

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№ **A2101655**

din
от **05.02.2021**

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
S.R.L. MEDLUX GROUP	1012600024871
Adresa sediului de bază (strada, numărul) Адрес основного месторасположения (улица, номер)	Codul - Denumirea localității Код - Наименование населенного пункта
Alba-Iulia nr.23 of.94	0120-SEC.BUIUCANI

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 20.02.2021

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

Șef al DDF Buiucani
din cadrul DGAF mun. Chișinău

Monle
Semnătura/Подпись

Anastasia MOVILĂ
Numele și prenumele/Фамилия и имя

Funcția/Должность
L.S./М.П.
Execuitor: **C. Coșanu**
Numele și prenumele/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului”// 05.02.2021 ora 13:08:00
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (7.801,71)

DECLARATION OF CONFORMITY

Diamond Diagnostics Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In Vitro Diagnostics Medical Device Directive 98/79/EC.

A Diamond Diagnostics Inc. ezúton kijelenti és biztosítja, hogy az alább felsorolt termékek megfelelnek az In Vitro Diagnosztikai Orvostechnikai eszközökről szóló Európai Unió 98/79/EC irányelvben foglaltaknak.

Diamond Diagnostics Inc. versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Diamond Diagnostics Inc. assure et declare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Diamond Diagnostics Inc. asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directive 98/79/EC de la Comunidad Europea para dispositivos medicos de diagnostic in vitro.

Diamond Diagnostics, Inc. 确保并声明以下列出的产品符合欧洲共同体关于体外诊断医疗器械的98/79/EC指令所列出的要求。

Diamond Diagnostics Inc. assegurar e declara que o produtos listado abaixo cumprir com os requisitos estabelecido no directiva 98/79/EC do Comunidade Europeia de dispositivos médicos de diagnóstico in vitro.

Diamond Diagnostics Inc. гарантирует и заявляет, что перечисленные ниже продукты соответствуют требованиям Директивы 98/79/EC Европейского союза о медицинском оборудовании для диагностики In-vitro.

المنتجات المذكورة أدناه تتوافق مع متطلبات الاتحاد الاوربي المدرجة في التعليمات 98/79/EC Vitro Diagnostica Medical Device
ان شركة دايموند داياغنونستكس تصرح و تؤكد أن

Diamond Diagnostics Inc. dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relative ai dispositivi medico-diagnostici in vitro.

Product(s) / Termék(ek) / Produkt(e) / Produit(s) / Producto(s) / 產品(S) / Produto(s) / Продукт(ы) / المنتج(ق) / Prodott(i) ;

Model: Diamond Diagnostics ProLyte, Medica EasyLyte, ILyte, Menarini SpotLyte

Reagent & Controls:

IL-2121D Fluid Pack	MN-2121D Fluid Pack	ME-2111D Urine Diluent
IL-2121D+ Fluid Pack	ME-2123D Fluid Pack	ME-2492D Internal Filling Solution
IL-2123D Fluid Pack Na/K/Ca/pH	ME-2118D Daily Rinse Kit	ME-2577D Urine Standard
ME-2121D Fluid Pack	ME-2309D Flush Solution	ME-2578D Red Test Dye

Electrodes & Accessories:

ME-2102D Na+ Electrode	ME-2104D Pump Tubing	ME-2572D Troubleshooting Service Kit
ME-2101D K+ Electrode	ME-2108D Solutions Valve	ME-2095D Maintenance Kit
ME-2113D Cl- Electrode	ME-2100D Calcium Tubing Kit	ME-2107D Sample Probe
ME-2150D Ca++ Electrode	ME-2323D Probe Wiper	ME-2106D Lithium Electrode
ME-2258D Membrane Assembly	ME-2541D Printer Paper	ME-2103D Reference Electrode
ME-2257D Sample Detector		

Authorized
Officer: _____

Kathy Fisher

Kathy Fisher
Global Quality Manager

Date: 30 April, 2018

Manufacturer's name: Diamond Diagnostics Inc. (USA)
Manufacturer's address: 333 Fiske Street
Holliston, MA 01746 USA
Tel: +1 (508) 429-0450
Fax: +1 (508) 429-0452

