ORDIN DE PLATA NR.: 697 TIP.DOC. 1

DATA EMITERII:20 aprilie 2021

PLATITI: 1500-00 LEI: Una Mie Cinci Sute lei 00 bani

PLATITOR: (R) 'BIOSISTEM MLD" SRL
CONTUL DE PLATI/CODUL IBAN
MD95ML000000002251429243
CODUL FISCAL :1010600028048 /

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

BENEFICIAR (R) IMSP. Asociatia Medicala Teritoriala Centru
CONTUL DE PLATI/CODUL IBAN
MD74VI0000022510171130MDL
CODUL FISCAL :1003600153267 /

PRESTATORUL BENEFICIAR
B.C."VICTORIABANK"S.A. fil.nr.17 Chisinau
CODUL BANCII:
:VICBMD2X457:

DESTINATIA PLATII:Pentru garantia pentru: oferta la procedura de achizi?ie publica nr. ocds-b3wdp1-MD-1617091515207 din 21.04.2021

TIPUL TRANSFERULUI NORMAL/URGENT :N:

L.S.

CODUL TRANZACTIEI:001:
DATA PRIMIRII:20/04/2021
DATA EXECUTARII:

SEMNATURILE EMITENTULUI

CONDUCATOR:Web Poiata Vitalie

MIIGYwYJKoZIhvcNAQcCoIIGVDCCBlACAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3DQEHAaCCBGwwggRoMIIDUKADAgECAhNHAACjbi1rgFksQ0G4AAAAAKNuMA0GCSqSIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4XDTIxMDEyODExMzgwNVoXDTI0MDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRAwDgYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQml

(semnatura electronica)

CONTABIL-SEF:Web Nasedchin Alexandr

MIIGZwYJKoZIhvcNAQcCoIIGWDCCBlQCAQExCzAJBgUrDgMCGgUAMAsGCSqGSIb3DQEHAaCCBHAwggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqGSIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFUlQxLUNBLU1vbGRpbmRjb25iYW5rMB4XDTIxMDEyODExMzkxOFoXDTI0MDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAwDgYDVQQIEwdNb2xkb3ZhMREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv

L.S. (semnatura electronica)

CONDUCATOR: _____ (semnatura manuala)

CONTABIL-SEF: _____ (semnatura manuala)

SEMNATURA PRESTATORUL L.S.

Digitally signed by Poiata Vitalie
Date: 2021.04.20 16:28:12 EEST
Reason: MoldSign Signature
Location: Moldova

MOTIVUL REFUZULUI L.S.

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 MD95ML0000000002251429243**.

Codul băncii MOLDMD2X329.

Director **Nina Țurcan**

Director financiar **Nina Balmuş**

Ex. Diana Brinza
Tel. 43-45-96

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

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

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării **12.08.2010**

Data eliberării **12.08.2010**

Svirepova Ludmila, registrator

Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

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

MD 0101250

„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 **Lazari Aliona**
tel. 022-266-252

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

Date cu caracter personal. **Deținător:** Î.S. „Camera Înregistrării de Stat", **NUID (număr de identificare unic)** 0000151-001

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.	Alexandru Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

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

CC 04 AE

CERTIFICAT
privind lipsa sau existenţa restanţelor faţă de bugetul public naţional

Nr. / № A2105690 **din** / от 09.04.2021

1. Destinaţia / Назначение

Pentru participare la proceduri de achizitii publice

2. Date despre contribuabil / Информация о налогоплательщике

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

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

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

4. Valabil pînă la / Действителен до 24.04.2021

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

Şef DDF Rîşcani
a DGAF mun.Chişinău
Funcţia/Должность

L.Ş/ М.П.

