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

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № A1947807 **din** / от 09.12.2019

1. Destinația / Назначение

Pentru participarea la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

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

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat / Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

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

4. Valabil pînă la / Действителен до 24.12.2019

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

Şef DDF Rîşcani a DGAF mun.Chişinău
Funcția/Должность

Semnătura/Подпись

Ana STOICOV
Numele și prenumele/Фамилия и имя

L.Ş/ М.П.

Executor: **Claudia GOJAN**
Numele și prenumele/Фамилия и имя

MINISTERUL FINANȚELOR AL REPUBLICII MOLDOVA
IDNO 1006601001182
SERVICIUL FISCAL DE STAT
S7

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 09.12.2019 ora 15:55:24 cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/309, 28.03.2014)

NOTA (0,29)

Digitally signed by Poiata Vitalie
Date: 2019.12.11 16:46:24 EET
Reason: MoldSign Signature
Location: Moldova

ORDIN DE PLATA NR.: 482 TIP.DOC. 1

DATA EMITERII:10 decembrie 2019

PLATITI: 100-00 LEI: Una Suta lei 00 bani

PLATITOR: (R) 'BIOSISTEM MLD" SRL

CONTUL DE PLATI/CODUL IBAN
MD95ML0000000002251429243
CODUL FISCAL :1010600028048 /

PRESTATORUL PLATITOR
BC"Moldindconbank"S.A. fil."Invest" Chisinau

CODUL BANCII:
:MOLDMD2X329:

BENEFICIAR (R) IMSP AMT Botanica

CONTUL DE PLATI/CODUL IBAN
MD63VI0000022510301O3MDL
CODUL FISCAL :1003600153360 /

PRESTATORUL BENEFICIAR
B.C."VICTORIABANK"S.A.

CODUL BANCII:
:VICBMD2X :

DESTINATIA PLATII:Pentru garantia pentru: oferta la licitatia publica nr. ocds-b3:wdp1-MD-1574326051466 din 12.12.2019

TIPUL TRANSFERULUI : NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:

DATA PRIMIRII:10/12/2019

DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGQQYJKoZIhvcNAQcCoIIGMjCCBi4CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb:

DQEHAaCCBEowggRGMIIDLqADAgECAhNHAABcVycdZVmKkP29AAAAAFxXMA0GCSq:

SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4:

DTE5MDEyODEwMTYyOFoXDTIxMDEyODEwMjYyOFowfjELMAkGA1UEBhMCTUQxGjA:
gNVBAoTEUJpb3Npc3RlbSBNTEQgU1JMMRIwEAYDVQQLEwkwNjkyMDAzMTQxFzA

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGUgYJKoZIhvcNAQcCoIIGQzCCBj8CAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3:
DQEHAaCCBFswggRXMIIDP6ADAgECAhNHAABcVpWe/gMeSmneAAAAAFxWMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTE5MDEyODEwMTQwNFoXDTIxMDEyODEwMjQwNFowgY4xCzAJBgNVBAYTAk1EMScw:
YDVQQKEx5NZWRlY29yIFNSTCwgQmlvc2lzdGVtIE1MRCBTUkwxEjAQBgNVBAsT

L.S. (semnatura electronica)

CONDUCATOR: (semnatura manuala)

CONTABIL-SEF: (semnatura manuala)

SEMNATURA PRESTATORUL L.S.

MOTIVUL REFUZULUI L.S.

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

„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

A A 7 * E A * 0 3 7 0 4 3 1 E A

SONY

Sony Belgium, bijkantoor van Sony Europe Limited
Da Vincilaan 7 – D1, B-1935 Zaventem
Phone: +32 (0) 2 706 43 11 - Fax : +32 (0) 2 706 43 20

EU DECLARATION OF CONFORMITY

Model Name: UPP-110S

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

SONY

Sony Belgium, bijkantoor van Sony Europe Limited
Da Vincilaan 7 – D1, B-1935 Zaventem
Phone: +32 (0) 2 706 43 11 - Fax : +32 (0) 2 706 43 20

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:
   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:
   93/42/EEC, 2007/47/EC, MDD
6. 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

Kris De Pauw
Director
Branch Manager

SONY

Sony Belgium, bijkantoor van Sony Europe Limited
Da Vincilaan 7 – D1, B-1935 Zaventem
Phone: +32 (0) 2 706 43 11 - Fax : +32 (0) 2 706 43 20

EU DECLARATION OF CONFORMITY

Model Name: UPP-110HG

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

SONY

Sony Belgium, bijkantoor van Sony Europe Limited
Da Vincilaan 7 – D1, B-1935 Zaventem
Phone: +32 (0) 2 706 43 11 - Fax : +32 (0) 2 706 43 20

