



America

CERTIFICATE

No. QS6 010051 0140 Rev. 01

Certificate Holder: **Abbott GmbH**
Max-Planck-Ring 2
65205 Wiesbaden
GERMANY

Certification Mark:



Scope of Certificate: **Design and Development, Manufacture and Distribution of In-Vitro Diagnostics Reagents used in the Diagnosis, Management and Detection of Blood Analytes, Immune Status, Complement Components, Cancer, Thyroid Markers, Fertility Testing, Endocrine Disorders, Bone and Mineral Metabolism, Hormones, Vitamins, Therapeutic Drug Monitoring, Rheumatoid - Inflammatory Diseases, Cardiac Markers, Immunological Typing Bacterial Infectious Diseases, Viral Infectious Diseases, and Parasitic Infectious Diseases**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F006151**

Effective Date: **2022-07-11**

Expiry Date: **2024-09-30**

Page 1 of 2

Date of Issue: 2022-10-31

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services



America

CERTIFICATE

No. QS6 010051 0140 Rev. 01

Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 16/2013
 - RDC ANVISA n. 23/2012
 - RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
 - PMD Act

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820

Facility(ies):

Abbott GmbH
 Max-Planck-Ring 2, 65205 Wiesbaden, GERMANY

Facility Scopes:

Design and Development, Manufacture and Distribution of In-Vitro Diagnostics Reagents used in the Diagnosis, Management and Detection of Blood Analytes, Immune Status, Complement Components, Cancer, Thyroid Markers, Fertility Testing, Endocrine Disorders, Bone and Mineral Metabolism, Hormones, Vitamins, Therapeutic Drug Monitoring, Rheumatoid - Inflammatory Diseases, Cardiac Markers, Immunological Typing Bacterial Infectious Diseases, Viral Infectious Diseases, and Parasitic Infectious Diseases
 REPs Facility ID: F006151

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Date of Issue: 2022-10-31

(Renee Walker)
 Manager, US Certification Body,
 Medical and Health Services



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.

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



Page: 1 of 2

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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

Latest Revision Date: 2022-04-12

Effective Date: 2021-10-13

Expiry Date: 2024-10-12

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

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 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

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brazil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, 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: 2022-05-31

Expiry Date: 2024-10-12



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 3

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Certificate No: **MDSAP 743463**

Registered Scope:

Design and Manufacture of In Vitro Diagnostic Medical Devices, used in the Screening of Blood Donor Units for Transmissible Diseases. 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: 2022-05-31

Expiry Date: 2024-10-12

Page: 2 of 3

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

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.
Abbott Japan LLC 278 Matsuhidai Matsudo-shi Chiba 270-2214 Japan Facility ID Number: F005418	Design and development in vitro diagnostics products including test kits, reagents, and accessories.

Original Registration Date: 2017-12-07

Effective Date: 2022-05-31

Expiry Date: 2024-10-12

Page: 3 of 3

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To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

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: 2022-06-22

Effective Date: 2021-10-13

Expiry Date: 2024-10-12

Page: 1 of 2



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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.
Abbott Japan LLC 278 Matsuhidai Matsudo-shi Chiba 270-2214 Japan	Design and Development of in vitro diagnostics products including test kits and reagents.

Original Registration Date: 2021-06-01

Latest Revision Date: 2022-06-22

Effective Date: 2021-10-13

Expiry Date: 2024-10-12

Page: 2 of 2

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
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Printed copies can be validated at www.bsigroup.com/ClientDirectory

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 of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 9001:2015



Cliff Muckleroy - Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 13 October 2018
Expiry date: 12 October 2021
Certificate identity number: 10155324

Original approval(s):
ISO 9001 – 3 December 2017

Approval number(s): ISO 9001 – 0015681

The scope of this approval is applicable to:

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



001

Certificate Schedule

Certificate identity number: 10155324

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	ISO 9001:2015 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States	ISO 9001:2015 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States	ISO 9001:2015 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.



001



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

Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

MDSAP Facility Identifier: 079226220

has been audited by LRQA and found to conform to the following audit criteria:

ISO 13485:2016

Australia:

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
(Excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

RDC ANVISA n. 16/2013
RDC ANVISA n. 23/2012
RDC ANVISA n. 67/2009

Canada:

Medical Devices Regulations – Part 1- SOR 98/282

Japan:

MHLW Ministerial Ordinance 169, Article 4 to Article 68
PMD Act

United States:

21 CFR 820
21 CFR 803
21 CFR 806



Cliff Muckleroy - Area Operations Manager Americas
Issued By: Lloyd's Register Quality Assurance, Inc.

Certificate Approval Number: UQA 00000846

Effective Date: 2018 October 13

Expiry Date: 2021 October 12

Certificate Issue Number: 10155325

Original Approval:

MDSAP/ ISO 13485 – 2017 December 7



Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>

Certificate Schedule

Certificate Issue Number: 10155325

Approval Number: MDSAP – 0015682

The scope of this approval is applicable to:

Design and Manufacture of In Vitro Diagnostic Medical Devices, used in the Screening of Blood Donor Units for Transmissible Diseases. 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.



Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>

Certificate Schedule

Certificate Issue Number: 10155325

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	MDSAP 2017 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States MDSAP Facility Identifier: 079226220-002	MDSAP 2017 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States MDSAP Facility Identifier: 079226220-003	MDSAP 2017 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.



Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>

Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 13485:2016



Cliff Muckleroy - Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 13 October 2018

Expiry date: 12 October 2021

Certificate identity number: 10155326

Original approval(s):

ISO 13485 – 7 December 2017

Approval number(s): ISO 13485 – 0015680

The scope of this approval is applicable to:

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



001

Certificate Schedule

Certificate identity number: 10155326

Location	Activities
100 Abbott Park Road, Abbott Park, IL, 60064, United States	ISO 13485:2016 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.
Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States	ISO 13485:2016 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites.
K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States	ISO 13485:2016 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.



001

Declaration of Conformity

Certificate Identification: SC-08H59

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
08H59-01	55866	CELL-DYN 26 Plus Control, Full Pack	Self-declared
08H59-02	55866	CELL-DYN 26 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
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.

<p>Signature: <u></u></p> <p>Full Name: <u>Barry Simpson</u></p> <p>Position: <u>Site Quality Manager</u></p> <p>Date of Approval: <u>18 June 2015</u></p> <p>Date Issued: <u>JUN 30 2015</u></p> <p>Supersedes: <u>IRIS V5 February 26, 2015</u></p>	<p>Signature: <u></u></p> <p>Full Name: <u>Marcy Jaqua</u></p> <p>Position: <u>Director, Regulatory Affairs</u></p> <p>Date of Approval: <u>30 June 2015</u></p> <p>Place Issued: <u>Abbott Santa Clara</u></p> <p>Effective (Date or Lot Number): <u>JUL 06 2015</u></p>
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Declaration of Conformity



Certificate Identification: SC-01H73
Legal Manufacturer's Name: Abbott Laboratories
Diagnosics 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
01H73-01	58237	CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/SHEATH	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: <u>Barry Simpson</u>	Full Name: <u>Marcy Jaqua</u>
Position: <u>Site Quality Manager</u>	Position: <u>Director, Regulatory Affairs</u>
Date of Approval: <u>29 Jun. 2015</u>	Date of Approval: <u>30 June 2015</u>
Date Issued: <u>JUN 30 2015</u>	Place Issued: <u>Abbott Santa Clara</u>
Supersedes: <u>IRIS V2</u> <u>January 10, 2014</u>	Effective (Date or Lot Number): <u>JUL 06 2015</u>

Declaration of Conformity

Certificate Identification: SC-99644
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
99644-01	59058	CELL-DYN ENZYMATIC CLEANER CONCENTRATE	Self-declared
93641-01	59058	CELL-DYN ENZYMATIC CLEANER CONCENTRATE	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	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:  Full Name: <u>Barry Simpson</u> Position: <u>Quality Manager</u> Date of Approval: <u>04. Sept. 2015</u> Date Issued: <u>SEP 04 2015</u> Supersedes: <u>IRIS V4, January 10, 2014</u>	Signature:  Full Name: <u>Marcy Jaqua</u> Position: <u>Regulatory Affairs, Director</u> Date of Approval: <u>04 Sep 2015</u> Place Issued: <u>Abbott Santa Clara</u> Effective (Date or Lot Number): <u>SEP 11 2015</u>
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Declaration of Conformity

Certificate Identification: SC-03H80
Legal Manufacturer's Name: Abbott Laboratories
Diagnosics 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
03H80-02	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems CN-FREE HGB/NOC 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
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: <u>Barry Simpson</u>	Full Name: <u>Marcy Jaqua</u>
Position: <u>Site Quality Manager</u>	Position: <u>Director, Regulatory Affairs</u>
Date of Approval: <u>29 Jun. 2015</u>	Date of Approval: <u>30 June 2015</u>
Date Issued: <u>JUN 30 2015</u>	Place Issued: <u>Abbott Santa Clara</u>
Supersedes: <u>IRIS V2</u> <u>January 10, 2014</u>	Effective (Date or Lot Number): <u>JUL 06 2015</u>

Declaration of Conformity



Certificate Identification: SC-08H52
Legal Manufacturer's Name: Abbott Laboratories
Diagnosics 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
08H52-01	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems WBC 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
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: <u>Barry Simpson</u>	Full Name: <u>Marcy Jaqua</u>
Position: <u>Site Quality Manager</u>	Position: <u>Director, Regulatory Affairs</u>
Date of Approval: <u>29 Jun 2015</u>	Date of Approval: <u>30 June 2015</u>
Date Issued: <u>JUN 30 2015</u>	Place Issued: <u>Abbott Santa Clara</u>
Supersedes: <u>IRIS V2, January 10, 2014</u>	Effective (Date or Lot Number): <u>JUL 06 2015</u>



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 010051 0103 Rev. 13

Manufacturer: **Abbott GmbH**
Max-Planck-Ring 2
65205 Wiesbaden
GERMANY

Product Category(ies): Products for determination of infection markers

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_010051_0103 Rev. 13](http://www.tuvsud.com/ps-cert?q=cert:V1_010051_0103_Rev.13)

Report no.: 713237273-04_SCN

Valid from: 2022-05-10

Valid until: 2025-05-26

Date, 2022-05-10

Christoph Dicks
Head of Certification/Notified Body



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 010051 0103 Rev. 13

Model(s): Products for the determination of
infection markers for HIV, Hepatitis B,
Hepatitis C, HTLV, toxoplasmosis

Facility(ies): Abbott GmbH
Max-Planck-Ring 2, 65205 Wiesbaden, GERMANY

The products detailed below are covered under the scope of this certificate:

Annex II List A Products

Product Name	REF N°
ABBOTT PRISM HIV O Plus Assay Kit	3D34-48
ABBOTT PRISM HBsAg Assay Kit	3A47-48
ABBOTT PRISM HCV Assay Kit	6A52-48
ABBOTT PRISM HTLV-I/HTLV-II Assay Kit	6A53-48
ABBOTT PRISM Positive Run Control Kit	5E22-11
ABBOTT PRISM Run Control Kit	5E22-10
ABBOTT PRISM HBcore Assay Kit	1A77-48
ABBOTT PRISM HBsAg Confirmatory Assay Kit	6D16-48
ABBOTT PRISM HIV Ag/Ab Combo Assay Kit	7G46-48
ABBOTT PRISM Run Control Kit	2K24-10
ABBOTT PRISM Positive Run Control Kit	2K24-11
ARCHITECT Anti-HCV Reagent Kit	6C37-22
ARCHITECT Anti-HCV Reagent Kit	6C37-27
ARCHITECT Anti-HCV Reagent Kit	6C37-32
ARCHITECT Anti-HCV Reagent Kit	6C37-37
ARCHITECT Anti-HCV Calibrator	6C37-01
ARCHITECT Anti-HCV Controls	6C37-10
ARCHITECT Anti-HCV Reagent Kit	6C37-28
ARCHITECT Anti-HCV Reagent Kit	6C37-33
ARCHITECT Anti-HCV Reagent Kit	6C37-38
ARCHITECT Anti-HCV Calibrator	6C37-02
ARCHITECT Anti-HCV Controls	6C37-15
ARCHITECT Anti-HBc IgM Reagent Kit	6C33-22
ARCHITECT Anti-HBc IgM Reagent Kit	6C33-27
ARCHITECT Anti-HBc IgM Calibrators	6C33-02
ARCHITECT Anti-HBc IgM Controls	6C33-11
ARCHITECT Anti-HBe Reagent Kit	6C34-20
ARCHITECT Anti-HBe Reagent Kit	6C34-25
ARCHITECT Anti-HBe Reagent Kit	6C34-35
ARCHITECT Anti-HBe Calibrator	6C34-01
ARCHITECT Anti-HBe Controls	6C34-10