Semnătura/Подпись

Viorica CĂUŞ
Numele şi prenumele/Фамилия и имя

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

Este extras din Sistemul Informaţional al SFS SIA „Contul curent al contribuabilului"// 09.04.2021 ora 10:51:57
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,27)

EC Declaration of Conformity

***In vitro* Diagnostic Medical Devices in accordance with Directive 98/79/EC**

Manufacturer:	Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side:	ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - Turkey
Product:	Fecal Occult Blood (FOB) Test
Brand:	Rapidan® Tester, Toyo®, Info®, Labmen®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223:2016 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 23640:2015 EN 13612:2002
Revision No:	5
Place, Date of Issue:	Izmir, 08.03.2019
Signature	Dr. Şahin Yağlıdere, Md General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10031 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH.10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81- FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

DOC03/02

EC Declaration of Conformity

***In vitro* Diagnostic Medical Devices in accordance with Directive 98/79/EC**

Manufacturer:	Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side:	ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - Turkey
Product:	H.Pylori Ag Test
Brand:	Rapidan® Tester, Toyo®, Info®, Labmen®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223:2016 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 23640:2015 EN 13612:2002
Revision No:	4
Place, Date of Issue:	Izmir, 08.03.2019
Signature	Dr. Şahin Yağlıdere, Md General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10031 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH.10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81- FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

DOC02/06

EC Declaration of Conformity

***In vitro* Diagnostic Medical Devices in accordance with Directive 98/79/EC**

Manufacturer:	Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side:	ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - Turkey
Product:	Anti-HBs Test
Brand:	Rapidan® Tester, Toyo®, Info®, Labmen®
Classification:	Annex II List A, 98/79/EC
Conformity Assessment Route:	Annex IV

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223:2016 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 23640:2015 EN 13612:2002
Notified Body:	Polish Centre for Testing and Certification (PCBC), ul. Klobucka 23a 02-699 Warszawa Poland (Notified Body # 1434)
Start of CE Marking:	29.08.2008
Revision No:	7
Place, Date of Issue:	Izmir, 08.03.2019
Signature	Dr. Şahin Yağlıdere, Md General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10031 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH.10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81- FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE 1434

DOC02/04

EC Declaration of Conformity

***In vitro* Diagnostic Medical Devices in accordance with Directive 98/79/EC**

Manufacturer:	Türklab Tıbbi Mal. San. ve Tic. A.Ş.
Headquarters / Manufacturing Side:	ITOB 10017 Sokak No: 2 Tekeli - Menderes / Izmir - Turkey
Product:	Troponin I Test
Brand:	Rapidan® Tester, Toyo®, Info®, Labmen®
Classification:	Professional Use IVD, 98/79/EC
Conformity Assessment Route:	Annex III

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223:2016 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 23640:2015 EN 13612:2002
Revision No:	4
Place, Date of Issue:	Izmir, 08.03.2019
Signature	Dr. Şahin Yağlıdere, Md General Manager

TÜRKLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10031 SK. NO:15 MENDERES / İZMİR
FABRİKA: İTOB OSB MAH.10017 SK. NO:2 MENDERES / İZMİR
TEL: 0 232 376 80 81- FAX: 0 232 376 80 40
MENDERES V.D. 879 009 6209

CE

DOC04/01

CERTIFICATE

No J - 2670/4/2020

This is to certify that:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş.
ITOB 10017 Sokak No: 2,
Tekeli - Menderes İzmir / Turkey

and

Location

listed in Annex to the certificate

is in conformance with

EN ISO 9001:2015

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: rapid tests intended for self-testing and for professional use, reagents and reagent products for blood grouping (gel cards and red blood cells reagents) and ECG electrodes

The audit carried out by the Polish Centre of Testing and Certification has affored evidence of the above

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

This certificate is valid:

from 22.12.2020 to 21.12.2023

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji Certyfikacja Systemów Zarządzania AC 019 QMS

IAF

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 08:47:33 +02'00'
Member of the Board

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No J - 2670/4/2020

This is to certify that the following Location:

Factory 2: ITOB 10031 Sokak No: 15,
Tekeli - Menderes İzmir / Turkey

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: reagents and reagent products for blood grouping (gel cards and red blood cells reagents), professional use IVD tests and ECG electrodes

meets the requirements of the standard listed on the certificate

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji Certyfikacja Systemów Zarządzania AC 019 QMS

IAF

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 08:48:40 +02'00'
Member of the Board

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

SOĞUK DAMGA VARDIR

TERCÜME

T.C. TORBALI 6. NOTERLİĞİ Tel: 0232 854 70 07 Fax: 0232 854 70 17

№09971

SERTİFİKA

No. M – 56/4/2020

İşbu sertifika ile;

