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Date: 2023.03.06 13:00:21 EET
Reason: MoldSign Signature
Location: Moldova

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Abbott Informatics Corporation
4000 Hollywood Blvd
Suite 333 - S
South Hollywood
Florida
33021
USA

Holds Certificate No: **FM 636368**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Design, manufacture, distribution, installation and servicing of Laboratory Information Management Systems software for various industries.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2016-05-20
Effective Date: 2021-06-26
Latest Revision Date: 2021-04-22
Expiry Date: 2024-06-25

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Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Informatics Corporation
4000 Hollywood Blvd
Suite 333 - S
South Hollywood
Florida
33021
USA

Holds Certificate No: **FM 636367**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, manufacture, distribution, installation and servicing of Laboratory Information Management Systems software for the medical device industry.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2016-05-20
Latest Revision Date: 2021-04-22

Effective Date: 2021-06-26
Expiry Date: 2024-06-25

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 103108 0003 Rev. 02

Manufacturer:

Abbott Diagnostics Medical Co., Ltd.
357 Matsuhidai
Matsudo-shi, Chiba
270-2214 JAPAN

Product Category(ies): **Products for determination of infection markers**
HIV-1/-2 marker and Hepatitis B marker

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1 103108 0003 Rev. 02

Report no.: **JN1648745**

Valid from: **2021-03-18**
Valid until: **2024-05-26**

Date, **2021-03-03**

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
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Product Service

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 103108 0003 Rev. 02

Model(s): **Not Applicable**

Facility(ies):

Abbott Diagnostics Medical Co., Ltd. Chiba Plant
357 Matsuhidai, Matsudo-shi, Chiba, 270-2214 JAPAN

Abbott Diagnostics Medical Co., Ltd. Chiba Logistic Center
483-2 Matsuhidai, Matsudo-shi, Chiba, 270-2214 JAPAN

-/-

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