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 010051 0103 Rev. 13

Annex II List A Products

Product Name	REF N°
ARCHITECT HBeAg Reagent Kit	6C32-20
ARCHITECT HBeAg Reagent Kit	6C32-25
ARCHITECT HBeAg Reagent Kit	6C32-27
ARCHITECT HBeAg Reagent Kit	6C32-37
ARCHITECT HBeAg Calibrators	6C32-01
ARCHITECT HBeAg Quantitative Calibrators	7P24-01
ARCHITECT HBeAg Controls	6C32-10
ARCHITECT HBeAg Quantitative Controls	7P24-10
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-22
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-27
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-32
ARCHITECT HIV Ag/Ab Combo Reagent Kit	4J27-37
ARCHITECT HIV Ag/Ab Combo Calibrator	4J27-03
ARCHITECT HIV Ag/Ab Combo Controls	4J27-12
ARCHITECT rHTLV I/II Reagent Kit	6L61-25
ARCHITECT rHTLV I/II Reagent Kit	6L61-30
ARCHITECT rHTLV I/II Reagent Kit	6L61-35
ARCHITECT rHTLV I/II Calibrator	6L61-01
ARCHITECT rHTLV I/II Controls	6L61-10
ARCHITECT Anti-HBc II Reagent Kit	8L44-25
ARCHITECT Anti-HBc II Reagent Kit	8L44-30
ARCHITECT Anti-HBc II Reagent Kit	8L44-35
ARCHITECT Anti-HBc II Calibrator	8L44-01
ARCHITECT Anti-HBc II Controls	8L44-10
ARCHITECT HCV Ag Controls	6L47-11
ARCHITECT HCV Ag Controls	6L47-19
ARCHITECT HCV Ag Calibrators	6L47-02
ARCHITECT HCV Ag Calibrators	6L47-09
ARCHITECT HCV Ag Reagent Kit	6L47-29
ARCHITECT HCV Ag Reagent Kit	6L47-74



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(List A and B and devices for self-testing)

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Annex II List A Products

Product Name	REF N°
Alinity i Anti-HBe Reagent Kit	07P6322
Alinity i Anti-HBe Reagent Kit	07P6332
Alinity i Anti-HBe Calibrator	07P6301
Alinity i Anti-HBe Controls	07P6310
Alinity i HIV Ag/Ab Combo Reagent Kit	08P0722
Alinity i HIV Ag/Ab Combo Reagent Kit	08P0732
Alinity i HIV Ag/Ab Combo Calibrator	08P0701
Alinity i HIV Ag/Ab Combo Controls	08P0710
Alinity i Anti-HCV Reagent Kit	08P0622
Alinity i Anti-HCV Reagent Kit	08P0632
Alinity i Anti-HCV Calibrator	08P0601
Alinity i Anti-HCV Controls	08P0610
Alinity i Anti-HCV Reagent Kit	08P0623
Alinity i Anti-HCV Reagent Kit	08P0633
Alinity i Anti-HCV Calibrator	08P0602
Alinity i Anti-HCV Controls	08P0611
Alinity i Anti-HBc IgM Reagent Kit	07P8622
Alinity i Anti-HBc IgM Calibrators	07P8601
Alinity i Anti-HBc IgM Controls	07P8610
Alinity i Anti-HBc II Reagent Kit	07P8722
Alinity i Anti-HBc II Reagent Kit	07P8732
Alinity i Anti-HBc II Calibrator	07P8701
Alinity i Anti-HBc II Controls	07P8710
Alinity i HCV Ag Reagent Kit	09P2322
Alinity i HCV Ag Controls	09P2310
Alinity i HCV Ag Calibrators	09P2301



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(List A and B and devices for self-testing)

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Annex II List A Products

Product Name	REF N°
Alinity i rHTLV-I/II Reagent Kit	07P6122
Alinity i rHTLV-I/II Reagent Kit	07P6132
Alinity i rHTLV-I/II Calibrator	07P6101
Alinity i rHTLV-I/II Controls	07P6110
Alinity i HBeAg Reagent Kit	07P6422
Alinity i HBeAg Reagent Kit	07P6432
Alinity i HBeAg Calibrators	07P6401
Alinity i HBeAg Controls	07P6410
Alinity i HBeAg Quantitative Calibrators	09P1001
Alinity i HBeAg Quantitative Controls	09P1010
Alinity s Anti-HBc Reagent Kit	06P0655
Alinity s Anti-HBc Calibrator Kit	06P0602
Alinity s Anti-HBc Assay Control Kit	06P0610
Alinity s Anti-HBc Release Control Kit	06P0612
Alinity s HIV Ag/Ab Combo Reagent Kit	06P0155
Alinity s HIV Ag/Ab Combo Calibrator Kit	06P0102
Alinity s HIV Ag/Ab Combo Assay Control Kit	06P0110
Alinity s HIV Ag/Ab Combo Release Control Kit	06P0112
Alinity s HIV Ag/Ab Combo Reagent Kit	06P0160
Alinity s HIV Ag/Ab Combo Calibrator Kit	06P0103
Alinity s HIV Ag/Ab Combo Assay Control Kit	06P0120
Alinity s HIV Ag/Ab Combo Release Control Kit	06P0124



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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 010051 0103 Rev. 13

Annex II List A Products

Product Name	REF N°
Alinity s Anti-HCV Reagent Kit	06P0455
Alinity s Anti-HCV Calibrator Kit	06P0402
Alinity s Anti-HCV Assay Control Kit	06P0410
Alinity s Anti-HCV Release Control Kit	06P0412
Alinity s Anti-HCV Reagent Kit	06P0477
Alinity s Anti-HCV Calibrator Kit	06P0409
Alinity s Anti-HCV Assay Control Kit	06P0419
Alinity s Anti-HCV Release Control Kit	06P0418
Alinity s Anti-HCV Reagent Kit	06P0460
Alinity s Anti-HCV Calibrator Kit	06P0403
Alinity s Anti-HCV Assay Control Kit	06P0420
Alinity s Anti-HCV Release Control Kit	06P0424
Alinity s Anti-HCV II Reagent Kit	04W5655
Alinity s Anti-HCV II Reagent Kit	04W5656
Alinity s Anti-HCV II Calibrator Kit	04W5602
Alinity s Anti-HCV II Assay Control Kit	04W5610
Alinity s Anti-HCV II Release Control Kit	04W5612
Alinity s HTLV I/II Reagent Kit	06P0755
Alinity s HTLV I/II Calibrator Kit	06P0702
Alinity s HTLV I/II Assay Control Kit	06P0710
Alinity s HTLV I/II Release Control Kit	06P0712
Alinity s HIV Ag/Ab Combo Reagent Kit	06P0177
Alinity s HIV Ag/Ab Combo Calibrator Kit	06P0109
Alinity s HIV Ag/Ab Combo Assay Control Kit	06P0119
Alinity s HIV Ag/Ab Combo Release Control Kit	06P0118



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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 010051 0103 Rev. 13

Annex II List A Products for ARCHITECT Plattform

Product Name	REF N°
Anti-HCV Reagent Kit	6C37-74
Anti-HCV Reagent Kit	6C37-77
Anti-HCV Reagent Kit	6C37-78
Anti-HCV Calibrator	6C37-09
Anti-HCV Controls	6C37-19
Anti-HBc IgM Reagent Kit	6C33-74
Anti-HBc IgM Reagent Kit	6C33-75
Anti-HBc IgM Calibrators	6C33-09
Anti-HBc IgM Controls	6C33-19
Anti-HBe Reagent Kit	6C34-74
Anti-HBe Reagent Kit	6C34-77
Anti-HBe Calibrator	6C34-09
Anti-HBe Controls	6C34-19
HBeAg Reagent Kit	6C32-74
HBeAg Reagent Kit	6C32-77
HBeAg Calibrators	6C32-09
HBeAg Quantitative Calibrators	7P24-09
HBeAg Controls	6C32-19
HBeAg Quantitative Controls	7P24-19
HIV Ag/Ab Combo Reagent Kit	4J27-74
HIV Ag/Ab Combo Reagent Kit	4J27-77
HIV Ag/Ab Combo Reagent Kit	4J27-78
HIV Ag/Ab Combo Reagent Kit	4J27-84
HIV Ag/Ab Combo Reagent Kit	4J27-87
HIV Ag/Ab Combo Reagent Kit	4J27-89
HIV Ag/Ab Combo Calibrator	4J27-09
HIV Ag/Ab Combo Controls	4J27-19
HIV Ag/Ab Combo Controls	4J27-17
Anti-HBc II Reagent Kit	8L44-74
Anti-HBc II Reagent Kit	8L44-77
Anti-HBc II Reagent Kit	8L44-78
Anti-HBc II Calibrator	8L44-09
Anti-HBc II Controls	8L44-19



EC Certificate

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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 010051 0103 Rev. 13

Annex II List A Products for Alinity i Plattform

Product Name	REF N°
Anti-HBe Reagent Kit	07P6374
Anti-HBe Reagent Kit	07P6377
Anti-HBe Calibrator	07P6309
Anti-HBe Controls	07P6319
HIV Ag/Ab Combo Reagent Kit	08P0774
HIV Ag/Ab Combo Reagent Kit	08P0777
HIV Ag/Ab Combo Reagent Kit	08P0784
HIV Ag/Ab Combo Reagent Kit	08P0787
HIV Ag/Ab Combo Calibrator	08P0709
HIV Ag/Ab Combo Controls	08P0719
HIV Ag/Ab Combo Controls	08P0717
Anti-HCV Reagent Kit	08P0674
Anti-HCV Reagent Kit	08P0677
Anti-HCV Calibrator	08P0609
Anti-HCV Controls	08P0619
Anti-HBc II Reagent Kit	07P8774
Anti-HBc II Reagent Kit	07P8777
Anti-HBc II Calibrator	07P8709
Anti-HBc II Controls	07P8719
Anti-HBc IgM Reagent Kit	07P8674
Anti-HBc IgM Calibrators	07P8609
Anti-HBc IgM Controls	07P8619
HBeAg Reagent Kit	07P6474
HBeAg Reagent Kit	07P6477
HBeAg Calibrators	07P6409
HBeAg Controls	07P6419
HBeAg Quantitative Calibrators	09P1009
HBeAg Quantitative Controls	09P1019



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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 010051 0103 Rev. 13

Annex II List B Products

Product Name	REF N°
ARCHITECT Toxo IgG Reagent Kit	6C19-25
ARCHITECT Toxo IgG Reagent Kit	6C19-35
ARCHITECT Toxo IgG Calibrators	6C19-01
ARCHITECT Toxo IgG Controls	6C19-10
ARCHITECT Toxo IgG Avidity Reagent Kit	6L37-25
ARCHITECT Toxo IgG Avidity Calibrator & Controls	6L37-11
ARCHITECT Toxo IgM Reagent Kit	6C20-25
ARCHITECT Toxo IgM Reagent Kit	6C20-35
ARCHITECT Toxo IgM Calibrator	6C20-01
ARCHITECT Toxo IgM Controls	6C20-10
Alinity i Toxo IgG Reagent Kit	07P4522
Alinity i Toxo IgG Reagent Kit	07P4532
Alinity i Toxo IgG Calibrators	07P4501
Alinity i Toxo IgG Controls	07P4510
Alinity i Toxo IgM Reagent Kit	07P4722
Alinity i Toxo IgM Reagent Kit	07P4732
Alinity i Toxo IgM Calibrator	07P4701
Alinity i Toxo IgM Controls	07P4710
Alinity i Toxo IgG Avidity Reagent Kit	07P4622
Alinity i Toxo IgG Avidity Controls	07P4610



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 (List A and B and devices for self-testing)

No. V1 010051 0103 Rev. 13

Annex II List B Products for ARCHITECT Plattform

Product Name	REF N°
Toxo IgG Calibrators	6C19-09
Toxo IgG Controls	6C19-19
Toxo IgG Reagent Kit	6C19-74
Toxo IgG Reagent Kit	6C19-77
Toxo IgM Calibrators	6C20-09
Toxo IgM Controls	6C20-19
Toxo IgM Reagent Kit	6C20-74
Toxo IgM Reagent Kit	6C20-77
Toxo IgG Avidity Reagent Kit	6L37-74