TÜRKLAB Tıbbi Mal. San. Tic. A.Ş.
ITOB 10017 Sokak No:2, Tekeli-Menderes
İzmir, Türkiye

ve sertifika ekinde listelenmiş

Lokasyon

Aşağıdaki faaliyetler kapsamında

EN ISO 13485:2016

ile uyumludur:

invitro tıbbi cihazların tasarımı, geliştirilmesi, üretimi, son kontrolü ve dağıtımı: kendi kendine test ve profesyonel kullanım için tasarlanmış hızlı testler, kan gruplaması için reaktifler ve reaktif ürünleri (jel kartları ve kırmızı kan hücreleri reaktifleri) ve EKG elektrotları

Polonya Test ve Sertifikasyon Merkezi tarafından yürütülen denetim, yukarıdaki kanıtları sağlamıştır. Bu Sertifika, Kuruluş tarafından yukarıdaki standarda uyulması kaydıyla geçerliliğini koruyacaktır.

Bu sertifikanın geçerlilik tarihi: 22.12.2020'den 21.12.2023'e kadar

Sözleşme Çerçevesinde Düzenleme No.2897/JM/4/2020
Sertifika kararının tarihi: 14.10.2020
Sertifika, yetkili imzayı taşımaktadır.
Varşova, 15.10.2020

Anna Małgorzata Wyroba <<Elektronik İmza>>
Yönetim Kurulu Üyesi

POLONYA TEST VE SERTİFİKASYON MERKEZİ 02-844 Varşova, 469 Pulawska Street, Tel: +48 22 46 45 200, e-posta: pcbc@pcbc.gov.pl

İşbu belge İngilizce aslından Türkçe'ye tarafımdan aslına uygun olarak tercüme edilmiştir.
I herebycertifythatthisdocument has beentranslatedfromits English intoTurkishtrulyandcorrectlyby me.03.12.2020

SWORN TRANSLATOR / YEMİNLİ TERCÜMAN
ERKAN ALTUNER

03 Aralık 2020

T.C. TORBALI 6. NOTERİ Selma ZİYREK

SOĞUK DAMGA VARDIR

№09971

CERTIFICATE

No M - 56/4/2020

This is to certify that:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş
ITOB 10017 Sokak No: 2,
Tekeli - Menderes İzmir / Turkey

and

Location

listed in Annex to the certificate

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: rapid tests intended for self-testing and for professional use, reagents and reagent products for blood grouping (gel cards and red blood cellsreagents) and ECG electrodes

The audit carried out by the Polish Centre of Testing and Certification has affored evidence of the above

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

This certificate is valid:

from 22.12.2020 to 21.12.2023

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020

T.C. TORBALI 6. NOTERİ Selma ZİYREK

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji Certyfikacja Systemów Zarządzania AC 019 QMS

IAF

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 09:00:16 +02'00'
Member of the Board

Polish Centre for Testing and Cerification 469 Puławska Street, 02-844 Warsaw, Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

TERCÜME

№09971

SERTİFİKA EKİ

SADECE SERTİFİKA İLE BAĞLANTILI OLARAK GEÇERLİDİR

No. M – 56/4/2020

İşbu sertifika, aşağıda yer alan faaliyetler kapsamındaLokasyonun tasdiki için hazırlanmıştır:

Fabrika 2:ITOB 10031 Sokak No: 15,
Tekeli-MenderesİZmir, Türkiye

invitro tıbbi cihazların tasarımı, geliştirilmesi, üretimi, son kontrolü ve dağıtımı: kan gruplaması için reaktifler ve reaktif ürünleri (jel kartları ve kırmızı kan hücreleri reaktifleri), profesyonel kullanım IVD testleri ve EKG elektrotları

Sertifikada listelenen standardın gereksinimlerini karşılar.

