

REPUBLICA MOLDOVA LICENŢĂ

Seria A MMII

Nr. 044322

Denumirea autorității de licențiere

Camera de Licențiere

Denumirea, forma juridică de organizare, sediul Societatea cu Răspundere Limitată (adresa juridică) a titularului de licență "BIOSISTEM MLD"

mun.Chişinău, str. Albişoara, 16/1, ap.7

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

Numărul de înregistrare a întreprinderii sau IDNO 12.08.2010 MD 0101250

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 Reperfectată: 1)19.10.2012; 2)14.05.2014

Valabilă pînă la

4 octombrie 2015

Valentin GUZNAC

4 octombrie 2010

Prelungită pînă la: 03.10.2020

Semnătura conducătorului autorității de licențiere

Director al Camerei de Licentiere

Notă: Licența este valabilă numai cu anexa autențificată de autonuvea 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. Chişînău, bd. Moscovei, 14/1 Tel. : (373-22) 43-44-81, 43-46-24 Fax : (373-22) 43-44-22 cod: MOLDMD2X329

IAN. 2016 Data

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 MD95ML00000002251429243.

Codul băncii MOLDMD2X329.

Director

Nina **Turcan**



1 Balmiy

Nina Balmuş

Ex. Diana Brinza Tel. 43-45-96



MOLDOVA

CERTIFICAT DE ÎMREGISTRARE

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

Numărul de identificare de stat - codul fiscal 1010600028048

Data înregistrării

Data eliberării

12.08.2010

12.08.2010

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

comnătura



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	Muinun	Lazari Aliona
	A A 7	* E A * 0 3 7 0 4 3 1 E



c/f 1010600028048; adresa: or. Chişinău, str. Albişoara 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.	Alexandru Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362



EU DECLARATION OF CONFORMITY

Model Name: UPP-110S

93/42/EEC, 2007/47/EC, MDD

EU DECLARATION OF CONFORMITY

- 1. Model No.: UPP-110S
- 2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe Limited, Da Vincilaan 7-D1, 1935 Zaventem, Belgium
- 3. This declaration of conformity is issued under the sole responsibility of the manufacturer: <u>Sony Corporation,1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan</u>
- 4. Object of the declaration: Thermal Print Media
- 5. The object of the declaration described above is in conformity with: <u>93/42/EEC, 2007/47/EC, MDD</u>
- Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared: <u>EN 60601-1:2006 + A1:2013</u>
- 7. Additional information: Following the provisions for Class I devices

Signed for and on behalf of: Sony Belgium, bijkantoor van Sony Europe Limited

Zaventem, 2017-08-19

Kris De Pauw Director Branch Manager

Sony Europe Limited. A company registered in England and Wales Registered Address: The Heights, Brooklands, Weybridge, Surrey, KT13 OXW, United Kingdom, – Registered company number: 2422874



EU DECLARATION OF CONFORMITY

Model Name: UPP-110HG

93/42/EEC, 2007/47/EC, MDD

SONY

EU DECLARATION OF CONFORMITY

1. Model No.: UPP-110HG

- 2. Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe Limited, Da Vincilaan 7-D1, 1935 Zaventem, Belgium
- 3. This declaration of conformity is issued under the sole responsibility of the manufacturer: <u>Sony Corporation,1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan</u>
- 4. Object of the declaration: Thermal Print Media
- 5. The object of the declaration described above is in conformity with: 93/42/EEC, 2007/47/EC, MDD
- Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared: <u>EN 60601-1:2006 + A1:2013</u>
- 7. Additional information: Following the provisions for Class I devices

Signed for and on behalf of: Sony Belgium, bijkantoor van Sony Europe Limited

Zaventem, 2017-08-19

hu

Kris De Pauw Director Branch Manager

Sony Europe Limited. A company registered in England and Wales Registered Address: The Heights, Brooklands, Weybridge, Surrey. KT13 OXW, United Kingdom. – Registered company number: 2422874



EU DECLARATION OF CONFORMITY

Model Name: UPP-110HD

93/42/EEC, 2007/47/EC, MDD

SONY

EU DECLARATION OF CONFORMITY

1. Model No.: UPP-110HD

- Name and address of the manufacturer's authorised representative: Sony Belgium, bijkantoor van Sony Europe Limited, Da Vincilaan 7-D1, 1935 Zaventem, Belgium
- 3. This declaration of conformity is issued under the sole responsibility of the manufacturer: Sony Corporation,1-7-1 Konan Minato-ku Tokyo, 108-0075 Japan
- 4. Object of the declaration: Thermal Print Media
- 5. The object of the declaration described above is in conformity with: <u>93/42/EEC, 2007/47/EC, MDD</u>
- Where applicable, references to the relevant harmonised standards used or references to the technical specifications in relation to which conformity is declared: EN 60601-1:2006 + A1:2013
- 7. Additional information: Following the provisions for Class I devices