Annex II List B Products for Alinity i Plattform

Product Name	REF N°
Toxo IgG Calibrators	07P4509
Toxo IgG Controls	07P4519
Toxo IgG Reagent Kit	07P4574
Toxo IgG Reagent Kit	07P4577
Toxo IgM Calibrators	07P4709
Toxo IgM Controls	07P4719
Toxo IgM Reagent Kit	07P4774
Toxo IgM Reagent Kit	07P4777
Toxo IgG Avidity Reagent Kit	07P4674

Declaration of Conformity


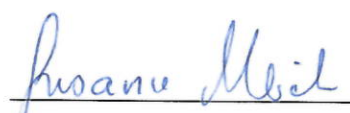
Certificate Identification: DoC-2K45-SD DELK TPM
Legal Manufacturer's Name: Abbott GmbH
Legal Manufacturer's Address: Max-Planck-Ring 2, 65205 Wiesbaden, Germany

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2K45-24	54588	ARCHITECT CA 125 II Reagent Kit	Self-declared
2K45-29	54588	ARCHITECT CA 125 II Reagent Kit	Self-declared
2K45-39	54588	ARCHITECT CA 125 II Reagent Kit	Self-declared
2K45-02	38231	ARCHITECT CA 125 II Calibrators	Self-declared
2K45-11	38230	ARCHITECT CA 125 II Controls	Self-declared

Authorized European Representative (name and address)	N/A
Storage site of technical documentation (name and address)	Fujirebio Diagnostics, Inc., 201 Great Valley Parkway, Malvern, Pennsylvania 19355, 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: <u></u>	Signature: <u></u>
Full Name: Dr. Jörg Amborn	Full Name: Susanne Ulrich
Position: Director Quality Assurance	Position: Senior Manager Regulatory Affairs
Date of Approval: <u>2020-05-14</u>	Date of Approval: <u>12/ May / 2020</u>
	Date Issued: <u>14- May- 2020</u>
	Place Issued: 65205 Wiesbaden, Germany
	Supersedes: 12-May-2017
	Effective (Date or Lot Number): <u>14- May- 2020</u>



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 001922 0008 Rev. 04

Manufacturer: **Abbott Ireland Diagnostics Division**
Finisklin Business Park
Sligo
IRELAND

Product Category(ies): **Products for determination of infection markers
and tumour markers**

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_001922_0008_Rev.04

Report no.: 713252089 / 713251178-02

Valid from: 2022-05-02

Valid until: 2025-05-26

Date, 2022-05-02

Christoph Dicks
Head of Certification/Notified Body



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 001922 0008 Rev. 04

Model(s):

**Products for the determination
of infection markers for Hepatitis B,
cytomegalovirus, rubella and tumour
marker PSA**

Facility(ies):

Abbott Ireland Diagnostics Division
Finisklin Business Park, Sligo, IRELAND

The products detailed below are covered under the scope of this certificate:

Annex II List A Products

Product Name	REF N°
ARCHITECT HBsAg Qualitative II Calibrators	2G22-01
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-25
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-30
ARCHITECT HBsAg Qualitative II Confirmatory Reagent Kit	2G23-25
ARCHITECT HBsAg Calibrators	3M61-02
ARCHITECT HBsAg Controls	6C36-10
ARCHITECT HBsAg Reagent Kit	6C36-29
ARCHITECT HBsAg Reagent Kit	6C36-34
ARCHITECT HBsAg Reagent Kit	6C36-35
ARCHITECT HBsAg Reagent Kit	6C36-43
ARCHITECT HBsAg Reagent Kit	6C36-44
ARCHITECT Anti-HBs Calibrators	7C18-01
ARCHITECT Anti-HBs Calibrators	7C18-03
ARCHITECT Anti-HBs Controls	7C18-10
ARCHITECT Anti-HBs Controls	7C18-13
ARCHITECT Anti-HBs Reagent Kit	7C18-20
ARCHITECT Anti-HBs Reagent Kit	7C18-25



EC Certificate

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 (List A and B and devices for self-testing)

No. V1 001922 0008 Rev. 04

Annex II List A Products

Product Name	REF N°
ARCHITECT Anti-HBs Reagent Kit	7C18-27
ARCHITECT Anti-HBs Reagent Kit	7C18-28
ARCHITECT Anti-HBs Reagent Kit	7C18-30
ARCHITECT Anti-HBs Reagent Kit	7C18-34
ARCHITECT Anti-HBs Reagent Kit	7C18-37
ARCHITECT Anti-HBs Reagent kit	7C18-38
ARCHITECT HBsAg Confirmatory V.1 Calibrators	9C94-01
ARCHITECT HBsAg Confirmatory V.1 Controls	9C94-10
ARCHITECT HBsAg Confirmatory V.1 Reagent Kit	9C94-25
ARCHITECT HBsAg Qualitative II Reagent Kit	2G22-35
ARCHITECT Anti-HBs Reagent Kit	7C18-29
ARCHITECT Anti-HBs Reagent Kit	7C18-41
ARCHITECT Anti-HBs Reagent Kit	7C18-39
ARCHITECT Anti-HBs Reagent Kit	7C18-42
ARCHITECT Anti-HBs Reagent Kit	7C18-33
Alinity i HBsAg Calibrators	08P0801
Alinity i HBsAg Controls	08P0810
Alinity i HBsAg Reagent Kit	08P0852
Alinity i HBsAg Confirmatory V.1 Calibrators	08P0901
Alinity i HBsAg Confirmatory V.1 Controls	08P0910
Alinity i HBsAg Confirmatory V.1 Reagent Kit	08P0922
Alinity i HBsAg Qualitative II Calibrators	08P1001
Alinity i HBsAg Qualitative II Controls	08P1010



EC Certificate

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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 001922 0008 Rev. 04

Annex II List A Products

Product Name	REF N°
Alinity i HBsAg Qualitative II Reagent Kit	08P1022
Alinity i HBsAg Qualitative II Confirmatory Reagent Kit	08P1122
Alinity i Anti-HBs Reagent Kit	07P8922
Alinity i Anti-HBs Controls	07P8910
Alinity i Anti-HBs Calibrators	07P8901
Alinity i Anti-HBs Reagent Kit	07P8952
Alinity s HBsAg Reagent Kit	06P0255
Alinity s HBsAg Reagent Kit	06P0260
Alinity s HBsAg Confirmatory Reagent Kit	06P0357
Alinity s HBsAg Confirmatory Reagent Kit	06P0359
Alinity s HBsAg Calibrator Kit	06P0202
Alinity s HBSAg Calibrator Kit	06P0204
Alinity s HBsAg Assay Control Kit	06P0210
Alinity s HBsAg Assay Control Kit	06P0213
Alinity s HBsAg Release Control Kit	06P0212
Alinity s HBsAg Release Control Kit	06P0215
ARCHITECT HBsAg Qualitative II Controls	2G22-10
Alinity i HBsAg Qualitative II Reagent Kit	08P1032
Alinity i HBsAg Reagent Kit	08P0832
Alinity i HBsAg Reagent Kit	08P0822
Alinity i HBsAg Reagent Kit	08P0857
Alinity i Anti-HBs Reagent Kit	07P8932
Alinity i Anti-HBs Reagent Kit	07P8957
Alinity i HBsAg Next Qualitative Calibrators	01R6401
Alinity i HBsAg Next Qualitative Controls	01R6410
Alinity i HBsAg Next Qualitative Reagent Kit	01R6422
Alinity i HBsAg Next Qualitative Reagent Kit	01R6432
Alinity i HBsAg Next Confirmatory Reagent Kit	01R6522
ARCHITECT HBsAg Next Qualitative Reagent Kit	4P76-25
ARCHITECT HBsAg Next Qualitative Reagent Kit	4P76-30
ARCHITECT HBsAg Next Qualitative Reagent Kit	4P76-35
ARCHITECT HBsAg Next Confirmatory Reagent Kit	4P77-25
ARCHITECT HBsAg Next Qualitative Calibrators	4P76-01
ARCHITECT HBsAg Next Qualitative Controls	4P76-10



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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 001922 0008 Rev. 04

Annex II List B Products

Product Name	REF N°
ARCHITECT Rubella IgM Reagent Kit	6C18-25
ARCHITECT Rubella IgM Calibrator	6C18-01
ARCHITECT Rubella IgM Controls	6C18-10
ARCHITECT Rubella IgM Controls	6C18-13
ARCHITECT Rubella IgG Reagent Kit	6C17-26/36
ARCHITECT Rubella IgG Calibrators	6C17-03
ARCHITECT Rubella IgG Controls	6C17-13
ARCHITECT Free PSA Reagent Kit	7K71-20/25
ARCHITECT Free PSA Calibrators	7K71-01
ARCHITECT Free PSA Controls	7K71-10
ARCHITECT Total PSA Reagent Kit	7K70-20/25/30/35
ARCHITECT Total PSA Calibrators	7K70-01
ARCHITECT Total PSA Controls	7K70-10
ARCHITECT CMV IgG Avidity Reagent Kit	3L46-25
ARCHITECT CMV IgG Avidity Calibrator and Controls	3L46-11
ARCHITECT CMV IgG Reagent Kit	6C15-20/25/30
ARCHITECT CMV IgG Calibrators	6C15-01
ARCHITECT CMV IgG Controls	6C15-10
ARCHITECT CMV IgM Reagent Kit	6C16-20/25/30
ARCHITECT CMV IgM Calibrator	6C16-01
ARCHITECT CMV IgM Controls	6C16-10
Alinity i CMV IgG Reagent Kit	07P4222 / 07P4232
Alinity i CMV IgG Calibrators	07P4201



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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 001922 0008 Rev. 04

Annex II List B Products

Product Name	REF N°
Alinity i CMV IgG Controls	07P4210
Alinity i CMV IgM Reagent Kit	07P4422 / 07P4432
Alinity i CMV IgM Calibrator	07P4401
Alinity i CMV IgM Controls	07P4410
Alinity i Rubella IgG Reagent Kit	08P4622 / 08P4632
Alinity i Rubella IgG Calibrators	08P4601
Alinity i Rubella IgG Controls	08P4610
Alinity i Rubella IgM Reagent Kit	08P4722 / 08P4732
Alinity i Rubella IgM Calibrator	08P4701
Alinity i Rubella IgM Controls	08P4710
Alinity i Rubella IgM Controls	08P4713
Alinity i CMV IgG Avidity Reagent Kit	07P4322
Alinity i CMV IgG Avidity Controls	07P4310
Alinity s CMV IgG Qualitative Reagent Kit	06P1045
Alinity s CMV IgG Qualitative Calibrator Kit	06P1002
Alinity s CMV IgG Qualitative Assay Control Kit	06P1010
Alinity s CMV IgG Qualitative Release Control Kit	06P1012
Alinity i Free PSA Reagent Kit	07P9320 / 07P9330
Alinity i Free PSA Calibrators	07P9301
Alinity i Free PSA Controls	07P9310
Alinity i Total PSA Reagent Kit	07P9220 / 07P9230
Alinity i Total PSA Calibrators	07P9201
Alinity i Total PSA Controls	07P9210



TECHNOPATH
CLINICAL DIAGNOSTICS

Multichem[®] IA Plus

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Immunoassay QC in a Liquid Stable Format



Features

- ◆ Human based proprietary formulation
- ◆ Mimics performance of patient samples.
- ◆ Targeted at key clinical decision points
- ◆ Liquid for ease of use.

Specifications

- ◆ 36 month closed vial stability at -20°C to -80°C.
- ◆ 10 day open vial stability at 2°C to 8°C.