Sözleşme Çerçevesinde Düzenleme No.2897/JM/4/2020
Sertifika kararının tarihi: 14.10.2020
Sertifika, yetkili imzayı taşımaktadır.
Varşova, 15.10.2020

Anna <<Elektronik İmza>>
Małgorzata
Wyroba
Yönetim Kurulu Üyesi

POLONYA TEST VE SERTİFİKASYON MERKEZİ 02-844 Varşova, 469 Pulawska Street, Tel: +48 22 46 45 200, e-posta: pcbc@pcbc.gov.pl

İşbu belge İngilizce aslından Türkçe'ye tarafımdan aslına uygun olarak tercüme edilmiştir.
I herebycertifythatthisdocument has beentranslatedfromits English intoTurkishtrulyandcorrectlyby me.03.12.2020

SWORN TRANSLATOR / YEMİNLİ TERCÜMAN
ERKAN ALTUNER

03 Aralık 2020

T.C.
TORBALI 6. NOTERİ
ZİYREK

ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No M - 56/4/2020

This is to certify that the following Location:

№09971

Factory 2: ITOB 10031 Sokak No: 15,
Tekeli - Menderes İzmir / Turkey

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: reagents and reagent products for blood grouping (gel cards and red blood cells reagents), professional use IVD tests and ECG electrodes

T.C.
TORBALI 6. NOTERİ
Selma ZİYREK

meets the requirements of the standard listed on the certificate

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji Certyfikacja Systemów Zarządzania
AC 019 QMS

IAF

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 09:02:27 +02'00'
Member of the Board

Page 1 of 1

CERTIFICATE

No M - 56/4/2020

This is to certify that:

TÜRKLAB Tibbi Mal. San. Tic. A.Ş
ITOB 10017 Sokak No: 2,
Tekeli - Menderes İzmir / Turkey

and

Location

listed in Annex to the certificate

is in conformance with

EN ISO 13485:2016

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: rapid tests intended for self-testing and for professional use, reagents and reagent products for blood grouping (gel cards and red blood cellsreagents) and ECG electrodes

The audit carried out by the Polish Centre of Testing and Certification has affored evidence of the above

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

This certificate is valid:

from 22.12.2020 to 21.12.2023

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji Certyfikacja Systemów Zarządzania
AC 019 QMS

IAF

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 09:00:16 +02'00'
Member of the Board

ANNEX TO THE CERTIFICATE

VALID ONLY IN CONNECTION WITH THE CERTIFICATE

No M - 56/4/2020

This is to certify that the following Location:

Factory 2: ITOB 10031 Sokak No: 15,
Tekeli - Menderes İzmir / Turkey

in the following scope of activities:

design, development, manufacturing, final control and distribution of in vitro medical devices: reagents and reagent products for blood grouping (gel cards and red blood cells reagents), professional use IVD tests and ECG electrodes

meets the requirements of the standard listed on the certificate

Issued under the Contract No. 2897/JM/4/2020
Date of certification decision: 14.10.2020
Certificate bears a qualified signature.
Warsaw, 15.10.2020

PARTNER OF IQNet

PCA Polskie Centrum Akredytacji Certyfikacja Systemów Zarządzania
AC 019 QMS

IAF

Anna Małgorzata Wyroba
Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2020.10.16 09:02:27 +02'00'
Member of the Board

Page 1 of 1

CERTIFICATE

EC No 1434-IVDD-432/2019
EC Design-Examination

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

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

in vitro diagnostic medical devices, List A

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

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 59/2019
Module: H6

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-432/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC No 1434-IVDD-433/2019
Full Quality Assurance System

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

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, 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 requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 59/2019
Module: H7

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-433/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC No 1434-IVDD-430/2019
EC Design-Examination

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

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

in vitro diagnostic medical devices, List A

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

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 58/2019
Module: H6

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-430/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Klobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC No 1434-IVDD-431/2019
Full Quality Assurance System

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

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, 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 requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 58/2019
Module: H7

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-431/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Klobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC No 1434-IVDD-436/2019
EC Design-Examination

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

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

in vitro diagnostic medical devices, List A

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

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 57/2019
Module: H6

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-436/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC No 1434-IVDD-437/2019
Full Quality Assurance System

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

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, 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 requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 57/2019
Module: H7

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-437/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC No 1434-IVDD-434/2019
EC Design-Examination

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

Polish Centre for Testing and Certification certifies
that manufactured by:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, Tekeli - Menderes
Izmir, Turkey

in vitro diagnostic medical devices, List A

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

in terms of design documentation, comply with requirements of Annex IV section 4 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 56/2019
Module: H6

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-434/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

CERTIFICATE

EC No 1434-IVDD-435/2019
Full Quality Assurance System

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

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

TÜRKLAB Tibbi Mal. San. ve Tic. A.Ş.

