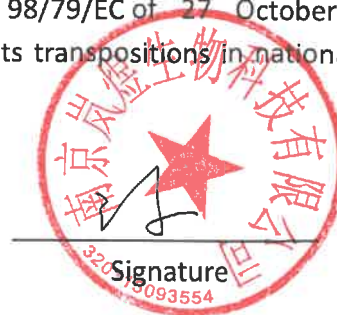
We herewith declare that the product meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

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

Nanjing, China March, 12, 2020

Place, Date



► **Test Items:**

Category	Test Item	Specimen Type	Sample Volume	Reaction Time	Measuring Range
Diabetes	HbA1c	WB	5μL	15min	3.0-14.0%
Inflammation	CRP	S/P/WB	5μL	3min	0.5-200μg/mL
	PCT	S/P/WB	100μL	10min	0.1-50ng/mL
	SAA	S/P/WB	5μL	15min	2.0-300μg/mL
Cardiac	CK-MB	S/P/WB	100μL	10min	2.0-80ng/mL
	cTnl	S/P/WB	100μL	10min	0.05-40ng/mL
	Myo	S/P/WB	100μL	10min	20-500ng/mL
	NT-proBNP	S/P/WB	100μL	15min	50-25000pg/mL
	D-Dimer	P/WB	100μL	10min	0.1-10μg/mL
	H-FABP	S/P/WB	100μL	15min	1-120ng/mL
Hormone	T3	S/P/WB	100μL	15min	0.5-10nmol/L
	T4	S/P/WB	100μL	10min	10-350nmol/L
	TSH	S/P/WB	100μL	15min	0.1-60μIU/mL
	25-OH-VD	S/P	100μL	10min	5-70ng/mL
	β-HCG	S/P/WB	50μL	15min	2-20000mIU/mL
	LH	S/P/WB	100μL	15min	5-200mIU/mL
	FSH	S/P/WB	100μL	10min	1-150mIU/mL
	GH	S/P/WB	100μL	10min	0.05-100ng/mL
	PRL	S/P/WB	100μL	10min	1-100ng/mL
	AMH	S/P/WB	100μL	10min	0.1-50ng/mL
Gastric Function	PGI	S/P/WB	100μL	10min	10-60ng/mL
	PGII	S/P/WB	100μL	10min	5-100ng/mL
	G-17	S/P/WB	100μL	10min	5-300ng/mL
Renal Function	NGAL	S/P/WB/Urine	100μL	10min	50-5000ng/mL
	mAlb	Urine	100μL	5min	10-200mg/L
	β2-MG	S/P/WB	10μL	10min	0.5-20mg/L
	Cys-C	S/P/WB	10μL	5min	0.5-10ng/L
Tumor	PSA	S/P/WB	100μL	10min	0.1-100ng/mL

LS-1100

Dry Fluorescence Immunoassay Analyzer (Portable)



Quantitative

Rapid

Sensitive

Reliable

Accurate, Anytime and Anywhere

New items are available soon!

Lansion Biotechnology Co., Ltd.

Add: No.2 Qiande Road, Jiangning District, Nanjing, China

E-mail: biz@lansionbio.com

Web: en.lansionbio.com

Tel: +86-25-5857 7600

Fax: +86-25-5875 8600



Lansion Biotechnology Co., Ltd.

LS-1100 Dry Fluorescence Immunoassay Analyzer (Portable)

► Analyzer Introduction:

LS-1100 uses the advanced method of Time-resolved Fluorescence Immunoassay (TRFIA), for the in-vitro quantitative detection of bio-markers for Diabetes Mellitus, Inflammation, Cardiovascular Diseases, Hormone, Gastric Diseases, Renal Diseases, Tumor, etc.

Application: Laboratory, ER, Cardiology, ICU, Respiratory, Pediatrics, etc.

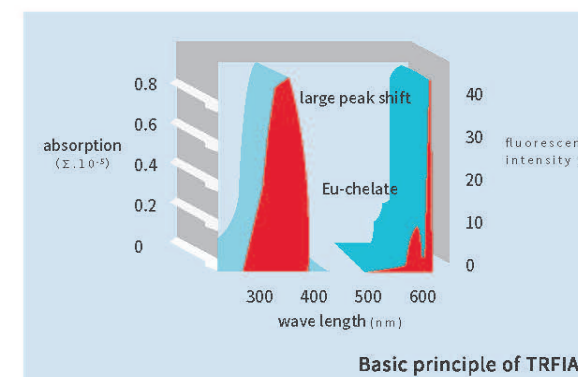
► Features:



“ **Quantitative, Rapid and High Sensitive
Reliable Result (QC system, QR code calibration)** ”