Signed for and on behalf of: Sony Belgium, bijkantoor van Sony Europe Limited

Zaventem, 2017-08-19

MIL

Kris De Pauw Director Branch Manager

Sony Europe Limited. A company registered in England and Wales Registered Address: The Heights, Brooklands, Weybridge, Surrey, KT13 OXW, United Kingdom, – Registered company number: 2422874

CISQ is a member of



www.imq.it

CERTIFICATO N. CERTIFICATE N. 9190.CRC3

SI CERTIFICA CHE IL SISTEMA QUALITA' DI WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / OPERATIVE UNITS

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

ISO 9001:2008

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso industriale, ferroviario, medicale e biglietteria anche conto terzi. Produzione e stampa di etichette e biglietti anche a lettura/scrittura in radio frequenza (RFID). Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercio di elettrodi per ECG. Immissione in commercio di piastre per elettrobisturi e defibrillatori. Commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical

and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2008 possono essere ottenute consultando l'organizzazione Further clarifications regarding the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization

> IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:

PRIMA CERTIFICAZIONE FIRST CERTIFICATION 2002-11-26 EMISSIONE CORRENTE CURRENT ISSUE 2017-10-13 scadenza *expiry* 2020-10-07

L'Organizzazione dovrà ottenere la certificazione secondo la norma ISO 9001:2015 entro il 2018/09/14; in caso contrario, il presente certificato cesserà la propria validità in tale data The Organization shall obtain the certification according to ISO 9001:2015 within 2018/09/14; otherwise the validity of this certificate will expire

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY Management Systems Division - Flavio Ornago

Data di scadenza del precedente ciclo di certificazione: 2017-10-07 Data di conclusione dell'audit di rinnovo: 2017-10-11 Data della decisione di rinnovo: 2017-10-13



federazione **CISQ**

www.cisq.com

SGQ N°005A, SGA N°006D, SCR N°005F, SSI N°0036, FSM N°007J, SGE N°006M, EMAS N°039, FDA N°058, PSR N°068C ISP N°053E, LOB N°0121, LAT N°021 Membro degli Accord di Mutuo Riconostimento EA, IAF e ILAC Signatory of E., Urd and ILAC Mutua Ricongiton Agreements IAF: 07, 09, 19, 29

Organismo di Certificazione Federato CISQ processi riconducibili a settori IAF sottolineati risultano non ancora coperti da accreditamento Processes related to underlined IAF sectors are not yet covered by accreditation La validità del certificato è subordinata a sorvegilanza annuale e riesame completo del Sistema di Gestione con periodicità triennale The validity of the certificate i submitted to annuale andi and a reassessment of the entite Margament System within three years

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale. CISQ is the Italian Federation of management system Certification Bodies.



IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

R



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

CISQ/IMQ as an IQNet Partner hereby states that the organization

CERACARTA SPA

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

for the following scope:

Manufacture and print of special recording chart papers for industrial, railway, medical use and ticketing also on behalf of third parties. Manufacture and print of labels and tickets also radio frequency reading/writing (RFID). Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories

Further clarifications regarding the applicability of ISO 9001:2008 requirements may be obtained by consulting the organization

has implemented and maintains a **Quality Management System**

which fulfills the requirements of the following standard

ISO 9001:2008

Issued on: **2017 – 10 – 13** First issued on: **2002 – 11 – 26** for the validity date, please refer to the original certificate* issued by IMQ

Registration Number: IT – 112265

Alex Stoichitoiu President of IQNET

10/0

Ing. Claudio Provetti President of CISQ

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 FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Certification Finland INTECO Costa Rica IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland PCBC Poland Quality Austria Austria RR Russia SIGE México SII Israel SIQ Slovenia SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey Vinçotte Belgium YUQS Serbia IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document ** The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

CISQ is a member of



CERTIFICATO N. CERTIFICATE N. 9124.CRC4

SI CERTIFICA CHE IL SISTEMA QUALITA' DI WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

CERACARTA SPA VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

UNITA' OPERATIVE / OPERATIVE UNITS

VIA SECONDO CASADEI 14 Z.I. VILLA SELVA - 47122 FORLI' (FC)

E' CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD EN ISO 13485:2012

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES

Produzione e stampa di carte speciali e diagrammate per registrazione ad uso medicale anche conto terzi. Produzione e stampa di etichette ad uso medicale. Sviluppo e produzione di creme, gel sterile e non sterile per applicazioni elettrodiagnostiche e ad ultrasuoni, anche conto terzi. Commercializzazione ed immissione in commercio di accessori per applicazioni elettrodiagnostiche, ad ultrasuoni e per strumenti elettromedicali. Sviluppo e produzione di elettrodi per ECG. Gestione della produzione ed immissione in commercializzazione di video stampanti, carte fotografiche per video stampanti, stampanti e relativi materiali di consumo ed accessori per uso medicale

