Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that:

Abbott Laboratories Diagnostics Division
100 Abbott Park Road
Abbott Park
Illinois
60064
USA

Holds Certificate Number: FM 743464

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

Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

Digitally signed by Ceaicovschi Tudor
Date: 2023.12.18 15:30:33 EET
Reason: MoldSign Signature
Location: Moldova

For and on behalf of BSI:

Matt Page, Managing Director Assurance - UK & Ireland

Original Registration Date: 2018-10-12
Effective Date: 2021-10-13
Latest Revision Date: 2022-04-12
Expiry Date: 2024-10-12

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Certificate No: FM 743464

Location	Registered Activities
Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park Illinois 60064 USA	Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Abbott Laboratories Diagnostics Division - Conway Park 675 North Field Drive Lake Forest Illinois 60045 USA	Oversight of the Quality Management System for the Abbott Diagnostics Division Sites
Abbott Laboratories Diagnostics Division - K Complex - Distribution Center Route 41 & Martin Luther King Drive North Chicago Illinois 60064 USA	QC Inspection of incoming materials and distribution of IVD products including test kits, reagents, accessories and instruments.

Original Registration Date: 2018-10-12

Effective Date: 2021-10-13

Latest Revision Date: 2022-04-12

Expiry Date: 2024-10-12

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Abbott Laboratories Diagnostics Division
100 Abbott Park Road
Abbott Park
Illinois
60064
USA

Holds Certificate Number: **MD 743461**

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

Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-06-01
Latest Revision Date: 2023-05-26

Effective Date: 2021-10-13
Expiry Date: 2024-10-12

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Certificate No: **MD 743461**

Location	Registered Activities
Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park Illinois 60064 USA	Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Abbott Laboratories Diagnostics Division - Conway Park 675 North Field Drive Lake Forest Illinois 60045 USA	Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
Abbott Laboratories Diagnostics Division - K Complex - Distribution Center Route 41 & Martin Luther King Drive North Chicago Illinois 60064 USA	QC inspection of incoming materials and distribution of IVD products including test kits, reagents, accessories and instruments.

Original Registration Date: 2021-06-01

Effective Date: 2021-10-13

Latest Revision Date: 2023-05-26

Expiry Date: 2024-10-12

Abbott

Declaration of Conformity

Certificate Identification: SC-09H59

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H59-01	35476	CELL-DYN Emerald 22 Instrument	**Self-declared**

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 BIT Group France Parc Euromedecine II, Rue de la Valsiere 34 099 – Montpellier, Cedex 5 France
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Kevin Richardson	Signature:	Mirna M. DiPano
Full Name:	Kevin Richardson	Full Name:	Mirna DiPano
Position:	Manager, Supplier Quality	Position:	Director of Regulatory Affairs
Date of Approval:	10-July-2017	Date of Approval:	10-July-2017
Date Issued:	JUL 10 2017	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V1, April 15, 2016	Effective (Date or Lot Number):	JUL 10 2017

Abbott

Declaration of Conformity

Certificate Identification: SC-09H60

Legal Manufacturer's Name: Abbot Laboratories Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H60-01	58236	CELL-DYN Emerald 22 Easy Cleaner	Self-Declared
09H60-03	58236	CELL-DYN Emerald 22 Easy Cleaner	Self-Declared

Authorized European Representative (name and address)	Abbott GmbH Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 USA Avantor Performance Materials Poland, S.A ul. Sowinskiego 11 44-101 Gliwice, Poland
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices, and 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, as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and Annex VI of the ROHS Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Cheryl Nowlan	Signature:	
Full Name:	Cheryl Nowlan	Full Name:	Thao Phan
Position:	Director, Quality Assurance	Position:	Associate Director, Regulatory Affairs
Date of Approval:	12 OCT 2020	Date of Approval:	12 OCT 2020
		Date of Issue:	OCT 12 2020
		Place Issued:	Abbott Santa Clara
		Supersedes:	September 24, 2020
		Effective (Date or Lot Number)	OCT 12 2020

Abbott

Declaration of Conformity

Certificate Identification: SC-09H72

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

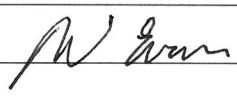
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H72-01	55866	CELL-DYN 22 Plus Control, Full Pack	**Self-declared**
09H72-02	55866	CELL-DYN 22 Plus Control, Half Pack	**Self-declared**

