

Diamond Diagnostics Inc. 333 Fiske Street • Holliston, MA 01746 USA 508.429.0450 • Fax: 508.429.0452 diamonddiagnostics.com

February 18, 2021

ISO Certificates

It is hereby certified the attached documents are true copies of ISO Certificates of Diamond Diagnostics Inc.

These documents have been granted, verified and signed by the appropriately authorized representative in each case.

ISO13485:2016 (US Cert 16590) ISO9001:2015 (US Cert 17163) ISO13485:2016 (HU-MSZT-503/1342(2)-1262(2)) ISO9001:2015 (HU-MSZT-503/1341 92)-1261(2))

Certified by:

Kathy ⊭isher Director. Qualitv Ass

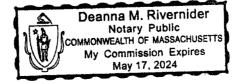
Director, Quality Assurance Diamond Diagnostics Inc.

2/18/2021

Date

On this 18th day of February, 2021 before me, the undersigned notary public, appeared Kathy Fisher; personally known to me to be the person whose name is signed on the preceding document and acknowledged to me that he signed it voluntarily for its stated purpose for Diamond Diagnostics.

Deann M. Rivernides NOTARY PUBLIC





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

Mus Joy

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

Page 1 of 1



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Diamond Diagnostics Inc.

333 Fiske Street Holliston MA 01746 United States of America

applicable to:

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

ISO 13485:2016

Mus In

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 OKURAT CERTUFICATIE

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 MSIN

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 Sertification 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



MAGYAR SZABVÁNYÜGYI TESTÜLET HUNGARIAN STANDARDS INSTITUTION

H-1082 Budapest, Horváth Mihály tér 1.

TANÚSÍTÁSI OKURAT CERTUFICATIE

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 gazgató



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CERTIFICATE

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which fulfils the requirements of the following standard:

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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 MIST

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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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