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
Effective Date: 2024-10-13
Latest Revision Date: 2024-10-03
Expiry Date: 2027-10-12

UKAS MANAGEMENT SYSTEMS 0003

Digitally signed by Ceaicovschi Tudor
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Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

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

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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-09H72

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

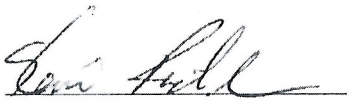
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

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 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:	Kevin Richardson	Full Name:	Zaman Khan
Position:	Manager, Supplier Quality	Position:	Associate Director, Regulatory Affairs
Date of Approval:	11-APR-2016	Date of Approval:	11-Apr-2016
Date Issued:	APR 15 2016	Place Issued:	Abbott Santa Clara
Supersedes:	N/A	Effective (Date or Lot Number):	APR 15 2016

Abbott

Declaration of Conformity

Certificate Identification: SC-09H60

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
09H60-01	58236	CELL-DYN Emerald 22 Easy Cleaner	**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
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:	Zaman Khan
Position:	Manager, Supplier Quality	Position:	Associate Director, Regulatory Affairs
Date of Approval:	11-APR-2016	Date of Approval:	11-Apr-2016
Date Issued:	APR 15 2016	Place Issued:	Abbott Santa Clara
Supersedes:	N/A	Effective (Date or Lot Number):	APR 15 2016

Abbott

Declaration of Conformity

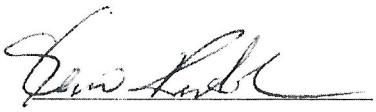
Certificate Identification:	SC-09H61
Legal Manufacturer's Name:	Abbott Laboratories Diagnostics Division
Legal Manufacturer's Address:	Abbott Park, IL 60064 USA

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 C2 Diagnostics, 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:		Signature:	
Full Name:	Kevin Richardson	Full Name:	Zaman Khan
Position:	Manager, Supplier Quality	Position:	Associate Director, Regulatory Affairs
Date of Approval:	11-APR-2016	Date of Approval:	11-Apr-2016
Date Issued:	APR 15 2016	Place Issued:	Abbott Santa Clara
Supersedes:	N/A	Effective (Date or Lot Number):	APR 15 2016

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