Manufacture and print of special recording chart papers for medical use also on behalf of third parties. Manufacture and print of labels for medical use. Development and manufacture of creams, gels sterile and not sterile for electromedical and ultrasound procedures also on behalf of third parties. Trade and placing on the market of accessories for electromedical and ultrasound diagnostic devices and for electromedical equipment. Development and manufacture of electrods for ECG. Production management and placing on the market of electrods for ECG. Placing on the market of electrosurgical plates and defibrillation pads. Trade of videoprinters, photographic papers for videoprinters, printers and related consumable and accessories for medical use

Ulteriori informazioni riguardanti l'applicabilità dei requisiti EN ISO 13485:2012 possono essere ottenute consultando l'organizzazione Further clarifications regarding the applicability of EN ISO 13485:2012 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

SCADENZA

2020-10-07

EXPIRY

DATE: PRIMA CERTIFICAZIONE EMISSIONE CORRENTE FIRST CERTIFICATION CURRENT ISSUE 1999-07-20 2017-10-13

L'Organizzazione dovrà ottenere la certificazione secondo la norma ISO 13485:2016 entro il 2019/02/28; in caso contrario, il presente certificato cesserà la propria validità in tale data The Organization shall obtain the certification according to ISO 13485:2016 within 2019/02/28; otherwise the validity of this certificate will expire

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY Management Systems Division - Flavio Ornago

Data di scadenza del precedente ciclo di certificazione: 2017-10-07 Data di conclusione dell'audit di rinnovo: 2017-10-11 Data della decisione di rinnovo: 2017-10-13



SGQ N°005A, SGA N°006D, SGR N°005F, SSI N°003G, FSM N°007I, SGE N°006M, EMAS N°039, FSD N°005B, PSS N°080C ISP N°0352, LAB N°0121, LAT N°021 Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years **I** Net

www.ignet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

> CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.

> > CISQ is the Italian Federation





www.cisq.com



Gessate, 7 February 2012

CONFORMITY OF GIMA PRODUCTS

According to the annex VII of the Council Directive 93/42/EEC

as amended by the European Directive 2007/47/EEC concerning medical devices

GIMA declares that all medical devices illustrated on

GIMA INTERNATIONAL CATALOGUE

meet the provisions of the following Council Directive (when applicable)

93/42/EEC AS AMENDED BY THE EUROPEAN DIRECTIVE 2007/47/EEC

as below:

- A) For all products classified in **CLASS I**, we have in our company a technical file as required from annex VII, and it is available a certificate of conformity signed by the responsible inside the EU (generally GIMA).
- B) For all products in CLASS IIa and IIb it is available, or it will be available in one month, a declaration of conformity signed by an official European Notified Body or the ISO 9002 certificate of the manufacturer.

GIMA S.p.A. Q.A. Department Nicola Manzoni

lore





Reg. Number	10164 - A	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2018-10-01
Valid Until	2021-10-14	IAF Sector	29

Quality Management System Certificate **ISO 9001:2015**

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Trade, packaging and service of medical devices (MD), in vitro diagnostic products (IVD), personal protective equipments (PPE), biocides, veterinary items, medical accessories furniture and aids

Chief Operating Officer

Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

GIMA S.p.A. Registered Headquarters - Via Grossi, 2 20121 Milano Italia Certified Sites - Via Marconi, 1 20060 Gessate (MI) Italia



SGQ N° 007A SGA N° 010D PRD N° 069B FSM N° 004I PRS N° 089C

Kiwa Cermet Italia S.p.A. Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl Via Cadriano, 23 40057 Granarolo dell'Emilia (BO) Tel +39.051.459.3.111 Fax +39.051.763.382 E-mail: info@kiwacermet.it www.kiwacermet.it







Reg. Number	10164 - M	Valid From	2018-10-01
First issue date	2012-10-15	Last change date	2018-10-01
Valid until	2021-10-14		

Quality Management System Certificate

ISO 13485:2016

We certify that the Quality Management System of the Organization:

GIMA S.p.A.

Is in compliance with the standard UNI CEI EN ISO 13485:2016 for the following products/services:

Trade, packaging and service of: medical devices (MD), in vitro diagnostic products (IVD), medical accessories, furniture and aids,

Chief Operating Officer

Giampiero Belcredi

The maintaining of certification is subject to annual surveillance and dependent upon the observance of Kiwa Cermet Italia contractual requirements.

Refer to quality manual for details of exclusion of UNI CEI EN ISO 13485:2016 requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A. Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl Via Cadriano, 23 40057 Granarolo dell'Emilia (BO) Tel +39.051.459.3.111 Fax +39.051.763.382 E-mail: info@kiwacermet.it www.kiwacermet.it



GIMA S.p.A. Registered Headquarters - Via Grossi, 2 20121 Milano Italia Certified Sites Via Marcerii 1 20000 Casesta (MI)

- Via Marconi, 1 20060 Gessate (MI) Italia



SGQ N° 007A SGA N° 010D PRD N° 069B FSM N° 004I PRS N° 089C