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 Streck, Inc. 7002 S. 109th Street La Vista, NE 68128 USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Alfred Evans	Full Name:	Thao Phan
Position:	Director, Quality Assurance	Position:	Associate Director, Regulatory Affairs
Date of Approval:	May 9, 2019	Date of Approval:	May 9, 2019
Date Issued:	MAY 09 2019	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V1 April 15, 2016	Effective (Date or Lot Number):	MAY 09 2019

Abbott

Declaration of Conformity

Certificate Identification: SC-09H62

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H62-01	58237	CELL-DYN Emerald 22 DILUENT	**Self-declared**

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 Avantor Performance Materials B.V. Teugseweg 20 Deventer, Overijssel Netherlands 7418 AM Avantor Performance Materials Poland S.A. ul. Sowinskiego 11 44-101 Gliwice, Poland
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Kevin Richardson	Full Name:	Mirna DiPano
Position:	Manager, Supplier Quality	Position:	Director of Regulatory Affairs
Date of Approval:	10-July-2017	Date of Approval:	10-July-2017
Date Issued:	JUL 10 2017	Place Issued:	Abbott Santa Clara
Supersedes:	IRI S V1, April 15, 2016	Effective (Date or Lot Number):	JUL 10 2017

Abbott

Declaration of Conformity

Certificate Identification: SC-09H61

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H61-01	61165	CELL-DYN Emerald 22 LYSE	**Self-declared**

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 BIT Group France Parc Euromedecine II, Rue de la Valsiere 34 099 – Montpellier, Cedex 5 France
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Kevin Richardson	Signature:	Mirna M. DiPano
Full Name:	Kevin Richardson	Full Name:	Mirna DiPano
Position:	Manager, Supplier Quality	Position:	Director of Regulatory Affairs
Date of Approval:	10-July-2017	Date of Approval:	10-July-2017
Date Issued:	JUL 10 2017	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V1, April 15, 2016	Effective (Date or Lot Number):	JUL 10 2017

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Abbott Laboratories Diagnostics Division
100 Abbott Park Road
Abbott Park
Illinois
60064
USA

Facility ID Number: F004943

Holds Certificate No: **MDSAP 743463**

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 Medical Devices

Original Registration Date: 2017-12-07 Effective Date: 2023-11-08 Expiry Date: 2024-10-12

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

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Certificate No: **MDSAP 743463**

Registered Scope:

Design and Manufacture of In Vitro Diagnostic Medical Devices used in the Diagnosis, Management and Detection of Cancer, Autoimmune Status, Cardiac Markers, Endocrine Disorders, and for Therapeutic Drug Monitoring.

Design, Development, Manufacture, Refurbishment, Distribution, and Post-Market Customer Service and Support of In Vitro Diagnostic Medical Devices for Immunoassay and Clinical Chemistry Systems. Manufacture, Design / Development of In Vitro Diagnostic Products including Instruments, Reagents, and Accessories for Hematology.

Original Registration Date: 2017-12-07 Effective Date: 2023-11-08 Expiry Date: 2024-10-12

Certificate No: **MDSAP 743463**

Location	Registered Activities
Abbott Laboratories Diagnostics Division 100 Abbott Park Road Abbott Park Illinois 60064 USA Facility ID Number: F004943	Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Abbott Laboratories Diagnostics Division - Conway Park 675 North Field Drive Lake Forest Illinois 60045 USA Facility ID Number: F004943	Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
Abbott Laboratories Diagnostics Division - K Complex - Distribution Center Route 41 & Martin Luther King Drive North Chicago Illinois 60064 USA Facility ID Number: F004943	QC Inspection of incoming materials and distribution of IVD products including test kits, reagents, accessories and instruments.

Original Registration Date: 2017-12-07 Effective Date: 2023-11-08 Expiry Date: 2024-10-12

CERTIFICATE OF TRAINING

THIS CERTIFIES THAT

Stefan Dumitras

HAS SUCCESSFULLY COMPLETED THE TRAINING COURSE

CELL-DYN EMERALD 18/22+22AL, Service & Application

November 5th-9th, 2018

Gustavo Rodriguez/ Srinivasan Gopalan

TRAINER NAME

ABBOTT DIAGNOSTICS

TRAINER SIGNATURE

09.11.2018

DATE DD.MM.YYYY

Germany - Delkenheim

Abbott