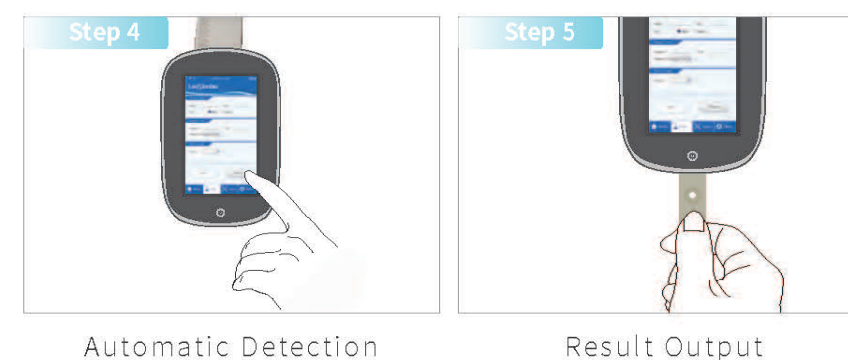
Method	Time-resolved Fluorescence Immunoassay (TRFIA)
Specimen	Serum/Plasma/Whole Blood/Urine
Weight	1.3kg
Dimensions	225mm × 152mm × 105mm (L×W×H)
Screen	7 inch touch screen
Data Storage	≥ 5000
Printer	Built-in thermal printer
Battery	Built-in lithium battery (super standby time)
Communication	RS232(LIS/HIS), RJ45, USB, WIFI, Bluetooth

► Time-resolved Fluorescence Immunoassay (TRFIA) Method:



TRFIA is super-sensitive detection technique characterized by specific fluorescence of rare earth ions. It is not only highly sensitive, but also overcomes the instability of enzyme marker and is the best choice for immunological detection. The high fluorescence intensity and long life of labeled ionic chelates are beneficial to eliminate the influence of fluorescent substances in samples and environment on the test results.

► Easy Operation:



21.08.2016
İzmir / Turkey

DECLARATION FOR THE ISSUANCE OF QUALITY CERTIFICATES

To Whom It May Concern,

According to IVD 98/79/EC directive,

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

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

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

Cordially,

TURKLAB TIBBİ MALZEMELER SAN TİC A.Ş



EC CERTIFICATE No. 1434-IVDD-56/2016

EC Design-Examination

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

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

HBsAg Test

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

manufactured by:

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

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

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

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

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



Anna Wyroba
Anna Wyroba
Vice President of PCBC

CE 1434

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

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

Module H6



EC CERTIFICATE No. 1434-IVDD-57/2016

Full Quality Assurance System

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

PCBC certifies quality assurance system in company:

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

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

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

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

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

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

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



Anna Wyroba
Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module H7



EC CERTIFICATE No. 1434-IVDD-52/2016

EC Design-Examination

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

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

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

manufactured by:

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

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

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

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

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



Anna Wyroba
Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module H6



EC CERTIFICATE No. 1434-IVDD-53/2016

Full Quality Assurance System

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

PCBC certifies quality assurance system in company:

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

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

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

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

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

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

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



Anna Wyroba
Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module H7



EC CERTIFICATE No. 1434-IVDD-54/2016

EC Design-Examination

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

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

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

manufactured by:

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

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

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

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

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



Anna Wyroba
Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module H6



EC CERTIFICATE No. 1434-IVDD-55/2016

Full Quality Assurance System

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

PCBC certifies quality assurance system in company:

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

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

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

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

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

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

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



Anna Wyroba
Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module H7



EC CERTIFICATE No. 1434-IVDD-58/2016

EC Design-Examination

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

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

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

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

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

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

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

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



Anna Wyroba
Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module H6



EC CERTIFICATE No. 1434-IVDD-59/2016

Full Quality Assurance System

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

PCBC certifies quality assurance system in company:

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

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

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

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

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

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

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



Anna Wyroba
Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module H7



EC CERTIFICATE No. 1434-IVDD-51/2016

EC Design-Examination

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

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

**hCG Pregnancy Test
Brands: Rapidan Nova®, Rapidan Optima®, Info®, Toyo®, Rapidan
Tester®, Rapidan Compact®, Labmen®**
manufactured by:

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

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

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

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

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



Anna Wyroba
Anna Wyroba
Vice President of PCBC

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

CE 1434

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

Module A1



CERTIFICATE

No. J - 2670/2/2018

This is to certify that:

TÜRKLAB TIBBI MALZ. SAN. VE TIC. A.Ş.
Sasalı Merkez Mh. Doğa Dostları Sitesi 131 Sk. No: 2/5
35621 Çiğli, İzmir, Turkey
Factory: ITOB 10031 Sk. No: 15 Menderes / İzmir - Turkey

is in conformance with

EN ISO 9001:2015

in the following scope of activities:

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

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

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from **24.08.2018** to **21.12.2020**



AC 019
QMS




Anna Wyroba, M.Sc.
Vice President



Certificate No. **J-2670/2/2018**
Issued under the Contract No. 2897/JM/3/2017
Date of certification decision: 24.08.2018
Bears the PCBC hologram.
Warsaw, 24.08.2018



CERTIFICATE

No. M - 56/2/2018

This is to certify that:

TÜRKLAB TIBBI MALZ. SAN. VE TIC. A.Ş.
Sasalı Merkez Mh. Doğa Dostları Sitesi 131 Sk. No: 2/5
35621 Çiğli, İzmir, Turkey
Factory: ITOB 10031 Sk. No: 15 Menderes / İzmir - Turkey

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

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

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

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from **24.08.2018** to **21.12.2020**



AC 019
QMS



Anna Wyroba
Anna Wyroba, M.Sc.
Vice President



Certificate No. **M - 56/2/2018**

Issued under the Contract No. 2897/JM/3/2017

Date of certification decision: 24.08.2018

Bears the PCBC hologram.

Warsaw, 24.08.2018

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

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



 **TÜVRheinland®**
Precisely Right.

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.

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