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ORDIN DE PLATA NR.: 1233                                TIP.DOC. 1 :
                                DATA EMITERII:18 martie 2022 :
=====:
PLATITI: 2200-00                                LEI: Doua Mii Doua Sute lei 00 bani :
:
:
=====:
PLATITOR: (R) "BIOSISTEM                                CONTUL DE PLATI/CODUL IBAN :
MLD" S.R.L.                                MD95ML000000002251429243 :
                                CODUL FISCAL :1010600028048 / :
:
:
=====:
PRESTATORUL PLATITOR                                CODUL BANCII:
BC"Moldindconbank"S.A. suc."Invest" Chisinau                                :MOLDMD2X329:
=====:
BENEFICIAR (R) AMT Centru                                CONTUL DE PLATI/CODUL IBAN :
                                MD92ML0000000022514094238 :
                                CODUL FISCAL :1003600153267 / :
:
:
=====:
PRESTATORUL BENEFICIAR                                CODUL BANCII:
BC"Moldindconbank"S.A.                                :MOLDMD2X :
=====:
DESTINATIA PLATII: Pentru garantia pentru: TIPUL TRANSFERULUI :
oferta la procedura de achizitie public: NORMAL/URGENT :N:
a nr. ocds-b3wdp1-MD-1646047232618 din 2: :
2.03.2022 : :
: :
: : L.S. :
=====:
                                CODUL TRANZACTIEI:001: :
DATA PRIMIRII:18/03/2022 : SEMNATURILE :
DATA EXECUTARII: : EMITENTULUI :
-----:
CONducator: Web Poiata Vitalie :
MIIGYwYJKoZIhvcNAQcCoIIGVDCcBlACAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBGwggRoMIIDUKADAgECAhNHAACjbilrgFksQ0G4AAAAAKNuMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzgwNVVoXDTIOMDEyODExNDgwNVowgZ8xCzAJBgNVBAYTAk1EMRAw:
YDVQOIEwdNb2xkb3ZhmREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
:
(semnatura electronica) :
CONTABIL-SEF: Web Nasedchin Alexandr :
MIIGZwYJKoZIhvcNAQcCoIIGWDCcBlQCAQExCzAJBgUrDgMCGGUAMAsGCSqGSIB3:
DQEHAaCCBHAWggRsMIIDVKADAgECAhNHAACjcahRKqbJeg8QAAAAAKNxMA0GCSqG:
SIb3DQEBCwUAMCIxIDAeBgNVBAMTF0NFULQxLUNBLU1vbGRpbmRjb25iYW5rMB4X:
DTIxMDEyODExMzkwOFoXDTIOMDEyODExNDkxOFowgaMxCzAJBgNVBAYTAk1EMRAw:
YDVQOIEwdNb2xkb3ZhmREwDwYDVQQHEwhDaGlzaW5hdTEWMBQGA1UEChMNQmlv :
:
L.S. (semnatura electronica) :
CONducator: :
(semnatura manuala) :
CONTABIL-SEF: :
(semnatura manuala) :
SEMnatura PRESTATORUL L.S. :
:
MOTIVUL REFUZULUI : L.S. :
-----:

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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: MOLDDMD2X329

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: MOLDDMD2X329

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

Codul băncii MOLDDMD2X329.

Director

Nina Turcan

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*

L. Svirepova
semnătura

MD 0101250





I.P. "AGENȚIA SERVICII PUBLICE"

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

nr. 8506 din 28.04.2021

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.**

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,

Asociați:

- 1. POIATA VITALIE 33,40 %**
- 2. NASEDCHIN ALEXANDR 33,30 %**
- 3. KOJEVNIKOV DMITRII 33,30 %.**

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: 28.04.2021.

Specialist coordonator
tel. 022-207-840



Lazari Aliona



EB 0358735

Lista fondatorilor Biosistem-mld SRL

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

To,
Biosistem-mld SRL
Albisoara 16/1 ap.7
Chisinau, R. Moldova

26.02.2019

MANUFACTURERS AUTHORIZATION

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.** ("Mindray") manufacturer of Hematology analyzers, hereby authorize: **Biosistem-mld SRL**, with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova, to submit bids and subsequently negotiate and sign Contracts for reagents and consumables for all auto-hematology analyzers supplied by company **Biosistem-mld SRL**.

The authorization period is valid one year from issue date and automatically renewable if no termination letter is issued by either part.