Product	Description	Configuration	Part Code
✓ Multichem IA Plus	Unassayed Tri-Level	3 × 4 × 5mL	IA310X
	Assayed Tri-Level	3 × 4 × 5mL	IA310A

THE QUALITY CONTROL COMPANY

Multichem® IA Plus Immunoassay Analyte List

Cancer Markers

Alpha Fetoprotein
CA 125
CA 15-3
CA 19-9
Carcinogenic Embryonic Antigen
Prostate Specific Antigen, Free
Prostate Specific Antigen, Total

Cardiac

BNP
CK-MB
Myoglobin
NT-pro BNP
Troponin I
Troponin T
Ultrasensitive CRP*

Allergy

IgE

Thyroid

Anti-Thyroperoxidase
Anti-Thyroglobulin
Calcitonin
Thyroglobulin
Thyroid Stimulating Hormone
Thyroxine Binding Globulin
Thyroxine, Free (FT4)
Thyroxine, Total (TT4)
Triiodothyronine, Free (FT3)
Triiodothyronine, Total (TT3)
T Uptake

Anaemia

Erythropoietin (EPO)
Ferritin
Folate
Vitamin B12

Pituitary/Adrenal

Adrenocorticotrophic hormone (ACTH)
Aldosterone*
Androstenedione*
Cortisol
Human Growth Hormone

Drugs

Acetaminophen
Amikacin
Caffeine*
Carbamazepine
Carbamazepine, Free*
Chloramphenicol
Cyclosporine*
Digoxin
Disopyramide*
Ethosuximide*
Gentamicin
Ibuprofen*
Lidocaine*
Lithium
N-Acetyl procainamide*
Phenobarbital
Phenytoin
Phenytoin, Free*
Primidone*
Procainamide*
Quinidine
Salicylate
Theophylline
Tobramycin
Valproic Acid
Valproic Acid, Free*
Vancomycin

Renal

Angiotensin*
Renin*

Bone Metabolism

Ostase*
Parathyroid hormone (PTH)
Procollagen NP Type 1*

Reproductive/Fertility

DHEA Sulfate
Estriol, Free
Estriol, Total*
Estrogen, Total*
Estradiol
Follicle Stimulating Hormone
Human Chorionic Gonadotropin
17-Hydroxyprogesterone*
Luteinizing Hormone
Progesterone
Prolactin
Sex Hormone Binding Globulin (SHBG)
Testosterone
Testosterone, Free*

Diabetes

C-Peptide
Insulin
Insulin-like Growth Factor (IGF-1)*

Esoterics

25 (OH) Vitamin D
Homocysteine

*Please refer to lot specific package inserts for stability and performance claims.



TECHNOPATH
CLINICAL DIAGNOSTICS

TECHNOPATH CLINICAL DIAGNOSTICS

Technopath Life Sciences Park, Fort Henry, Ballina, Co. Tipperary, V94 FF1P, Ireland.
For Multichem QC Support: qc.support@technopathcd.com Website: www.technopathcd.com



TECHNOPATH
CLINICAL DIAGNOSTICS

DECLARATION OF CONFORMITY



Manufacturer

Techno-path Manufacturing Ltd.
Fort Henry Business Park,
Ballina,
Co. Tipperary,
Ireland

Product(s):

Product Name	Category	Catalogue Number
Multichem IA Plus	Assayed/tri-level	05P76-10

GMDN:	47869
Classification:	Annex II List B
Conformity Route:	Annex IV
Quality Management System:	EN ISO 13485:2016
QMS/CE Certification No.:	V11038520001
Issued By:	TÜV SÜD, Ridlerstraße 65, 80339 Munich, Germany
Expiry Date:	26 May 2024
Notified Body Number:	0123

Standards Applied: See attached list of standards for which documented evidence of compliance can be provided.

Techno-path Manufacturing Ltd. hereby declares that the product(s) specified above comply with the requirements listed in European Union In-vitro Diagnostic Medical Device Directive 98/79/EC.

I am fully responsible for all the information provided in this declaration. This declaration of conformity is valid from 31 (Day) 01 (Month) 20 (Year)

Signed for and on behalf of Techno-path Manufacturing Ltd.,

B. Hass
Bernd Hass,
VP of Quality and Regulatory Affairs
Techno-path Manufacturing Ltd.

Ballina, Co. Tipperary 31-01-20.
Place and Date of Issue



TECHNOPATH
CLINICAL DIAGNOSTICS

STANDARDS USED IN FULL OR PART FOR CE MARKING AS PER IVDD 98/79/EC

Standard	Title
EN ISO15223-1:2016	Symbols to be used with medical device labels, labelling and information to be supplied.
EN ISO13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612:2002 + AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in vitro diagnostic medical devices – statistical aspects
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
EN 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
SOR/98-282, May 7, 1998	Canada Medical Device Regulations



EU Declaration of Conformity

Basic UDI-DI: 038074DAL0005FW
Basic UDI-DI Name: ARCHITECT Reaction Vessels
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
7C15-03	ARCHITECT Reaction Vessels	56676	W0201020185

Manufacturer (Name and Address)	Abbott Laboratories 1915 Hurd Drive Irving, TX 75038 USA
Manufacturer SRN	US-MF-000017777
Authorized Representative (Name and Address)	Abbott GmbH Max-Planck-Ring 2 65205 Wiesbaden, Germany
Authorized Representative SRN	DE-AR-000009457
Produced by (Site of Manufacture) (Name and Address)	NYPRO CHICAGO 955 Tri-State Parkway Gurnee, IL 60031 USA
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: Thomas Creel
Sr. Director, Instrument and Automation

Function: Quality

Signature: *Thomas Creel*

Date of Approval: 31-Aug-2022

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

Full Name: Michele Smith-Waheed

Function: Associate Director, Regulatory Affairs

Signature: *Michele Smith-Waheed*

Date of Approval: 02-Sept-2022

Date Issued: 02-Sept-2022

Supersedes: 24 May 2022

Place Issued: Irving, Texas
Effective (Date or Lot Number): 02-Sept-2022

EN	EU Declaration of Conformity	Basic UDI-DI	Basic UDI-DI Name
BG	ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ	Базов UDI-DI	Наименование на базов UDI-DI
CS	EU PROHLÁŠENÍ O SHODĚ	Základní UDI-DI	Název základního UDI-DI
DA	EU-OVERENSSTEMMELSEERKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄTSERKLÄRUNG	Basis-UDI-DI	Basis-UDI-DI Name
EL	ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ	Βασικό UDI-DI	Όνομασία βασικού UDI-DI
ES	DECLARACIÓN UE DE CONFORMIDAD	UDI-DI Básico	Nombre UDI-DI Básico
ET	ELi vastavusdeklaratsioon	Põhi-UDI-DI	Põhi-UDI-DI nimi
FR	Déclaration de conformité UE	IUD-ID de base	Nom IUD-ID de base
HR	EU IZJAVA O SUKLADNOSTI	Osnovni UDI-DI	Naziv osnovnog UDI-DI
HU	EU-MEGFELELŐSÉGI NYILATKOZAT	Alapvető UDI-DI	Alapvető UDI-DI neve
IT	Dichiarazione di conformità UE	UDI-DI di base	Nome UDI-DI di base
LV	ES atbilstības deklarācija	Pamata UDI-DI	Pamata UDI-DI nosaukums
LT	ES ATITIKTIES DEKLARACIJA	Bazinis UDI-DI	Bazinio UDI-DI pavadinimas
NO	EU-samsvarserklæring	Grunnleggende UDI-DI	Grunnleggende UDI-DI-navn
PL	DEKLARACJA ZGODNOŚCI UE	Kod Basic UDI-DI	Nazwa kodu Basic UDI-DI
PT	DECLARAÇÃO UE DE CONFORMIDADE	UDI-DI básico	Nome UDI-DI Básico
RO	Declarația de Conformitate UE	UDI-DI de bază	Nume UDI-DI de bază
SK	EU VYHLÁŠENIE O ZHODE	Základný UDI-DI	Názov základného UDI-DI
SV	EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE	Grundläggande UDI-DI	Namn på grundläggande UDI-DI
TR	AB Uygunluk Beyanı	Temel UDI-DI	Temel UDI-DI İsmi

EN	Risk Class	List Number and Size Code	Product and Trade Name
BG	Клас според риска	Каталожен номер и код на размера	Име на продукта и търговско наименование
CS	Riziková třída	Katalogové číslo a koncové dvojciferní určující velikost soupravy	Název produktu a obchodní název
DA	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og varemærkenavn
DE	Risikoklasse	Bestellnummer und Größencode	Produkt- und Handelsname
EL	Κατηγορία κινδύνου	Κωδικός Προϊόντος και Κωδικός Συσκευασίας	Προϊόν και Εμπορική Ονομασία
ES	Clase de riesgo	Número de referencia y código de tamaño	Producto y marca comercial
ET	Risikuklass	Katalooginumber ja suurusekood	Toote nimetus ja kaubanimi
FR	Classe de risque	Référence	Nom de produit et de marque
HR	Klasa rizika	Kataloški broj i oznaka pakiranja	Naziv proizvoda i zaštićeni naziv
HU	Kockázati osztály	Listaszám és készletkiszerezés-kód	Termék- és kereskedelmi név
IT	Classe di rischio	Numero di listino e codice formato	Prodotto e nome commerciale
LV	Riska klase	Kataloga numurs un izmēra kods	Produkta nosaukums un tirdzniecības nosaukums
LT	Rizikos klasė	Katalogo numeris ir dydžio kodas	Gaminio ir prekybos pavadinimai
NO	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og handelsnavn
PL	Klasa ryzyka	Numer katalogowy	Nazwa produktu i nazwa handlowa
PT	Classe de risco	Número de lista e código de apresentação	Produto e nome comercial
RO	Clasă de risc	Număr de listă și cod dimensiune	Denumirea produsului și denumirea comercială
SK	Riziková trieda	Katalógové číslo	Názov produktu a obchodný názov
SV	Risikklass	Listnummer och storlekskod	Produkt och firmanamn
TR	Risk Sınıfı	Liste Numarası ve Boyut Kodu	Ürün ve Ticari İsmi

EN	GMDN Code	EMDN Code	Manufacturer (Name and Address)	Manufacturer SRN
BG	Κοδ GMDN	Κοδ EMDN	Производител (име и адрес)	EPH на производител
CS	Kód GMDN	Kód EMDN	Výrobce (název a adresa)	Jediné registrační číslo výrobce
DA	GMDN-kode	EMDN-kode	Fabrikant (navn og adresse)	Fabrikants SRN
DE	GMDN-Code	EMDN-Code	Hersteller (Name und Adresse)	Hersteller-SRN
EL	Κωδικός GMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κωδικός EMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κατασκευαστής (Όνομα και Διεύθυνση)	SRN (Μοναδικός Αριθμός Μητρώου) Κατασκευαστή
ES	Código GMDN	Código EMDN	Fabricante (nombre y dirección)	SRN (número de registro único) del fabricante
ET	GMDN-kood	EMDN-kood	Tootja (nimi ja aadress)	Tootja unikaalne registreerimisnumber
FR	Code GMDN	Code EMDN	Fabricant (nom et adresse)	Numéro d'enregistrement unique du fabricant
HR	GMDN kod	EMDN kod	Proizvođač (naziv i adresa)	SRN (jedinstveni registracijski broj) proizvođača
HU	GMDN-kód	EMDN-kód	Gyártó (név és cím)	Gyártó egyedi regisztrációs száma (SRN)
IT	Codice GMDN	Codice EMDN	Fabbricante (nome e indirizzo)	SRN (numero di registrazione unico) del fabbricante
LV	GMDN kods	EMDN kods	Ražotājs (nosaukums un adrese)	Ražotāja vienotais reģistrācijas numurs (VRN)
LT	Visuotinės medicinos priemonių nomenklatūros kodas	Europos medicinos priemonių nomenklatūros kodas	Gamintojas (pavadinimas ir adresas)	Gamintojo unikalasis registracijos numeris
NO	GMDN-kode	EMDN-kode	Produsent (navn og adresse)	Produsentens SRN
PL	Kod GMDN	Kod Europejskiej Nomenklatury Wyrobów Medycznych	Producent (nazwa i adres)	Niepowtarzalny numer rejestracyjny producenta
PT	Código GMDN	Código EMDN	Fabricante (Nome e Morada)	Número único de registo do fabricante
RO	Cod GMDN	Cod EMDN	Producător (nume și adresă)	SRN producător
SK	Kód GMDN	Kód EMDN	Výrobca (Názov a adresa)	Jediné registračné číslo (SRN) výrobcu
SV	GMDN-kod	EMDN-kod	Tillverkare (namn och adress)	Tillverkarens SRN
TR	GMDN Kodu	EMDN Kodu	Üretici (İsim ve Adres)	Üretici SRN'si

EN	Authorized Representative (Name and Address)	Authorized Representative SRN	Produced by (Site of Manufacture) (Name and Address)
BG	Упълномощен представител (име и адрес)	EPH на упълномощения представител	Произведено от (място на производство) (име и адрес)
CS	Zplnomocněný zástupce (název a adresa)	Jediné registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fabrikationssted) (Navn og adresse)
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Όνομασία και Διεύθυνση)
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimismumber	Tootnud (tootmiskoht) (nimi ja aadress)
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)
LT	Igaliojasis atstovas (pavadinimas ir adresas)	Igaliojoto atstovo unikalasis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)
RO	Reprezentant autorizat (nume și adresă)	SRN reprezentant autorizat	Produs de către (locuție producție) (nume și adresă)
SK	Autorizovaný zástupca (názov a adresa)	Jediné registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesis) (İsim ve Adres)