ITOB 10017 Sokak No: 2, 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 requirements of Annex IV excluding section 4 and 6 to Directive 98/79/EC (as amended) implemented into Polish law, as evidenced by the audit conducted by the PCBC.

Validity of Certificate: from 29.08.2019 to 28.08.2024
The date of issue of the Certificate: 29.08.2019
The date of the first issue of the Certificate: 29.08.2008

CE 1434

Application No: 56/2019
Module: H7

Michał Pachowski, PhD
President

Certificate No 1434-IVDD-435/2019
Issued under the Contract No MD-31/2019
Bears the PCBC hologram.
Warsaw, 29.08.2019

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

BioSystems
REAGENTS & INSTRUMENTS

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

BioSystems
Costa Brava, 30
08030 BCN

Dr. Antonio Elduque
Managing director
BioSystems S.A.

www.tuv.com ID:9091006696
TÜVRheinland
- Certified Management System
- EN ISO 9001
- EN ISO 13485

Biosystems S.A. Costa Brava 30, 08030 Barcelona (Spain) Tel. +34-93 311 00 00 Fax +34-93 346 77 99
biosystems@biosystems.es
www.biosystems.es

Inscrita R.M. Barcelona, tomo 4.538, folio 127, hoja 48.411, libro 3.864, Sección 2ª N.I.F. A08678823

CLINICAL CHEMISTRY – BIOCHEMISTRY:

a-Amylase-Direct
a-Amylase-EPS
a-Amylase-Pancreatic
Acid Phosphatase (ACP)
Alanine Aminotransferase (ALT/GPT)
Albumin
Alkaline Phosphatase (ALP)-AMP
Alkaline Phosphatase (ALP)-DEA
AspartateAminotranferase (AST/GOT)
Bilirubin (direct)
Bilirubin (total and direct)
Bilirubin (total)
Calcium – Arsenazo
Calcium – MTB
Cholesterol
Cholesterol HDL
Cholesterol HDL direct
Cholesterol HDL Precipitating reagent
Cholesterol LDL direct
Cholesterol LDL Precipitating reagent
Cholinesterase (CHE)
Citrate
Creatine Kinase (CK)
Creatine Kinase-MB (CK-MB)
Creatinine
Fructosamine
Fructose
g-Glutamyltransferase (g-GT)
Glucose
Iron – Chromazurol
Iron – Ferrozine
Iron Binding Capacity
Lactate Dehydrogenase (LDH)
Lactate Dehydrogenase (LDH) – IFCC
Lipase
Magnesium
Phosphorus
Protein (total)
Protein (urine)
Pyridoxal Phosphate
Triglycerides
Urea/BUN-Color
Urea/BUN-UV
Uric Acid

CLINICAL CHEMISTRY – TURBIDIMETRY:

a1-acid Glycoprotein
Albumin (Microalbuminuria)
Anti-Streptolysin O (ASO)
Antithrombin III
Apolipoprotein A-I (Apo A-I)
Apolipoprotein B (Apo B)
b2-Microglobulin
Complement Component C3
Complement Component C4
C-Reactive Protein (CRP)
C-Reactive Protein-hs (CRP-hs)
Ferritin
Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Prealbumin
Rheumatoid Factors (RF)
Transferrin

CLINICAL CHEMISTRY – MICROCOLUMN CHROMATOGRAPHY:

17-Hydroxycorticosteroids
17-Ketosteroids
5-Aminolevulinic Acid (ALA) / Porphobilinogen (PBG)
5-Hydroxyindoleacetic acid (5-HIAA)
Hemoglobin A1C
Hemoglobin A2
Metanephrines
Vanilmandelic Acid

CLINICAL CHEMISTRY – STANDARDS and CALIBRATORS:

a-1-acid Glycoprotein Standard
Adenosine Deaminase (ADA) Standard
Albumin (Microalbuminuria) Standard
Anti-Streptolysin O (ASO) Standard
Antithrombin III Standard
Apolipoprotein A-I Standard
Apolipoprotein B Standard
b2-Microglobulin Standard
Bilirubin Standard
Biochemistry Calibrator
Biochemistry Calibrator (Human)
Cholesterol HDL/LDL Calibrator
CRP/CRP-hs Standard
Ferritin Standard
Hemoglobin A1C-Turbi (HbA1C-Turbi) Standard
Prealbumin Standard
Protein Calibrators
Protein (urine) Standard
Rheumatoid Factors (RF) Standard