(AR) Authorized Representative

Diamond Diagnostics Kft.
6 Óradna Street
1044 Budapest Hungary
Tel: + 3617872222 Fax: + 3617872255

Quality Systems Registration

ISO 13485:2016
ISO 9001:2015

Conformity Assessment Procedure

Annex III, Self-Declared



The names of various manufacturers and their instruments referred to herein may be protected by trademark or other law, and are used herein solely for purpose of reference. Diamond Diagnostics Inc. expressly disclaims any affiliation with them or sponsorship by them.



MAGYAR SZABVÁNYÜGYI TESTÜLET
HUNGARIAN STANDARDS INSTITUTION

H-1082 Budapest, Horváth Mihály tér 1.

TANÚSÍTÁSI OKIRAT CERTIFICATE

Tanúsítjuk, hogy a
We certify that the Management System of
Diamond Diagnostics Inc. Magyarországi Fióktelepe

H-1044 Budapest, Óradna utca 6.

Tanúsított székhely: H-1044 Budapest, Óradna utca 6.

irányítási rendszere megfelel a szabvány követelményeinek a következő alkalmazási területen:
ionszelektív laboratóriumi mérőműszerek és alkatrészek, fogyóanyagok gyártása és
klinikai diagnosztikai készülékek felújítása

meets the requirements of the standard for the following activities:
the manufacture of blood electrolyte systems, consumables and
re-manufacture of clinical diagnostic equipment

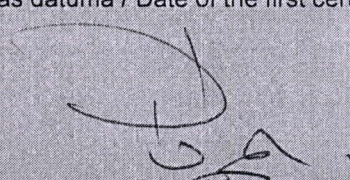
MSZ EN ISO 13485:2016 (ISO 13485:2016)

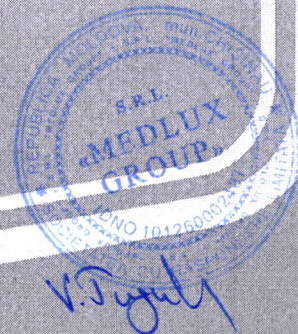


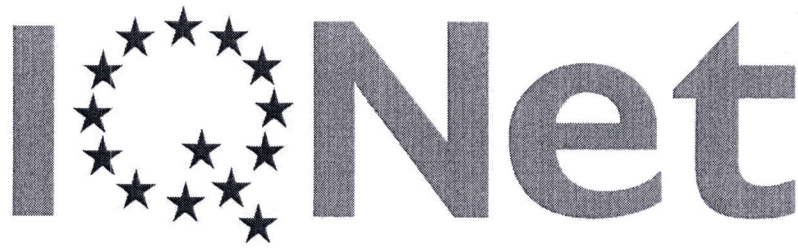
A tanúsítási okirat érvényes / The certificate is valid: **2020. 12. 21. – 2023. 06. 21.**
Ez a tanúsítvány az MSZT által évente kiadott fenntartási határozattal együtt érvényes.
This certificate is valid together with the maintenance decision annually issued by MSZT.

A tanúsítási okirat száma / Reg. number: **503/1342(2)**
Budapest, **2020. december 21.**

Az első tanúsítás dátuma / Date of the first certification: **2014. 06. 26.**


Pónyai György
Ügyvezető igazgató





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

MSZT has issued an IQNet recognized certificate that the organization:

Diamond Diagnostics Inc.

Magyarországi Fióktelepe

H-1044 Budapest, Óradna utca 6.

Certified headquarters: H-1044 Budapest, Óradna utca 6.

has implemented and maintains a

Quality Management System

for the following scope

the manufacture of blood electrolyte systems, consumables and re-manufacture of clinical diagnostic equipment

which fulfils the requirements of the following standard:

ISO 13485:2016

Issued on: **21-12-2020**

First issued on: **26-06-2014**

Expires on: **21-06-2023**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: **HU-MSZT-503/1342(2)-1262(2)**

Alex Stoichitoiu
President of IQNet

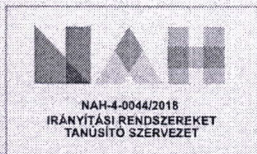
György Pónyai
General Director of MSZT



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 EAGLE Certification Group
- USA FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica
- IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
- NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
- SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com



MAGYAR SZABVÁNYÜGYI TESTÜLET
HUNGARIAN STANDARDS INSTITUTION
H-1082 Budapest, Horváth Mihály tér 1.