EN	Conformity Assessment Procedure	Annex II and III	Full Name
BG	Процедура за оценка на съответствието	Приложение II и III	Пълно наименование
CS	Postup posuzování shody	Příloha II a III	Celý název
DA	Overensstemmelsesvurderingsprocedure	Bilag II og III	Fulde navn
DE	Konformitätsbewertungsverfahren	Anhang II und III	Vollständiger Name
EL	Διαδικασία αξιολόγησης συμμόρφωσης	Παράρτημα II και III	Πλήρης ονομασία
ES	Procedimiento de evaluación de la conformidad	Anexos II y III	Nombre completo
ET	Vastavushindamismenetlus	II ja III lisa	Täisnimi
FR	Procédure d'évaluation de la conformité	Annexes II et III	Nom complet
HR	Postup ocjenjivanja sukladnosti	Prilog II. i III.	Puni naziv
HU	Megfelelőségértékelési eljárás	II. és III. melléklet	Teljes név
IT	Procedura di valutazione della conformità	Allegati II e III	Nome completo
LV	Atbilstības novērtēšanas procedūra	II un III pielikums	Pilns nosaukums
LT	Atitikties vertinimo procedūra	II ir III priedai	Vardas ir pavardė
NO	Framgangsmåte for samsvarsvurdering	Vedlegg II og III	Fullt navn
PL	Procedura oceny zgodności	Załącznik II oraz III	Imię i nazwisko
PT	Procedimento de avaliação da conformidade	Anexo II e III	Nome completo
RO	Procedură de evaluare a conformității	Anexa II și III	Numele complet
SK	Postup posudzovania zhody	Príloha II a III	Celý názov
SV	Förfarande för bedömning av överensstämmelse	Bilaga II och III	Fullständigt namn
TR	Uygunluk Değerlendirme Prosedürü	Ek II ve III	Adı Soyadı

EN	Function	Signed for, and on behalf of	Date Issued
BG	Длъжност	Подписано за и от името на	Дата на издаване
CS	Funkce	Podepsáno za a jménem	Datum vydání
DA	Funktion	Underskrevet for og på vegne af	Udstedelsesdato
DE	Funktion	Unterzeichnet für und im Auftrag von	Datum
EL	Λειτουργία	Υπογράφεται για και εκ μέρους του/της	Ημερομηνία έκδοσης
ES	Función	Firmada por, y en nombre de	Fecha
ET	Funktsioon	Alla kirjutanud (kelle poolt ja nimel)	Väljaandmise kuupäev
FR	Fonction	Signé par et au nom de	Date d'établissement
HR	Funkcija	Potpisano za i u ime	Datum izdavanja
HU	Beosztás	Aláíró a következő képviselőtében és nevében	Kiadás dátuma
IT	Funzione	Firmato a nome e per conto di	Data di rilascio
LV	Amats	Parakstāts šādas personas vārdā	Izdošanas datums
LT	Pareigos	Subjekto, kurio vardu pasirašoma, pavadinimas	Išdavimo data
NO	Funksjon	Signert for, og på vegne av	Ustedelsesdato
PL	Funkcja	Podpisano w imieniu	Data wydania
PT	Função	Assinado e em nome de	Data de emissão
RO	Funcția	Semnat pentru și în numele	Data eliberării
SK	Funkcia	Podpísané za a v mene	Dátum vydania
SV	Funktion	Undertecknat för och på uppdrag av	Datum för utfärdande
TR	Görevi	Namına ve temsilen imza	Düzenlenme Tarihi

EN	Supersedes	Signature	Date of Approval
BG	Замества	Подпис	Дата на одобрение
CS	Nahrazuje	Podpis	Datum schválení
DA	Erstatter	Underskrift	Godkendelsesdato
DE	Ersetzt	Unterschrift	Datum der Genehmigung
EL	Αντικαθιστά	Υπογραφή	Ημερομηνία έγκρισης
ES	Sustituye	Firma	Fecha de aprobación
ET	Asendab	Allkiri	Heakskiitmise kuupäev
FR	Annule et remplace	Signature	Date de l'autorisation
HR	Zamjenjuje	Potpis	Datum odobrenja
HU	Hatályalanítja a következő dokumentumot:	Aláírás	Jóváhagyás dátuma
IT	Sostituisce	Firma	Data di approvazione
LV	Aizstāj	Paraksts	Apstiprināšanas datums
LT	Pakeičia	Parašas	Patvirtinimo data
NO	Erstatter	Signatur	Godkjenningsdato
PL	Zastępuje	Podpis	Data zatwierdzenia
PT	Substitui	Assinatura	Data de aprovação
RO	Înlocuitor	Semnătură	Data aprobării
SK	Nahrádza	Podpis	Dátum schválenia
SV	Ersätter	Namteckning	Datum för godkännande
TR	Yerini aldığı belge	İmza	Onay Tarihi

EN	Place Issued	Effective (Date or Lot Number)
BG	Място на издаване	В сила от/за (дата или номер на партида)
CS	Místo vydání	Účinné od (datum nebo číslo šarže)
DA	Udstedelsessted	Ikrafttrædelse (dato eller lotnummer)
DE	Ort	Gültig ab (Datum oder Chargenbezeichnung)
EL	Τόπος έκδοσης	Σε ισχύ από (Ημερομηνία ή αρ. партида.)
ES	Expedida en	Efectiva (fecha o número de lote)
ET	Väljaandmise koht	Jõustumine (kuupäev või partinumber)
FR	Lieu d'établissement	Entrée en vigueur (date ou numéro de lot)
HR	Mjesto izdavanja	Stupa na snagu (datum ili broj serije)
HU	Kiadás helye	Hatálybalépés (datum vagy tételszám)
IT	Luogo di rilascio	Valido da (data o numero di lotto)
LV	Izdošanas vieta	Spēkā no (datums vai partijas numurs)
LT	Išdavimo vieta	Įsigalioja (data arba partijos numeris)
NO	Utstedelsessted	Gjelder fra (dato eller lotnummer)
PL	Miejsce wydania	Obowiązuje od (data lub numer partii)
PT	Local de emissão	Efetividade (Data ou número de lote)
RO	Locul eliberării	Valabilitate (data sau numărul lotului)
SK	Miesto vydania	Účinnosť od (dátum alebo číslo šarže)
SV	Plats för utfärdande	Verkställtigt (datum eller lotnummer)
TR	Düzenlendiği Yer	Yürürlük (Tarih veya Lot Numarast)

EN	<p>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.</p>
BG	<p>Ние, долуподписаните, с настоящото декларираме, че гореписаното(ите) медицинско(и) изделие(я) за инвитро диагностика отговаря(т) на приложимите разпоредби на Регламент (ЕС) 2017/746 на Европейския парламент и на Съвета от 5 април 2017 г. относно медицинските изделия за инвитро диагностика; освен това отговаря(т) на приложимите разпоредби на Директива 2011/65/ЕС на Европейския парламент и на Съвета от 8 юни 2011 г. относно ограничението на употребата на определени опасни вещества в електрическото и електронното оборудване и на приложимите разпоредби на Директива 2006/42/ЕО на Европейския парламент и на Съвета от 17 май 2006 г. относно машините, и за изменение на Директива 95/16/ЕО, както е транспонирана в националното законодателство на държавите членки. Тази декларация се прави в съответствие с Приложение IV на Регламента за IVD, Приложение VI на Директивата за ограничаване на опасните вещества (ROHS) и Приложение II на Директивата относно машините и за нейното издаване отговорност носи единствено производителят.</p>
CS	<p>My, níže podepsaní, tímto prohláším, že diagnostický(-é) zdravotnický(-é) prostředek (prostředky) in vitro uvedený(-é) výše je (jsou) ve shodě s příslušnými ustanoveními nařízení Evropského parlamentu a Rady (EU) 2017/746 ze dne 5. dubna 2017 o diagnostických zdravotnických prostředcích in vitro; a že je (jsou) dále ve shodě s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2011/65/EU ze dne 8. června 2011 o omezení používání některých nebezpečných látek v elektrických a elektronických zařízeních a s příslušnými ustanoveními směrnice Evropského parlamentu a Rady 2006/42/ES ze dne 17. května 2006 o strojních zařízeních a o změně směrnice 95/16/ES, jak byla provedena ve vnitrostátním právu členských států. Toto prohlášení je v souladu s Přílohou IV nařízení IVD, Přílohou VI směrnice ROHS a Přílohou II směrnice o strojních zařízeních a je vydáno na výhradní odpovědnost výrobce.</p>
DA	<p>Vi, undertegnede, erklærer herved, at det in vitro-diagnostiske medicinske udstyr, der er beskrevet ovenfor, er i overensstemmelse med de gældende bestemmelser i Europa-Parlamentets og Rådets forordning (EU) 2017/746 af 5. april 2017 om in vitro-diagnostisk medicinsk udstyr, ligesom det overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2011/65/EU af 8. juni 2011 om begrænsning af brugen af visse farlige stoffer i elektrisk og elektronisk udstyr samt overholder gældende bestemmelser i Europa-Parlamentets og Rådets direktiv 2006/42/EF af 17. maj 2006 om maskiner og ændring af direktiv 95/16/EF, som det er transponeret i medlemsstaternes lovgivning. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV, ROHS-direktivets bilag VI samt maskindirektivets bilag II og udstedes under fabrikantens eneansvar.</p>
DE	<p>Wir, die Unterzeichner, erklären hiermit, dass das oben beschriebene In-vitro-Diagnostikum/die oben beschriebenen In-vitro-Diagnostika die entsprechenden Bestimmungen der Verordnung (EU) 2017/746 des Europäischen Parlaments und des Rates vom 5. April 2017 über In-vitro-Diagnostika erfüllen und zusätzlich die entsprechenden Bestimmungen der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten sowie der Richtlinie 2006/42/EG des Europäischen Parlaments und des Rates vom 17. Mai 2006 über Maschinen und zur Änderung der Richtlinie 95/16/EG gemäß Umsetzung in den Gesetzen der Mitgliedsstaaten. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung, Anhang VI der RoHS-Richtlinie und Anhang II der Maschinen-Richtlinie und wird unter alleiniger Verantwortung des Herstellers ausgestellt.</p>
EL	<p>Εμείς, οι υπογράφοντες, δηλώνουμε με το παρόν ότι τα προαναφερόμενα διαγνωστικά ιατροτεχνολογικά προϊόντα συμμορφώνονται με τις ισχύουσες διατάξεις του Κανονισμού (ΕΕ) 2017/746 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 5^{ης} Απριλίου 2017 σχετικά με τα in vitro διαγνωστικά ιατροτεχνολογικά προϊόντα και επίσης συμμορφώνονται με τις ισχύουσες διατάξεις της Οδηγίας 2011/65/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 8^{ης} Ιουνίου 2011 σχετικά με τους περιορισμούς στη χρήση συγκεκριμένων επικίνδυνων ουσιών στον ηλεκτρικό και ηλεκτρονικό εξοπλισμό, καθώς και με τις ισχύουσες διατάξεις της Οδηγίας 2006/42/ΕΚ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 17^{ης} Μαΐου 2006 σχετικά με τον μηχανικό εξοπλισμό και την τροποποιητική Οδηγία 95/16/ΕΚ όπως αυτή μεταφέρθηκε στη νομοθεσία των κρατών μελών. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD, το Παράρτημα VI της Οδηγίας ROHS και το Παράρτημα II της Οδηγίας για τον μηχανικό εξοπλισμό και εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή.</p>
ES	<p>Nosotros, los abajo firmantes, por la presente declaramos que el(los) producto(s) sanitario(s) para diagnóstico <i>in vitro</i> descrito(s) anteriormente cumple(n) las disposiciones aplicables del reglamento (UE) 2017/746 del Parlamento Europeo y del Consejo del 5 de abril de 2017 sobre productos sanitarios para diagnóstico <i>in vitro</i>; y además cumple(n) las disposiciones aplicables de la Directiva 2011/65/UE del Parlamento Europeo y del Consejo del 8 de junio de 2011 sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos, y las disposiciones aplicables de la Directiva 2006/42/EC del Parlamento Europeo y del Consejo del 17 de mayo de 2006 sobre maquinaria, y la Directiva de enmienda 95/16/EC tal y como se ha incorporado en las leyes de los Estados Miembros. Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD, Anexo VI de la Directiva ROHS y Anexo II de la Directiva de máquinas y es emitida bajo la exclusiva responsabilidad del fabricante.</p>
ET	<p>Meie, allakirjutanud, kinnitame, et eespool kirjeldatud <i>in vitro</i> diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (<i>in vitro</i> diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele ning lisaks vastab see kohaldatavatele sätetele Euroopa Parlamendi ja nõukogu 8. juuni 2011. aasta direktiivis 2011/65/EÜ. (teatavate ohtlike ainete kasutamise piiramise kohta elektri- ja elektroonikaseadmetes) ja Euroopa Parlamendi ja nõukogu direktiivis 2006/42/EÜ, 17. mai 2006, mis käsitleb masinaid ja millega muudetakse direktiivi 95/16/EÜ, nagu see on üle võetud liikmesriikide seadustes. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale, ROHS direktiivi VI lisale ja masinadirektiivi II lisale ning see on välja antud tootja vastutusel.</p>
FR	<p>Nous soussigné(e)s, déclarons par la présente que le(s) dispositif(s) médical(aux) de diagnostic <i>in vitro</i> indiqué(s) ci-dessus est/sont conforme(s) aux dispositions applicables du Règlement (UE) 2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic <i>in vitro</i>, aux dispositions applicables de la Directive 2011/65/UE du Parlement européen et du Conseil du 8 juin 2011 relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques, aux dispositions applicables de la Directive 2006/42/CE du Parlement européen et du Conseil du 17 mai 2006 relative aux machines et modifiant la Directive 95/16/CE, telles que transposées dans le droit national des États membres. Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV, à l'Annexe VI de la Directive ROHS ainsi qu'à l'Annexe II de la Directive Machines sous la seule responsabilité du fabricant.</p>
HR	<p>Mi, niže potpisani, ovim putem izjavljujemo da su gore navedeni <i>in vitro</i> dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o <i>in vitro</i> dijagnostičkim medicinskim proizvodima; i dodatno primjenjivim odredbama Direktive 2011/65/EU Europskog parlamenta i Vijeća od 8. lipnja 2011. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi, te primjenjivim odredbama Direktive 2006/42/EZ Europskog parlamenta i Vijeća od 17. svibnja 2006. o strojevima zamjenjujući Direktivu 95/16/EZ kako je pretočeno u zakone država članica. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD, Prilogom VI. Direktive ROHS i Prilogom II. Direktive o strojevima i izdaje se pod isključivom odgovornošću proizvođača.</p>
HU	<p>Alulírottak ezennel kijelentjük, hogy a fent leírt <i>in vitro</i> orvostechnikai eszköz(ök) megfelel(nek) az Európai Parlament és a Tanács <i>in vitro</i> diagnosztikai orvostechnikai eszközökről szóló (EU) 2017/746 (2017. április 5.) rendelete vonatkozó rendelkezéseit; továbbá az Európai Parlament és a Tanács egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról szóló 2011/65/EU (2011. június 8.) irányelve (RoHS irányelv) vonatkozó rendelkezéseit, valamint az Európai Parlament és a Tanács a gépekről és a 95/16/EK irányelv módosításáról szóló 2006/42/EK (2006. május 17.) irányelve vonatkozó rendelkezéseit a tagállamok jogrendjébe áttételt rendelkezőeknek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében, a RoHS irányelv VI. mellékletében és a gépekről szóló irányelv II. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége alapján került kiadásra.</p>

