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

Digitally signed by Poiata Vitalie
Date: 2024.02.20 12:15:13 EET
Reason: MoldSign Signature
Location: Moldova

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

AGENŢIA SERVICII PUBLICE

Departamentul înregistrare şi licenţiere a unităţilor de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. **531522** data **15.09.2023**

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 (IDNO): **1010600028048**
Data înregistrării de stat: **12.08.2010**
Sediul: **MD-2001, str. Albişoara, 16/1, ap. 7, mun. Chişinău, Republica Moldova.**
Obiectul principal de activitate:
1. Activitatea farmaceutică; importul şi (sau) producerea articolelor de parfumerie şi cosmetică
2. Fabricarea, comercializarea, asistenţa tehnică, repararea şi verificarea articolelor de tehnică şi optică medicală
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, IDNP 0983103892591,**

Asociaţii:
1. POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%
Beneficiar efectiv:
1.1. POIATA VITALIE, IDNP 0983103892591,

2. NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%
Beneficiar efectiv:
2.1. NASEDCHIN ALEXANDR, IDNP 2002001070747,

3. KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%
Beneficiar efectiv:
3.1. KOJEVNIKOV DMITRII, IDNP 0972305012362

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: **15.09.2023**.

Registrator în domeniul înregistrării de stat

Digitally signed by Rusu Diana
Date: 2023.09.15 16:44:17 EEST
Reason: MoldSign Signature
Location: Moldova

Rusu Diana

EB 0461494

Date cu caracter personal

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

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

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

OSRAM
Opto Semiconductors

OSRAM Opto Semiconductors GmbH
Leibnizstraße 4
93055 Regensburg
Germany

has established and applies
a Quality Management System for

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

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

Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled.

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

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

Product Compliance Management
Munich, 2016-11-25

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-03

TÜV SÜD Management Service GmbH • Zertifizierungsstelle • Ridlerstraße 65 • 80339 München • Germany
www.tuev-sued.de/certificate-validity-check

TÜV®

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

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

OSRAM
Opto Semiconductors

OSRAM Opto Semiconductors (Malaysia) SDN. BHD

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

has established and applies
a Quality Management System for

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

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

Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled.

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

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

Product Compliance Management
Munich, 2016-11-25

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-03

TÜV SÜD Management Service GmbH • Zertifizierungsstelle • Ridlerstraße 65 • 80339 München • Germany
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Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

OSRAM
Opto Semiconductors

OSRAM Opto Semiconductors, Inc.
Kifer Road 1150
Sunnyvale, California, CA 94086
USA

has established and applies
a Quality Management System for

Sales, marketing, customer service and logistics.

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

Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled.

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

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

Product Compliance Management
Munich, 2016-11-25

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-03

M/S/01-07/2014

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

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

OSRAM
Opto Semiconductors

OSRAM Opto Semiconductors (China) Co. Ltd.

No. 57, XiQin Rd
Wuxi New District, Jiangsu, P.R. China
Post Code: 214028

Organisation code: 05524191-X

has established and applies
a Quality Management System for

Production of
Opto Semiconductor components and displays.

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

Proof has been furnished that the requirements
according to

ISO 9001:2008

are fulfilled.

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

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

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

Product Compliance Management
Munich, 2016-11-25

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-03

M/S/01-07/2014

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EU Declaration of Conformity

OSRAM

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

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

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

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

Place and date of signatures: München, 20.04.2016

Signatures:	LS QM QMP Veser Alwin	QM&EHS LAB 1 Schemmel Bernhard
	Quality Management	Quality Assurance
Names:	Mr. Alwin Veser	Mr. Bernhard Schemmel

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

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

1051 04/2016

EU Declaration of Conformity
Annex

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

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

☒	**EN 61347-1:** 2008 + A1:2011 + A2:2013	Lamp controlgear — Part 1: General and safety requirements
☒	**EN 61347-2-3:** 2011 + Corr. 2011	Lamp controlgear — Part 2-3: Particular requirements for a. c. and/or d. c. supplied electronic ballasts for fluorescent lamps

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

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

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

☒	**EN 62442-1:** 2011	Energy performance of lamp controlgear - Part 1: Controlgear for fluorescent lamps - Method of measurement to determine the total input power of controlgear circuits and the efficiency of the controlgear

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

☐	**EN 50581:** 2012	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
☒	**internal report**	

