Digitally signed by Ceaicovschi Tudor
Date: 2025.01.20 12:09:20 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

By Royal Charter

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 and Distribution 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, Installation, Service and Distribution of In Vitro Diagnostic Medical Devices for Immunoassay and Clinical Chemistry Systems.

Design, Development, Manufacture, Installation, Service and Distribution of In Vitro Diagnostic medical devices including Analyzers, Reagents, and related Accessories for the identification of hematologic parameters.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-06-01
Latest Revision Date: 2024-10-03

Effective Date: 2024-10-13
Expiry Date: 2027-10-12

...making excellence a habit.™

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: 2024-10-13

Latest Revision Date: 2024-10-03

Expiry Date: 2027-10-12

Abbott

Declaration of Conformity

Certificate Identification: SC-09H46

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

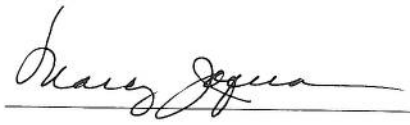
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H46-02	58236	CELL-DYN Emerald CLEANER	**Self-declared**
09H47-02	61165	CELL-DYN Emerald CN-FREE LYSE	**Self-declared**
09H48-02	58237	CELL-DYN Emerald 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
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:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	02-Dec-2015	Date of Approval:	01 DEC 2015
Date Issued:	DEC 02 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V6 July 6, 2015	Effective (Date or Lot Number):	DEC 03 2015

Abbott

Declaration of Conformity

Certificate Identification:	SC-09H39
Legal Manufacturer's Name:	Abbott Laboratories
Legal Manufacturer's Address:	100/200 Abbott Park Road, Abbott Park, IL 60064
	USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H39-01	35476	CELL-DYN Emerald	**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 USA
Harmonized Standards	Refer to the product Essential Requirements Checklist

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.

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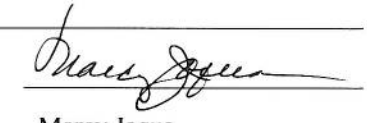
Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Quality Manager	Position:	Regulatory Affairs, Associate Director
Date of Approval:	16 Jan 2014	Date of Approval:	16 Jan 2014
Date Issued:	16-Jan-2014	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V4, November 13, 2013	Effective (Date or Lot Number):	07 Feb 2014

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