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:
   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:
   93/42/EEC, 2007/47/EC, MDD
6. 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

Kris De Pauw
Director
Branch Manager

SONY

Sony Belgium, bijkantoor van Sony Europe Limited
Da Vincilaan 7 – D1, B-1935 Zaventem
Phone: +32 (0) 2 706 43 11 - Fax : +32 (0) 2 706 43 20

EU DECLARATION OF CONFORMITY

Model Name: UPP-110HD

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

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

SONY

Sony Belgium, bijkantoor van Sony Europe Limited
Da Vincilaan 7 – D1, B-1935 Zaventem
Phone: +32 (0) 2 706 43 11 - Fax : +32 (0) 2 706 43 20

EU DECLARATION OF CONFORMITY

1. Model No.:
   UPP-110HD
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:
   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:
   93/42/EEC, 2007/47/EC, MDD
6. 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

Kris De Pauw
Director
Branch Manager

CSQ

www.imq.it

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-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.

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*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2002-11-26	2017-10-13	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

IMQ

FEDERAZIONE CISQ

www.cisq.com

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

IAF: 07, 09, 19, 29

SGQ N°005A, SGA N°006D, SCR N°005F,
SSI N°003G, FSM N°007I, SGE N°006M,
EMAS N°003P, PRD N°005B, PRS N°080C
ISP N°063E, 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

I 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 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

Organismo di Certificazione Federato CISQ
www.imq.it

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

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

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

CSQ

MED

www.imq.it

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-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.

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 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 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

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	1999-07-20	2017-10-13	2020-10-07

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

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

CISQ is the Italian Federation of management system Certification Bodies.

FEDERAZIONE CISQ

www.cisq.com

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N°005A, SGA N°006D, SCR N°005F,
SSI N°003G, FSM N°007I, SGE N°006M,
EMAS N°003P, PRD N°005B, PRS N°080C
ISP N°063E, 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

AB UYGUNLUK BEYANI
EC DECLARATION OF CONFORMITY

ÜRETİCİ FİRMA ADI: *COMPANY NAME:*	Turkuaz Sağlık Hizmetleri Medikal Temizlik Kimyasal Ürünler Sanayi ve Ticaret A.Ş.
ADRES: *ADDRESS:*	Yakuplu Mahallesi, Birlik Caddesi, No: 32/1, 34524, Beylikdüzü / İstanbul / Türkiye
TELEFON: *TELEPHONE:*	+902124286848
FAKS: *FAX:*	+902124286853
E-MAIL:	info@turkuazsaglik.com.tr
Avrupa Yetkili Temsilcisi *European Authorized Representative*	Obelis s.a Bd. Général Wahis 53 1030 Brussels, BELGIUM Tel: +(32) 2.732.59.54 Fax: +(32) 2.732.60.03 E-Mail : mail@obelis.net
ÜRÜN ADI: *PRODUCTS:*	Ultrasonografi Jeli Non-Sterile Ultrasound Gel
MARKA: *TRADE MARK:*	Konix

Modeller ve Referans No.: *MODEL(S)and Ref No.:*	
20 ml	T01.01.01.0134
60 ml	T01.02.0039
250 ml	T06.02.0007
500 ml	T06.02.0111
1000 ml	T06.02.0008
5000 ml	T06.02.0009
5000 ml (Gallon)	T06.02.0145

GMDN KODU: *GMDN CODE:*	15321
SINIFLANDIRMA: *CLASSIFICATION:*	Annex IX of The MDD 93/42 EEC Class I, Rule 1
UYGUNLUK DEĞERLENDİRME YOLU: *CONFORMITY ASSESSMENT ROUTE:*	MDD 93/42/EEC ANNEX 7
UYGULANABİLİR STANDARTLAR: *APPLICABLE STANDARDS:*	EK I'e bakınız See Appendix I
VERİLİŞ TARİHİ: *ISSUE DATE:*	6.06.18

YUKARIDA ADI GEÇEN ÜRÜNLERİN 2007/47/EC EKLENTİSİ DAHİL 93/42/EEC TIBBİ CİHAZLAR YÖNETMELİĞİ GEREKSİNİMLERİNİ KARŞILADIĞINI BEYAN EDERİZ. İLGİLİ DESTEKLEYİCİ TÜM DOKÜMANLAR ÜRETİCİ TESİSİNDE BULUNMAKTADIR.

WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC INCLUDING 2007/47/EC AMENDMENT FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

İMZA: *SIGNATURE:*

Nurhan IRMAK
GENEL MÜDÜR YARDIMCISI
DEPUTY GENERAL MANAGER

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2018101009284-01KYS Sayılı rapordaki inceleme ile/
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Sertifika Yayın Tarihi / Date of Issue	**: 10.10.2018**
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