EN	<p>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.</p>
IT	<p>Noi, i sottoscritti, con la presente dichiariamo che il(i) dispositivo(i) medico-diagnostico(i) <i>in vitro</i> sopra descritto(i) è(sono) conforme(i) alle disposizioni applicabili del regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medico-diagnostici <i>in vitro</i>; è(sono) inoltre conforme(i) alle disposizioni applicabili della direttiva 2011/65/UE del Parlamento europeo e del Consiglio dell'8 giugno 2011 sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche, e alle disposizioni applicabili della direttiva 2006/42/CE del Parlamento europeo e del Consiglio del 17 maggio 2006 relativa alle macchine e che modifica la direttiva 95/16/CE come recepite nelle legislazioni degli Stati membri. Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD, all'allegato VI della direttiva ROHS e all'allegato II della direttiva macchine ed è rilasciata sotto la responsabilità esclusiva del fabbricante.</p>
LV	<p>Mēs, apakšā parakstījušies, ar šo paziņojam, ka iepriekš aprakstītā(-s) <i>in vitro</i> diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par <i>in vitro</i> diagnostikas medicīniskām ierīcēm un papildus prasībām, kas noteiktas Eiropas Parlamenta un Padomes Direktīvā 2011/65/ES (2011. gada 8. jūnijs) par dažu bīstamu vielu izmantošanu ierobežotā elektriskās un elektroniskās iekārtās un Eiropas Parlamenta un Padomes Direktīvā 2006/42/EK (2006. gada 17. maijs) par mašīnām, un ar kuru groza Direktīvu 95/16/EK, kā tā ieviesta dalībvalstu tiesību aktos.</p> <p>Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu, ROHS direktīvas VI pielikumu un Direktīvas par mašīnām II pielikumu un par izdošanu atbild vienīgi ražotājs.</p>
LT	<p>Mes, toliau pasirašiusieji (-jusios), pareikiame, kad anksčiau minėta (-os) <i>in vitro</i> diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl <i>in vitro</i> diagnostikos medicinos priemonių taikytinas nuostatas; taip pat ji (jos) atitinka 2011 m. birželio 8 d. Europos Parlamento ir Tarybos direktyvos 2011/65/ES dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo taikomas nuostatas ir 2006 m. gegužės 17 d. Europos Parlamento ir Tarybos direktyvos 2006/42/EB dėl mašinų, iš dalies keičiančios Direktyvą 95/16/EB, taikomas nuostatas, perkeltas į valstybių narių teisės aktus.</p> <p>Ši deklaracija yra parengta vadovaujantis IVD reglamento IV priedu, ROHS direktyvos VI priedu ir Mašinų direktyvos II priedu ir yra išduodama tik gamintojo atsakomybe.</p>
NO	<p>Vi, undertegnede, erklærer herved at utstyret til <i>in vitro</i>-diagnostikk som er anført ovenfor, er i samsvar med gjeldende bestemmelser i Europaparlaments- og rådsforordning (EU) 2017/746 av 5. april 2017 om medisinsk utstyr til <i>in vitro</i>-diagnostikk, og ytterligere overholder gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2011/65/EU av 8. juni 2011 om bruksbegrensninger av visse farlige stoffer i elektrisk og elektronisk utstyr, og til gjeldende bestemmelser i Europaparlaments- og rådsdirektiv 2006/42/EF av 17. mai 2006 om maskiner, og endring av direktiv 95/16/EF som innarbeidet i medlemsstatenes lovgivning.</p> <p>Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen, vedlegg VI i ROHS-direktivet og vedlegg II i maskindirektivet og er utstedt under produsentens eiansvar.</p>
PL	<p>My, niżej podpisani, niniejszym oświadczamy, że wymieniony(-e) powyżej wyrób(wyroby) medyczny(-e) do diagnostyki <i>in vitro</i> spełnia(-ją) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki <i>in vitro</i>, a ponadto wymagania Dyrektywy 2011/65/UE Parlamentu Europejskiego i Rady z dnia 8 czerwca 2011 r. w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym, Dyrektywy 2006/42/WE Parlamentu Europejskiego i Rady z dnia 17 maja 2006 r. w sprawie maszyn, zmieniającej Dyrektywę 95/16/WE, w sposób, w jaki zostały one wdrożone do ustawodawstwa państw członkowskich.</p> <p>Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR, Załącznikiem VI Dyrektywy ROHS oraz Załącznikiem II Dyrektywy Maszynowej i wydana na wyłączną odpowiedzialność producenta.</p>
PT	<p>Nós, abaixo assinados, declaramos que os dispositivos médicos para diagnóstico <i>in vitro</i> descritos acima estão em conformidade com as disposições aplicáveis do Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho, de 5 de abril de 2017, relativo aos dispositivos médicos para diagnóstico <i>in vitro</i>; e adicionalmente, em conformidade com as disposições aplicáveis da Diretiva 2011/65/UE do Parlamento Europeu e do Conselho, de 8 de junho de 2011, relativa à restrição do uso de determinadas substâncias perigosas em equipamentos elétricos e eletrônicos, e com as disposições aplicáveis da Diretiva 2006/42/CE do Parlamento Europeu e do Conselho, de 17 de maio de 2006, sobre máquinas, que altera a Diretiva 95/16/CE, conforme transposta nas leis dos Estados membros. Esta declaração é feita de acordo com o Anexo IV do Regulamento IVD, o Anexo VI da Diretiva ROHS e o Anexo II da Diretiva relativa às Máquinas e é emitida sob a exclusiva responsabilidade do fabricante.</p>
RO	<p>Subsemnatii, declarăm că dispozitivul (dispozitivele) medical(e) pentru diagnostic <i>in vitro</i> descrise mai sus sunt conforme cu dispozitiile aplicabile din Regulamentul (UE) 2017/746 al Parlamentului European și al Consiliului din 5 aprilie 2017 privind Dispozitivele medicale pentru diagnostic <i>in vitro</i>; și, în plus, respectă dispozitiile aplicabile din Directiva 2011/65/UE a Parlamentului European și a Consiliului din 8 iunie 2011 privind restricția utilizării anumitor substanțe periculoase în echipamentele electrice și electronice și cu dispozitiile aplicabile din Directiva 2006/42/CE a Parlamentului European și a Consiliului din 17 mai 2006 privind utilajele și modificarea Directivei 95/16/CE, transpusă în legile statelor membre.</p> <p>Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD, anexa VI la Directiva ROHS și anexa II la Directiva utilajelor și este emisă sub responsabilitatea exclusivă a producătorului.</p>
SK	<p>My, dolupodpisani, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) <i>in vitro</i> uvedená(-é) vyššie je (sú) v zhode s príslušnými ustanoveniami Nariadenia Európskeho parlamentu a Rady (EÚ) 2017/746 z 5. apríla 2017 o diagnostických zdravotníckych pomôckach <i>in vitro</i>; a že je (sú) ďalej v zhode s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2011/65/EÚ z 8. júna 2011 o obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach a s príslušnými ustanoveniami Smernice Európskeho parlamentu a Rady 2006/42/ES zo 17. mája 2006 o strojových zariadeniach a o zmene a doplnení Smernice 95/16/ES tak, ako boli transponované do zákonov členských štátov. Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD, Prílohou VI k Smernici ROHS a Prílohou II k Smernici o strojových zariadeniach a vydáva sa na výhradnú zodpovednosť výrobcu.</p>
SV	<p>Vi, undertecknade, försäkrar härmed att den eller de medicintekniska produkter för <i>in vitro</i>-diagnostik som beskrivs ovan överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets förordning (EU) 2017/746 av den 5 april 2017 om medicintekniska produkter för <i>in vitro</i>-diagnostik samt även överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning samt med de tillämpliga bestämmelserna i Europaparlamentets och rådets direktiv 2006/42/EG av den 17 maj 2006 om maskiner och om ändring av direktiv 95/16/EG (omarbetning) som införlivats i medlemsstaternas lagstiftning.</p> <p>Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen, bilaga VI till ROHS-direktivet samt bilaga II till maskindirektivet och utfärdas under tillverkarens enskilda ansvar.</p>
TR	<p>Biz, aşağıda imzalaraki bulunan, yukarıda belirtilen <i>in vitro</i> diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli <i>In Vitro</i> Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu ve ayrıca elektrikli ve elektronik cihazlarda belirli tehlikeli maddelerin kullanımının sınırlandırılmasına ilişkin 8 Haziran 2011 tarihli Konseyin ve 2011/65/EU sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine, makinelere ilişkin 17 Mayıs 2006 tarihli Konseyin ve 2006/42/EC sayılı Avrupa Parlamentosu Direktifinin ilgili hükümlerine ve üye devlet yasalarına atılan 95/16/EC sayılı ek Direktife uygun olduğunu beyan ederiz.</p> <p>Bu beyan IVD Yönetmeliği Ek IV, ROHS Direktifi Ek VI ve Makineler Direktifi Ek II uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altında yayınlanmıştır.</p>

End of form



EU Declaration of Conformity

Basic UDI-DI: 038074SLI0002T5
Basic UDI-DI Name: ARCHITECT Trigger Solution
Risk Class: Class A

List Number and Size Code	Product and Trade Name	GMDN Code	EMDN Code
6C55-60	ARCHITECT Trigger Solution	58793	W0201020185
6C55-82	ARCHITECT Trigger Solution	58793	W0201020185

Manufacturer (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland
Manufacturer SRN	IE-MF-000009849
Authorized Representative (Name and Address)	N/A
Authorized Representative SRN	N/A
Produced by (Site of Manufacture) (Name and Address)	Abbott Ireland Diagnostics Division Finisklin Business Park Sligo, Ireland
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. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.

