Digitally signed by Ceaicovschi Tudor
Date: 2026.01.27 10:02:09 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Abbott

EU Declaration of Conformity

Basic UDI-DI: 038074DAL0002FQ
Basic UDI-DI Name: Alinity c Processing Module
Risk Class: **Class A**

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
03R67-01	Alinity c Processing Module	**56676**	**W0201010108**

Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, Texas 75038 USA
Manufacturer SRN	US-MF-000017777
Authorized Representative (Name and Address)	Abbott, GmbH Max-Planck-Ring 2 65205 Wiesbaden
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	Canon Medical Systems Corporation 1385 Shimoishigami, Otawara-Shi Tochigi 324-8550, Japan
Conformity Assessment Procedure	**Annex II and III**

We, the undersigned, hereby declare that the in vitro diagnostic medical device(s) described above conform with the applicable provisions of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on In Vitro Diagnostic Medical Devices; and additionally conforms applicable provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, and to applicable provisions of Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC as transposed into the laws of the member states.

This declaration is made in accordance with Annex IV of the IVD Regulation, Annex VI of the ROHS Directive, and Annex II of the Machinery Directive and is issued under the sole responsibility of the manufacturer.

Full Name: Kevin Richardson
Function: Director, Instrument Quality
Signature: Kevin Richardson
Date of Approval: 11-APRIL-2025

Full Name: Amanda Peoples
Function: Regulatory Affairs Project Manager
Signature: Amanda Peoples
Date of Approval: 11-April-2025

Signed for, and on behalf of: Abbott Laboratories, 1915 Hurd Drive, Irving, TX 75038 USA

Date Issued: 11-April-2025
Supersedes: 12 September 2024

Place Issued: Irving, Texas
Effective (Date or Lot Number): 11-April-2025

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Laboratories
1915 Hurd Drive
Irving
Texas
75038
USA

Facility ID Number: F005921

Holds Certificate No: **MDSAP 762409**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
Japan: MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-12-18 Effective Date: 2024-12-09 Expiry Date: 2027-11-01

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 762409**

Registered Scope:

Design, development, manufacture, and distribution of in vitro diagnostic analyzers for immunoassay and clinical chemistry systems used in the diagnosis, management, and detection of cancer, autoimmune status, cardiac markers, pregnancy, endocrine disorders, and for therapeutic drug monitoring.
Design, development, and manufacture of In Vitro Diagnostic products including instruments, reagents, and accessories for Hematology.

Original Registration Date: 2019-12-18 Effective Date: 2024-12-09 Expiry Date: 2027-11-01

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Laboratories
1915 Hurd Drive
Irving
Texas
75038
USA

Holds Certificate Number: MD 762422

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

Design, development, manufacture, distribution and refurbishment of in vitro diagnostic analyzers, reagents, and accessories for immunoassay, clinical chemistry, and hematology systems used in the diagnosis, management, and detection of cancer, autoimmune status, cardiac markers, pregnancy, endocrine disorders, and for therapeutic drug monitoring.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2022-06-13
Latest Revision Date: 2024-12-12

Effective Date: 2024-12-12
Expiry Date: 2027-11-01

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