Neither this Letter of Authorization nor any further extension, will impose any obligation or grant any rights regarding further distribution of Product, nor allow any party to seek compensation for goodwill developed during the term of Letter of Authorization or any further extension.

Best regards,



SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
4403055603015

Luan Haijiao

Deputy Manager of International Sales and Marketing System,
Commonwealth of Independent States
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

**SHENZHEN MINDRAY
BIO-MEDICAL ELECTRONICS CO., LTD.**

Mindray Building, Keji 12th Road South,
High-tech Industrial Park, Nanshan,
Shenzhen 518057, P.R. China

Tel: +86 755 81888998

Fax: +86 755 26582680

Website: www.mindray.com

Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial
Park, Nanshan, Shenzhen, 518057, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: Auto Hematology Analyzer

Model: BC-5000

Including reagents as following:
M-52D DILUENT
M-52DIFF LYSE
M-52LH LYSE
PROBE CLEANSER

Classification: The device not in IVDD annex II and not for self
testing/performance evaluation

Conformity Assessment Route: IVDD Annex III(excluding Section 6)

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2013-9-26

Place, Date of Issue: Shenzhen, 2013-9-26

Signature: _____

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial
Park, Nanshan, Shenzhen, 518057, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: Auto Hematology Analyzer

Model: BC-5150

Including reagents as following:

M-52D DILUENT
M-52DIFF LYSE
M-52LH LYSE
PROBE CLEANSER

Classification: The device not in IVDD annex II and not for self
testing/performance evaluation

Conformity Assessment Route: IVDD Annex III(excluding Section 6)

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

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

Start of CE-Marking: 2013-9-26

Place, Date of Issue: Shenzhen, 2013-9-26

Signature: _____

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Applied Standards List

Product: **Auto Hematology Analyzer**

BC-5150、BC-5000

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2009	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
ENISO 18113-2:2009	I In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer(labeling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1: 2003+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
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

Declaration of Conformity V 1.0

IEC 61010-2-010: 2005	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
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
EN 62304:2008	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices

AMZ MEDICAL



America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Certificate Holder: Shenzhen Mindray Bio-Medical
Electronics Co., Ltd.
Mindray Building
Keji 12th Road South
High-Tech Industrial Park
Nanshan
518057 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: See Page 2 for Overall Scope Statement.

Standard(s): ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: SH2005501

Effective Date: 2020-08-12

Expiry Date: 2023-06-30

Page 1 of 4

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services



America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Overall Scope Statement

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunossay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Page 2 of 4

Date of Issue: 2020-08-20

Tina Israel
 Manager, US Certification Body,
 Medical and Health Services



America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Facility(ies): **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**
Mindray Building, Keji 12th Road South, High-Tech Industrial Park, Nanshan, 518057, Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes: Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor, Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Page 3 of 4

Date of Issue: 2020-08-20

Tina Israel
Manager, US Certification Body,
Medical and Health Services



America

CERTIFICATE

No. QS5 044751 0140 Rev. 02

Facility(ies)

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
 1203 Nanhuan Avenue, Guangming District, 518106
 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Facility Scopes:

Design and Development, Production and Distribution of Medical Electronic Equipment (including Patient Monitor and Accessories, Vital Signs Monitor, Center Monitoring System, Telemetry Monitoring System, Pulse Oximeter, Temperature Probe, Flow Sensor, Ambulatory Blood Pressure Monitor , Defibrillator / Monitor and Accessories, Electrocardiograph, Anesthesia Machine and Accessories, Ventilator, Air Compressor, Endoscope Camera System, Ultrasonic Diagnostic Equipment and Accessories, Digital Radiography System, Radiography System, Hematology Analyzer, Clinical Chemistry Analyzer, Urine Analyzer, Microplate Reader, Microplate Washer for In-Vitro Diagnostic Use, Chemiluminescence Immunoassay Analyzer, Flow Cytometer, (Auto) Sample Processing System, Auto Slide Maker and Stainer, Glycohemoglobin Analyzer, Specific Protein Analyzer), Reagents for Hematology Analyzer, Reagents for Clinical Chemistry Analyzer, Chemiluminescence Immunoassay Reagents, Chemiluminescence Immunoassay Calibrators and Controls, Reagents for Flow Cytometer, Reagents for Glycohemoglobin Analyzer, Calibrators and Controls for Glycohemoglobin Analyzer, Disposable Anesthesia Mask, Reusable Anesthesia Mask, Respiratory Mask, Disposable Breathing Circuit, Reusable Breathing Circuit, Heat and Moisture Exchanger, Filter, Breathing Bag