Full Name: Noel Haren

Function: Manager Regulatory Affairs

Signature:

Date of Approval: 15 Jul 2022

Signed for, and on behalf of: Abbott Ireland Diagnostics Division, Sligo

Date Issued: 15 Jul 2022

Supersedes: 23 May 2022

Full Name: Joe Murray

Function: Director Quality Assurance

Signature:

Date of Approval: 15 Jul 2022

Place Issued: Sligo, Ireland

Effective (Date or Lot Number): 15 Jul 2022

EU Declaration of Conformity

EN	EU Declaration of Conformity	Basic UDI-DI	Basic UDI-DI Name
BG	ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ	Базов UDI-DI	Наименование на базов UDI-DI
CS	EU PROHLÁŠENÍ O SHODĚ	Základní UDI-DI	Název základního UDI-DI
DA	EU-OVERENSSTEMMELSESESKLÆRING	Grundlæggende UDI-DI	Grundlæggende UDI-DI-navn
DE	EU-KONFORMITÄTSESKLÄRUNG	Basis-UDI-DI	Basis-UDI-DI Name
EL	ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ	Βασικό UDI-DI	Όνομασία βασικού UDI-DI
ES	DECLARACIÓN UE DE CONFORMIDAD	UDI-DI Básico	Nombre UDI-DI Básico
ET	ELi vastavusdeklaratsioon	Põhi-UDI-DI	Põhi-UDI-DI nimi
FR	Déclaration de conformité UE	IUD-ID de base	Nom IUD-ID de base
HR	EU IZJAVA O SUKLADNOSTI	Osnovni UDI-DI	Naziv osnovnog UDI-DI
HU	EU-MEGFELELŐSÉGI NYILATKOZAT	Alapvető UDI-DI	Alapvető UDI-DI neve
IT	Dichiarazione di conformità UE	UDI-DI di base	Nome UDI-DI di base
LV	ES atbilstības deklarācija	Pamata UDI-DI	Pamata UDI-DI nosaukums
LT	ES ATITIKTIES DEKLARACIJA	Bazinis UDI-DI	Bazinio UDI-DI pavadinimas
NO	EU-samsvarserklæring	Grunnleggende UDI-DI	Grunnleggende UDI-DI-navn
PL	DEKLARACJA ZGODNOŚCI UE	Kod Basic UDI-DI	Nazwa kodu Basic UDI-DI
PT	DECLARAÇÃO UE DE CONFORMIDADE	UDI-DI básico	Nome UDI-DI Básico
RO	Declarația de Conformitate UE	UDI-DI de bază	Nume UDI-DI de bază
SK	EÚ VYHLÁSENIE O ZHODE	Základný UDI-DI	Názov základného UDI-DI
SV	EU-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE	Grundläggande UDI-DI	Namn på grundläggande UDI-DI
TR	AB Uygunluk Beyanı	Temel UDI-DI	Temel UDI-DI İsmi

EN	Risk Class	List Number and Size Code	Product and Trade Name
BG	Клас според риска	Каталожен номер и код на размера	Име на продукта и търговско наименование
CS	Riziková třída	Katalogové číslo a koncové dvojciferné určující velikost soupravy	Název produktu a obchodní název
DA	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og varemærkenavn
DE	Risikoklasse	Bestellnummer und Größencode	Produkt- und Handelsname
EL	Κατηγορία κινδύνου	Κωδικός Προϊόντος και Κωδικός Συσκευασίας	Προϊόν και Εμπορική Ονομασία
ES	Clase de riesgo	Número de referencia y código de tamaño	Producto y marca comercial
ET	Risikiklass	Katalooginumber ja suurusekood	Toote nimetus ja kaubanimi
FR	Classe de risque	Référence	Nom de produit et de marque
HR	Klasa rizika	Kataloški broj i oznaka pakiranja	Naziv proizvoda i zaštiteni naziv
HU	Kockázati osztály	Listaszám és készletkiszerezés-kód	Termék- és kereskedelmi név
IT	Classe di rischio	Numero di listino e codice formato	Prodotto e nome commerciale
LV	Riska klase	Kataloga numurs un izmēra kods	Produkta nosaukums un tirdzniecības nosaukums
LT	Rizikos klasė	Katalogo numeris ir dydžio kodas	Gaminio ir prekės pavadinimai
NO	Risikoklasse	Bestillingsnummer og størrelseskode	Produkt- og handelsnavn
PL	Klasa ryzyka	Numer katalogowy	Nazwa produktu i nazwa handlowa
PT	Classe de risco	Número de lista e código de apresentação	Produto e nome comercial
RO	Clasă de risc	Număr de listă și cod dimensiune	Denumirea produsului și denumirea comercială
SK	Riziková trieda	Katalógové číslo	Názov produktu a obchodný názov
SV	Risikklass	Listnummer och storlekskod	Produkt och firmanamn
TR	Risk Sınıfı	Liste Numarası ve Boyut Kodu	Ürün ve Ticari İsmi

EU Declaration of Conformity

EN	GMDN Code	EMDN Code	Manufacturer (Name and Address)	Manufacturer SRN
BG	Код GMDN	Код EMDN	Производител (име и адрес)	EPH на производителя
CS	Kód GMDN	Kód EMDN	Výrobce (název a adresa)	Jediné registrační číslo výrobce
DA	GMDN-kode	EMDN-kode	Fabrikant (navn og adresse)	Fabrikants SRN
DE	GMDN-Code	EMDN-Code	Hersteller (Name und Adresse)	Hersteller-SRN
EL	Κωδικός GMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κωδικός EMDN (Ονοματολογία ιατροτεχνολογικών προϊόντων)	Κατασκευαστής (Όνομα και Διεύθυνση)	SRN (Μοναδικός Αριθμός Μητρώου) Κατασκευαστή
ES	Código GMDN	Código EMDN	Fabricante (nombre y dirección)	SRN (número de registro único) del fabricante
ET	GMDN-kood	EMDN-kood	Tootja (nimi ja aadress)	Tootja unikaalne registreerimisnumber
FR	Code GMDN	Code EMDN	Fabricant (nom et adresse)	Numéro d'enregistrement unique du fabricant
HR	GMDN kod	EMDN kod	Proizvođač (naziv i adresa)	SRN (jedinstveni registracijski broj) proizvođača
HU	GMDN-kód	EMDN-kód	Gyártó (név és cím)	Gyártó egyedi regisztrációs száma (SRN)
IT	Codice GMDN	Codice EMDN	Fabbricante (nome e indirizzo)	SRN (numero di registrazione unico) del fabbricante
LV	GMDN kods	EMDN kods	Ražotājs (nosaukums un adrese)	Ražotāja vienotais reģistrācijas numurs (VRN)
LT	Visuotinės medicinos priemonių nomenklatūros kodas	Europos medicinos priemonių nomenklatūros kodas	Gamintojas (pavadinimas ir adresas)	Gamintojo unikalasis registracijos numeris
NO	GMDN-kode	EMDN-kode	Produsent (navn og adresse)	Produsentens SRN
PL	Kod GMDN	Kod Europejskiej Nomenklatury Wyrobów Medycznych	Producent (nazwa i adres)	Niepowtarzalny numer rejestracyjny producenta
PT	Código GMDN	Código EMDN	Fabricante (Nome e Morada)	Número único de registo do fabricante
RO	Cod GMDN	Cod EMDN	Producător (nume și adresă)	SRN producător
SK	Kód GMDN	Kód EMDN	Výrobca (Názov a adresa)	Jediné registračné číslo (SRN) výrobcu
SV	GMDN-kod	EMDN-kod	Tillverkare (namn och adress)	Tillverkarens SRN
TR	GMDN Kodu	EMDN Kodu	Üretici (İsim ve Adres)	Üretici SRN'si

EU Declaration of Conformity

EN	Authorized Representative (Name and Address)	Authorized Representative SRN	Produced by (Site of Manufacture) (Name and Address)	Conformity Assessment Procedure
BG	Упълномощен представител (име и адрес)	ЕРН на упълномощения представител	Произведено от (място на производство) (име и адрес)	Процедура за оценка на съответствието
CS	Zplnomocněný zástupce (název a adresa)	Jediné registrační číslo zplnomocněného zástupce	Vyrobeno (místo výroby) (název a adresa)	Postup posuzování shody
DA	Autoriseret repræsentant (navn og adresse)	Autoriseret repræsentants SRN	Produceret af (fremstillingssted) (navn og adresse)	Overensstemmelsesvurderingsprocedure
DE	Bevollmächtigter (Name und Adresse)	SRN des Bevollmächtigten	Hergestellt von (Herstellungsstandort) (Name und Adresse)	Konformitätsbewertungsverfahren
EL	Εξουσιοδοτημένος Αντιπρόσωπος (Όνομα και Διεύθυνση)	SRN Εξουσιοδοτημένου Αντιπροσώπου	Κατασκευάζεται από (Εργοστάσιο παραγωγής) (Όνομασία και Διεύθυνση)	Διαδικασία αξιολόγησης συμμόρφωσης
ES	Representante autorizado (nombre y dirección)	SRN (número de registro único) del representante autorizado	Producido por (Lugar de fabricación) (Nombre y dirección)	Procedimiento de evaluación de la conformidad
ET	Volitatud esindaja (nimi ja aadress)	Volitatud esindaja unikaalne registreerimisnumber	Tootja (tootmiskoht) (nimi ja aadress)	Vastavushindamismenetlus
FR	Mandataire (nom et adresse)	Numéro d'enregistrement unique du mandataire	Produit par (site de fabrication) (nom et adresse)	Procédure d'évaluation de la conformité
HR	Ovlašteni zastupnik (naziv i adresa)	SRN (jedinstveni registracijski broj) ovlaštenog zastupnika	Proizvodi (Mjesto proizvodnje) (Naziv i adresa)	Postupak ocjenjivanja sukladnosti
HU	Meghatalmazott képviselő (név és cím)	Meghatalmazott képviselő egyedi regisztrációs száma (SRN)	Gyártó (gyártás helye) (név és cím)	Megfelelőségértékelési eljárás
IT	Mandatario (nome e indirizzo)	SRN (numero di registrazione unico) del mandatario	Prodotto da (sito di fabbricazione) (nome e indirizzo)	Procedura di valutazione della conformità
LV	Pilnvarotais pārstāvis (nosaukums un adrese)	Pilnvarotā pārstāvja vienotais reģistrācijas numurs (VRN)	Ražots (ražošanas vieta) (nosaukums un adrese)	Atbilstības novērtēšanas procedūra
LT	Igaliotasis atstovas (pavadinimas ir adresas)	Igaliojojo atstovo unikalasis registracijos numeris	Pagaminta (gamybos vieta) (pavadinimas ir adresas)	Atitikties vertinimo procedūra
NO	Autorisert representant (navn og adresse)	Den autoriserte representantens SRN	Produsert av (produksjonssted) (navn og adresse)	Framgangsmåte for samsvarsvurdering
PL	Upoważniony przedstawiciel (nazwa i adres)	Niepowtarzalny numer rejestracyjny upoważnionego przedstawiciela	Wyprodukowano przez (miejsce produkcji) (nazwa i adres)	Procedura oceny zgodności
PT	Mandatário (Nome e Morada)	Número único de registo do mandatário	Produzido por (Local de fabrico) (Nome e Morada)	Procedimento de avaliação da conformidade
RO	Reprezentant autorizat (nume și adresă)	SRN reprezentant autorizat	Produs de către (locuție producție) (nume și adresă)	Procedură de evaluare a conformității
SK	Autorizovaný zástupca (názov a adresa)	Jediné registračné číslo (SRN) autorizovaného zástupcu	Výrobené (miesto výroby) (názov a adresa)	Postup posudzovania zhody
SV	Auktoriserad representant (namn och adress)	Auktoriserad representants SRN	Tillverkas av (tillverkningsort) (namn och adress)	Förfarande för bedömning av överensstämmelse
TR	Yetkili Temsilci (İsim ve Adres)	Yetkili Temsilci SRN'si	Üretici (Üretim Tesisi) (İsim ve Adres)	Uygunluk Değerlendirme Prosedürü