EU Declaration of Conformity
Attached list

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

QTi 1x14/24/21/39 GII

QTi 1x28/54/35/49 GII

QTi 2x14/24/21/39 GII

QTi 2x28/54/35/49 GII

QTi 1x/35/49/80 GII

QTi 2x35/49/80 GII

QTP-OPTIMAL 1x18-40

QTP-OPTIMAL 2x18-40

QTP-OPTIMAL 1x54-58

QTP-OPTIMAL 2x54-58

QTP5 1x49

QTP5 1x80

QTP5 1x14-35

QTP5 2x14-35

QTP5 2x49

QTP5 3x14, 4x14

QTP-FC 1x55

QTP-M 1x26-42

QTP-M 2x26-32

QT-M 2x26-42/220-240 S

QT-FQ 2x80

QTP-DL 1x18-24

QTP-DL 1x36-40

QTP-DL 2x18-24

QTP-DL 2x36-40

QTP-DL 1x55 GII

QTP-DL 2x55 GII

QTP-D/E 1x10-13

QTP-D/E 2x10-13

QTP-T/E 1x26-42, 2x26

QTP-T/E 1x18, 2x18

QT-FIT 5/8 1x18-39

QT-FIT 5/8 2x18-39

QT-FIT 5/8 1x54-58

QT-FIT 5/8 2x54-58

1051 04/2016

Declaration of Conformity
Attached list

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

QT-FIT5 1x14-35

QT-FIT5 2x14-35

QT-FIT5 3x14, 4x14

QT-FIT5 1x49

QT-FIT5 2x49

QT-FIT8 1x18

QT-FIT8 1x36

QT-FIT8 1x58-70

QT-FIT8 2x18

QT-FIT8 2x36

QT-FIT8 3x18, 4x18

QT-FIT8 3x36

QT-FIT8 2x58

QT-FIT8 2x58-70

QT-ECO 1x4-16/220-240 S

QT-ECO 1x4-16/220-240 L

QT-ECO 1x18-21/220-240 S

QT-ECO 2x5-11/220-240 S

QT-ECO 1x18-24/220-240 S

QT-ECO 1x18-24/220-240 L

QT-ECO 1x26/220-240 S

QT-COMBI 1x36/220-240

QT-COMBI 1x58/220-240

QT-ECO 1x18-24/220-240 LI

QT-ECO 1x4-16/220-240 LI

QT ENDURA 70-100/120-240 S

QT ENDURA 100-150/120-240 S

1051 04/2016

Declaration of Conformity CE

Manufacturer:	Beijing Precil Instrument Co., Ltd. 2F East 5 Building, Qunying kejiyuan, Shangdi Information Base, Haidian District, Beijing 100085, China
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Product:	Auto Coagulation Analyzer
Model:	C3100
Consumables :	Auto Cuvettes Probe Cleanser Cleanser
Classification:	Others(Not listed in the Annex II, Directive 98/79/EC)

Conformity assessment route: Annex III(Except 6), Directive 98/79/EC

We herewith declare that the above-mentioned products meet the previsions of the following EC Council Directives 98/79/EC for in-vitro-diagnostics. All supporting documentation is retained under the premises of the manufacturer.

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

Start of CE-Marking: 2016-09-01

Place, Date: Beijing, 2016-09-01

Signature: _____

Name of Authorized Signatory: Zhang Yaohui

Position Held in Company: Management Representative

Applied Standards List

Product: Auto Coagulation Analyzer

Applied Standards:

EN 980:2008	Graphical symbols for use in the labeling of medical devices
EN ISO 13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)
EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN13640:2002	Stability testing of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-1)
EN ISO 15193:2009	In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin
EN ISO 15194:2009	In vitro diagnostic medical devices. Measurement of quantities in samples of biological origin. Requirements for certified reference materials and the content of supporting documentation
EN ISO 17511:2003	In vitro diagnostic medical devices. Measurement of quantities in biological samples. Metrological traceability of values assigned to calibrators and control materials
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Part 2:In vitro diagnostic reagents for professional use CORR:January 31,2012
EN 62366:2008	Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements -- Part 1: General requirements IEC 61326-1:2005
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 IEC 61326-2-6:2005
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use -- Part 1: General requirements IEC 61010-1:2001
EN 61010-2-081:2002+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 IEC 61010-2-081:2001
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 61010-2-101:2002 (Modified)

Drafted by: 李志宏

Checked by:

BioSystems
REAGENTS & INSTRUMENTS

Prin prezenta compania Biosystems SA producătorul Analizorului biochimic A-15 / A-25 / BA-400 confirmă faptul, că produsele următoare sunt certificate de DECLARATIA DE CONFORMITATE CE № Ref . I-010 fiind parte integrală și indispensabilă al aparatului A-15 / A-25 / BA-400:

1. Rotor de reacție AC11485
2. Cuvă pentru ser AC10770
3. Soluție concentrată de spălare BO13416
4. Soluție de sistem BO11524
5. Lampă Halogenă LA10429
6. Ac pentru dozare AC11500
7. Reactivi biochimici, turbidimetrici, cromatografici, standarde, controale, aglutinație latex, indicate in anexa declarației de conformitate CE.

Produsele sus menționate sunt confecționate in conformitate cu standardele ISO 9001 si ISO 13485.

BioSystems
Costa Brava, 30
08030 BCN

Xavier Palomar
Area Manager
27-April-2011

ISO 13485

BioSystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
e-mail:biosystems@biosystems.es www.biosystems-sa.com