TANÚSÍTÁSI OKIRAT CERTIFICATE

Tanúsítjuk, hogy a
We certify that the Management System of
Diamond Diagnostics Inc. Magyarországi Fióktelepe
H-1044 Budapest, Óradna utca 6.
Tanúsított székhely: H-1044 Budapest, Óradna utca 6.

irányítási rendszere megfelel a szabvány követelményeinek a következő alkalmazási területen:
**ionszelektív laboratóriumi mérőműszerek és alkatrészek, fogyóanyagok gyártása és
klinikai diagnosztikai készülékek felújítása**

meets the requirements of the standard for the following activities:
**the manufacture of blood electrolyte systems, consumables and re-manufacture of
clinical diagnostic equipment**

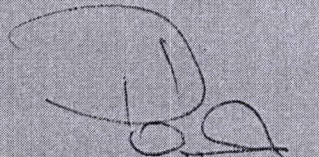
MSZ EN ISO 9001:2015 (ISO 9001:2015)

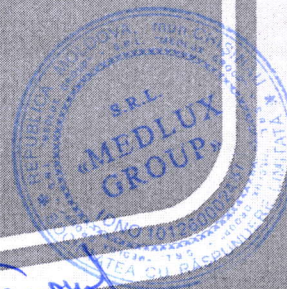
A tanúsítási okirat érvényes / The certificate is valid: **2020. 12. 21. – 2023. 06. 21.**
Ez a tanúsítvány az MSZT által évente kiadott fenntartási határozattal együtt érvényes.
This certificate is valid together with the maintenance decision annually issued by MSZT.

A tanúsítási okirat száma / Reg. number: **503/1341(2)**

Budapest, **2020. december 21.**

Az első tanúsítás dátuma / Date of the first certification: **2014. 06. 26.**


Pónyai György
ügyvezető igazgató





THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

MSZT has issued an IQNet recognized certificate that the organization:

Diamond Diagnostics Inc.

Magyarországi Fióktelepe

H-1044 Budapest, Óradna utca 6.

Certified headquarters: H-1044 Budapest, Óradna utca 6.

has implemented and maintains a

Quality Management System

for the following scope

the manufacture of blood electrolyte systems, consumables and re-manufacture of clinical diagnostic equipment

which fulfils the requirements of the following standard:

ISO 9001:2015

Issued on: **21-12-2020**

First issued on: **26-06-2014**

Expires on: **21-06-2023**

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: HU-MSZT-503/1341(2)-1261(2)

Alex Stoichitoiu
President of IQNet

György Pónyai
General Director of MSZT



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 EAGLE Certification Group
- USA FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica
- IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
- NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
- SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia

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Certificate of Registration



global assurance

This is to certify that the Quality Management System of:

Diamond Diagnostics Inc.

333 Fiske Street
Holliston MA 01746
United States of America

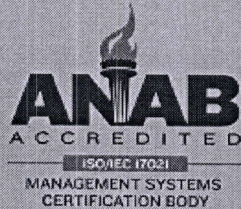
applicable to:

Design, development, manufacture, distribution, and sales of in-vitro diagnostics systems, reagents, and consumables. Re-Manufacture, distribution, installation and servicing activities of Clinical Diagnostic Equipment.

has been assessed and approved by
National Quality Assurance, U.S.A., against the provisions of:

ISO 9001:2015

For and on behalf of NQA, USA



Certificate Number: 16590
EAC Code: 34
Certified Since: November 10, 2005
Valid Until: November 6, 2023
Reissued: November 7, 2020
Cycle Issued: November 7, 2020