CLINICAL CHEMISTRY – INSTRUMENTS:

A15
A25
BA400
BTS-350

CLINICAL CHEMISTRY – BIOCHEMISTRY – REAGENTS AUTOMATED SYSTEMS:

a-Amylase-Direct
a-Amylase-Pancreatic
Adenosine Deaminase (ADA)
Alanine Aminotransferase (ALT/GPT)
Albumin
Alkaline Phosphatase (ALP)-AMP
Alkaline Phosphatase (ALP)-DEA
Aspartate Aminotransferase (AST/GOT)
Bilirubin (direct)
Bilirubin (total)
Calcium-Arsenazo
Cholesterol
Cholesterol HDL direct
Cholesterol LDL direct
Creatine Kinase (CK)
Creatine Kinase-MB (CK-MB)
Creatinine
g-Glutamyltransferase (g-GT)
Glucose
Iron Ferrozine
Lactate dehydrogenase (LDH)
Lipase
Magnesium
Phosphorus
Protein (total)
Protein (urine)
Triglycerides
Urea/BUN UV
Uric acid

CLINICAL CHEMISTRY – TURBIDIMETRY – REAGENTS AUTOMATED SYSTEMS:

Albumin (Microalbuminuria)
Anti-Streptolysin O (ASO)
Antithrombin III
Complement Component C3
Complement Component C4
C-Reactive Protein (CRP)
C-Reactive Protein-hs (CRP-hs)
Ferritin
Hemoglobin A1C-Turbi (HbA1C-Turbi)
Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Rheumatoid Factors (RF)
Transferrin

CLINICAL CHEMISTRY – INTERNAL QUALITY CONTROL:

ADA Controls
Biochemistry Control Serum (Human) I
Biochemistry Control Serum (Human) II
Biochemistry Control Serum I
Biochemistry Control Serum II
CK-MB Control Serum
Control Urine
Fertility Biochemistry Control
Hemoglobin A1C Control (Elevated)
Hemoglobin A1C Control (Normal)
Hemoglobin A2 Control
Lipid Control Serum I
Lipid Control Serum II
Protein Control Serum I
Protein Control Serum II
Rheumatoid Control Serum I
Rheumatoid Control Serum II

AUTOIMMUNITY – IFA (IMMUNOFLUORESCENCE):

Anti-Adrenal Cortex Antibodies (AACA)
Anti-Endomysium Antibodies (AEA)
Anti-Islet Cell Antibodies (AICA)
Anti-Keratin Antibodies (AKA)
Anti-Mitochondrial Antibodies (AMA)
Anti-nDNA antibodies (nDNA)
Anti-Neutrophil Cytoplasmic Antibodies (ANCA)
Anti-Nuclear Antibodies HEp-2 (ANA HEp-2)
Anti-Nuclear Antibodies RL (ANA-RL)
Anti-Skin Antibodies (ASA)
Anti-Smooth Muscle Antibodies (ASMA)
Anti-Striated Muscle Antibodies (AStMA)
Anti-Thyroid Antibodies (ATA)
Autoantibodies DUO-HEp2/ML (DUO-HEp2/ML)
Autoantibodies MsK/MsS (AA-MsK/MsS)
Autoantibodies MsL/MsK/MsS (AA-MsL/MsK/MsS)
Autoantibodies RK/RS (AA-RK/RS)
Autoantibodies RL/RK/RS (AA-RL/RK/RS)
Autoantibodies RL/RKm/RS (AA-RL/RKm/RS)
Glomerular Basement Membrane Antibodies (GBMA)

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

10/201 10.17 E A4 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

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

10/201 10.17 E A4 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

Klicken Sie hier, um Text einzugeben.
www.tuv.com
TÜVRheinland®
Precisely Right.

TÜVRheinland®

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

10/020 h 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2020-01-08

D. Swiatko

10/020 h 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

CE CE

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

Signature