

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

A handwritten signature in black ink, appearing to read 'Mike S. Long', is positioned over the large, faint 'nqa' watermark in the background.

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

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

ISO 13485:2016

A handwritten signature in black ink, likely belonging to a representative of NQA, USA.

For and on behalf of NQA, USA



Certificate Number: 17163
EAC Code: 34
Certified Since: February 7, 2006
Valid Until: November 6, 2023
Reissued: November 7, 2020
Cycle Issued: November 7, 2020



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**

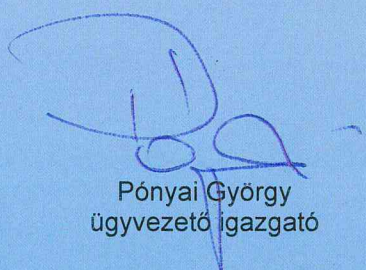
MSZ EN ISO 9001:2015 (ISO 9001:2015)

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.

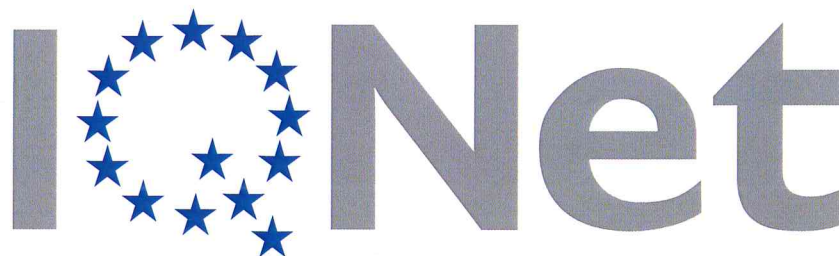
A tanúsítási okirat száma / Reg. number: **503/1341(2)**

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

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



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

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

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

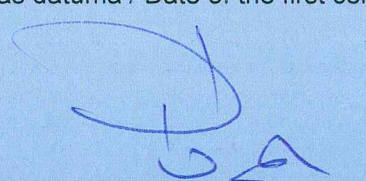


A tanúsítási okirat érvényes / The certificate is valid: **2020. 12. 21. – 2023. 06. 21.**
Ez a tanúsítvány az MSZT által évente kiadott fenntartási határozattal együtt érvényes.
This certificate is valid together with the maintenance decision annually issued by MSZT.

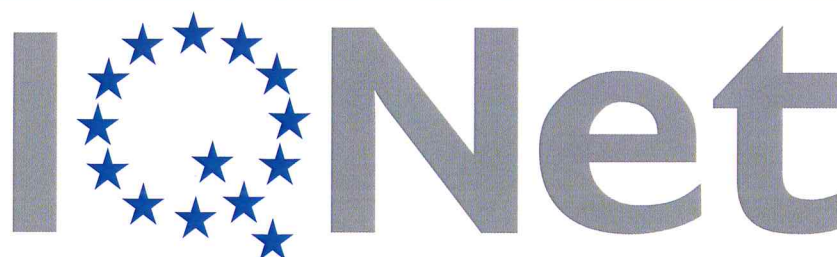
A tanúsítási okirat száma / Reg. number: **503/1342(2)**

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

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Magyarországi Fióktelepe

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

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

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

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

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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
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