Page 4 of 4

Date of Issue: 2020-08-20

Tina Israel
 Manager, US Certification Body,
 Medical and Health Services



Certificate

No. Q5 044751 0164 Rev. 02

For the product(s)/product category (ies):

Patient Monitor and Accessories, Vital Signs Monitor,
 Center Monitoring System, Telemetry Monitoring System,
 Pulse Oximeter, Temperature Probe, Flow Sensor,
 Ambulatory Blood pressure Monitor,
 Defibrillator/Monitor and Accessories, Electrocardiograph,
 Anesthesia Machine and accessories, Ventilator,
 Air compressor, Endoscope Camera System,
 Ultrasonic Diagnostic Equipment and Accessories,
 Digital Radiography System, Radiography System,
 Hematology Analyzer, Clinical Chemistry Analyzer,
 Urine Analyzer, Microplate Reader,
 Microplate Washer for invitro diagnostic use,
 Chemiluminescence Immunoassay Analyzer,
 Flow Cytometer, (Auto) Sample Processing System,
 Auto Slide Maker&Stainer, Glycohemoglobin Analyzer,
 Specific Protein Analyzer, Reagents for Hematology Analyzer,
 Reagents for Clinical Chemistry Analyzer,
 Chemiluminescence Immunoassay Reagents,
 Chemiluminescence Immunoassay Calibrators and Controls,
 Reagents for Flow Cytometer,
 Reagents for Glycohemoglobin Analyzer,
 Calibrators and Controls for Glycohemoglobin Analyzer,
 Disposable Anesthesia Mask, Reusable Anesthesia Mask,
 Respiratory Mask, Disposable Breathing Circuit,
 Reusable Breathing Circuit, Heat and Moisture Exchanger,
 Filter, Breathing Bag.

13.02.2020

MANUFACTURER'S AUTHORIZATION

We [TÜRKLAB Tibbi Malzemeler San. Ve Tic. A.Ş.] who are established and reputable Manufacturers of [RAPID DIAGNOSTIC TEST Brand Name: Rapidan Tester] having factories at [ITOB 10017 Sokak No: 2 Tekeli - Menderes - Izmir – Turkey] do hereby authorize [Biosistem-mld SRL] located in: [Albisoara 16/1 ap.7, Chisinau, MOLDOVA] of Supplier/ Agent/ Distributor to submit a bid in tenders, sales, subsequently negotiate and sign the Contract with you against the Invitation Bids for the goods manufactured by us with in territory of country MOLDOVA.

We hereby extend our full guarantee and warranty as per the General Conditions of Contract for the goods offered for supply by the above firm against this Invitation for Bids. This Letter is valid for 1 Year from issue date.

Dr. Şahin Yağlıdere
General Manager



TÜRKLAB TIBBİ MALZEMELER SAN. ve TİC. A.Ş.

Headquarters / Factory I : ITOB 10017 Sokak No: 2 Tekeli - Menderes - Izmir / TURKEY
Factory II : ITOB 10031 Sokak No: 15 Tekeli - Menderes - Izmir / TURKEY
TEL: +90 232 376 80 81 FAX: +90 232 376 80 40 www.turklab.com.tr

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: İTOB 10017 Sokak No: 2 Tekeli - Menderes / İzmir - 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: İzmir, 08.03.2019

Signature Dr. Şahin Yağlıdere, Md
General Manager

TÜRLAB
TIBBİ MALZ. SAN. VE TİC. A.Ş.
MERKEZ: İTOB OSB MAH. 10017 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/ 079 009 6209





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 afforded 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



AC 019
QMS



Anna
Małgorzata
Wyroba
Member of the Board

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



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



AC 019
QMS



Anna
Małgorzata
Wyroba
Member of the Board

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



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 cells reagents) and ECG electrodes**

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

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

This certificate is valid:

from **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



AC 019
QMS



Anna
Małgorzata
Wyroba
Member of the Board

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2020.10.16
09:00:16 +02'00'



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



AC 019
QMS



Anna
Małgorzata
Wyroba
Member of the Board

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2020.10.16
09:02:27 +02'00'