EU Declaration of Conformity

EN	Annex II and III	Full Name
BG	Приложение II и III	Пълно наименование
CS	Příloha II a III	Celý název
DA	Bilag II og III	Fulde navn
DE	Anhang II und III	Vollständiger Name
EL	Παράρτημα II και III	Πλήρης ονομασία
ES	Anexos II y III	Nombre completo
ET	II ja III lisa	Täisnimi
FR	Annexes II et III	Nom complet
HR	Prilog II. i III.	Puni naziv
HU	II. és III. melléklet	Teljes név
IT	Allegati II e III	Nome completo
LV	II un III pielikums	Pilns nosaukums
LT	II ir III priedai	Vardas ir pavardė
NO	Vedlegg II og III	Fullt navn
PL	Załącznik II oraz III	Imię i nazwisko
PT	Anexo II e III	Nome completo
RO	Anexa II și III	Numele complet
SK	Příloha II a III	Celý názov
SV	Bilaga II och III	Fullständigt namn
TR	Ek II ve III	Adı Soyadı

EN	Function	Signed for, and on behalf of	Date Issued
BG	Длъжност	Подписано за и от името на	Дата на издаване
CS	Funkce	Podepsáno za a jménem	Datum vydání
DA	Funktion	Underskrevet for og på vegne af	Udstedelsesdato
DE	Funktion	Unterzeichnet für und im Auftrag von	Datum
EL	Λειτουργία	Υπογράφεται για και εκ μέρους του/της	Ημερομηνία έκδοσης
ES	Función	Firmada por, y en nombre de	Fecha
ET	Funktsioon	Alla kirjutanud (kelle poolt ja nimel)	Väljaandmise kuupäev
FR	Fonction	Signé par et au nom de	Date d'établissement
HR	Funkcija	Potpisano za i u ime	Datum izdavanja
HU	Beosztás	Aláíró a következő képviseletében és nevében	Kiadás dátuma
IT	Funzione	Firmato a nome e per conto di	Data di rilascio
LV	Amats	Parakstīts šādas personas vārdā	Izdošanas datums
LT	Pareigos	Subjekto, kurio vardu pasirašoma, pavadinimas	Išdavimo data
NO	Funksjon	Signert for, og på vegne av	Utstedelsesdato
PL	Funkcja	Podpisano w imieniu	Data wydania
PT	Função	Assinado e em nome de	Data de emissão
RO	Funcția	Semnăt pentru și în numele	Data eliberării
SK	Funkcia	Podpísané za a v mene	Dátum vydania
SV	Funktion	Undertecknat för och på uppdrag av	Datum för utfärdande
TR	Görevi	Namina ve temsilen imza	Düzenlenme Tarihi

EU Declaration of Conformity

EN	Supersedes	Signature	Date of Approval
BG	Замества	Подпис	Дата на одобрение
CS	Nahrazuje	Podpis	Datum schválení
DA	Erstatter	Underskrift	Godkendelsesdato
DE	Ersetzt	Unterschrift	Datum der Genehmigung
EL	Αντικαθιστά	Υπογραφή	Ημερομηνία έγκρισης
ES	Sustituye	Firma	Fecha de aprobación
ET	Asendab	Allkiri	Heakskiiitmise kuupäev
FR	Annule et remplace	Signature	Date de l'autorisation
HR	Zamjenjuje	Potpis	Datum odobrenja
HU	Hatálytalanítja a következő dokumentumot:	Aláírás	Jóváhagyás dátuma
IT	Sostituisce	Firma	Data di approvazione
LV	Aizstāj	Paraksts	Apstiprināšanas datums
LT	Pakeičia	Parašas	Patvirtinimo data
NO	Erstatter	Signatur	Godkjenningsdato
PL	Zastępuje	Podpis	Data zatwierdzenia
PT	Substitui	Assinatura	Data de aprovação
RO	Înlocuitor	Semnătură	Data aprobării
SK	Nahrádza	Podpis	Dátum schválenia
SV	Ersätter	Namnteckning	Datum för godkännande
TR	Yerini aldiği belge	İmza	Onay Tarihi

EN	Place Issued	Effective (Date or Lot Number)
BG	Място на издаване	В сила от/за (дата или номер на партида)
CS	Místo vydání	Účinné od (datum nebo číslo šarže)
DA	Udstedelsessted	Ikrafttrædelse (dato eller lotnummer)
DE	Ort	Gültig ab (Datum oder Chargenbezeichnung)
EL	Τόπος έκδοσης	Σε ισχύ από (Ημερομηνία ή αρ. παρτίδας)
ES	Expedida en	Efectiva (fecha o número de lote)
ET	Väljaandmise koht	Jõustumine (kuupäev või partiinumber)
FR	Lieu d'établissement	Entrée en vigueur (date ou numéro de lot)
HR	Mjesto izdavanja	Stupa na snagu (datum ili broj serije)
HU	Kiadás helye	Hatálybalépés (dátum vagy tételszám)
IT	Luogo di rilascio	Valido da (data o numero di lotto)
LV	Izdošanas vieta	Spēkā no (datums vai partijas numurs)
LT	Išdavimo vieta	Įsigalioja (data arba partijos numeris)
NO	Utstedelsessted	Gjelder fra (dato eller lotnummer)
PL	Miejsce wydania	Obowiązuje od (data lub numer partii)
PT	Local de emissão	Efetividade (Data ou número de lote)
RO	Locul eliberării	Valabilitate (data sau numărul lotului)
SK	Miesto vydania	Účinnosť od (dátum alebo číslo šarže)
SV	Plats för utfärdande	Verkställtigt (datum eller lotnummer)
TR	Düzenlendiği Yer	Yürürlük (Tarih veya Lot Numarası)

EU Declaration of Conformity

EN	We, the undersigned, hereby declare that the <i>in vitro</i> 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. This declaration is made in accordance with Annex IV of the IVD Regulation and is issued under the sole responsibility of the manufacturer.
BG	Ние, долуподписаните, с настоящото декларираме, че гореописаното(ите) медицинско(и) изделие(я) за инвитро диагностика отговаря(т) на приложимите разпоредби на Регламент (ЕС) 2017/746 на Европейския парламент и на Съвета от 5 април 2017 г. относно медицинските изделия за инвитро диагностика. Тази декларация е направена в съответствие с Приложение IV на Регламента за IVD и за нейното издаване отговорност носи единствено производителят.
CS	My, níže podepsaní, tímto prohlašujeme, že diagnostický(-é) zdravotnický(-é) prostředek (prostředky) <i>in vitro</i> uvedený(-é) výše je (jsou) ve shodě s příslušnými ustanoveními nařízením Evropského parlamentu a Rady (EU) 2017/746 ze dne 5. dubna 2017 o diagnostických zdravotnických prostředcích <i>in vitro</i> . Toto prohlášení je v souladu s Přílohou IV nařízení IVD a je vydáno na výhradní odpovědnost výrobce.
DA	Vi, undertegnede, erklærer herved, at det <i>in vitro</i> -diagnostiske medicinske udstyr, der er beskrevet ovenfor, er i overensstemmelse med de gældende bestemmelser i Europa-Parlamentets og Rådets forordning (EU) 2017/746 af 5. april 2017 om <i>in vitro</i> -diagnostisk medicinsk udstyr. Denne erklæring afgives i overensstemmelse med IVD-forordningens bilag IV og udstedes under fabrikantens eneansvar.
DE	Wir, die Unterzeichner, erklären hiermit, dass das oben beschriebene In-vitro-Diagnostikum/die oben beschriebenen In-vitro-Diagnostika die entsprechenden Bestimmungen der Verordnung (EU) 2017/746 des Europäischen Parlaments und des Rates vom 5. April 2017 über In-vitro-Diagnostika erfüllen. Diese Erklärung erfolgt gemäß Anhang IV der IVD-Verordnung und wird unter alleiniger Verantwortung des Herstellers ausgestellt.
EL	Εμείς, οι υπογράφωντες, δηλώνουμε με το παρόν ότι τα προαναφερόμενα διαγνωστικά ιατροτεχνολογικά προϊόντα συμμορφώνονται με τις ισχύουσες διατάξεις του Κανονισμού (ΕΕ) 2017/746 του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου της 5 ^{ης} Απριλίου 2017 σχετικά με τα <i>in vitro</i> διαγνωστικά ιατροτεχνολογικά προϊόντα. Η δήλωση αυτή γίνεται σύμφωνα με το Παράρτημα IV του Κανονισμού IVD και εκδίδεται με αποκλειστική ευθύνη του κατασκευαστή
ES	Nosotros, los abajo firmantes, por la presente declaramos que el(los) producto(s) sanitario(s) para diagnóstico <i>in vitro</i> descrito(s) anteriormente cumple(n) las disposiciones aplicables del reglamento (UE) 2017/746 del Parlamento Europeo y del Consejo del 5 de abril de 2017 sobre productos sanitarios para diagnóstico <i>in vitro</i> . Esta declaración se realiza en conformidad con el Anexo IV del Reglamento IVD y es emitida bajo la exclusiva responsabilidad del fabricante.
ET	Meie, allkirjutanud, kinnitame, et eespool kirjeldatud <i>in vitro</i> diagnostikameditsiiniseadmed vastavad Euroopa Parlamendi ja nõukogu 5. aprilli 2017. aasta määruse (EL) 2017/746 (<i>in vitro</i> diagnostikameditsiiniseadmete kohta) kohaldatavatele sätetele. See deklaratsioon on koostatud vastavalt IVD määruse IV lisale ning selle väljastamise eest vastutab ainult tootja.
FR	Nous soussigné(e)s, déclarons par la présente que le(s) dispositif(s) médical(aux) de diagnostic <i>in vitro</i> indiqué(s) ci-dessus est/sont conforme(s) aux dispositions applicables du Règlement (UE) 2017/746 du Parlement européen et du Conseil du 5 avril 2017 relatif aux dispositifs médicaux de diagnostic <i>in vitro</i> . Cette déclaration est établie conformément à l'Annexe IV du Règlement DIV sous la seule responsabilité du fabricant.
HR	Mi, niže potpisani, ovim putem izjavljujemo da su gore navedeni <i>in vitro</i> dijagnostički medicinski proizvod(i) sukladni primjenjivim odredbama Uredbe (EU) 2017/746 Europskog parlamenta i Vijeća od 5. travnja 2017. o <i>in vitro</i> dijagnostičkim medicinskim proizvodima. Ova je izjava sastavljena u skladu s Prilogom IV. Uredbe IVD i izdaje se pod isključivom odgovornošću proizvođača.
HU	Alulírottak ezennel kijelentjük, hogy a fent leírt <i>in vitro</i> orvostechikai eszköz(ök) megfelel(nek) az Európai Parlament és a Tanács <i>in vitro</i> diagnosztikai orvostechikai eszközökről szóló (EU) 2017/746 (2017. április 5.) rendelete (IVD rendelet) vonatkozó rendelkezéseinek. A jelen nyilatkozat megfelel az IVD rendelet IV. mellékletében foglalt előírásoknak, és a gyártó kizárólagos felelőssége aláján került kiadásra.
IT	Noi, i sottoscritti, con la presente dichiariamo che il(i) dispositivo(i) medico-diagnostico(i) <i>in vitro</i> sopra descritto(i) è(sono) conforme(i) alle disposizioni applicabili del regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio del 5 aprile 2017 relativo ai dispositivi medico-diagnostici <i>in vitro</i> . Questa dichiarazione è redatta in conformità all'allegato IV del regolamento IVD ed è rilasciata sotto la responsabilità esclusiva del fabbricante.
LV	Mēs, apakšā parakstījušies, ar šo paziņojam, ka iepriekš aprakstītā(-s) <i>in vitro</i> diagnostikas medicīniskā(-s) ierīce(-es) atbilst Eiropas Parlamenta un Padomes Regulas (ES) 2017/746 (2017. gada 5. aprīlis) piemērojamajām prasībām par <i>in vitro</i> diagnostikas medicīniskām ierīcēm. Šī deklarācija ir sagatavota saskaņā ar IVD regulas IV pielikumu un par izdošanu atbild vienīgi ražotājs.
LT	Mes, toliau pasirašiusieji (-iusiosios), pareiškiame, kad anksčiau minėta (-os) <i>in vitro</i> diagnostikos medicinos priemonė (-ės) atitinka 2017 m. balandžio 5 d. Europos Parlamento ir Tarybos reglamento (ES) 2017/746 dėl <i>in vitro</i> diagnostikos medicinos priemonių taikytinas nuostatas. Ši deklaracija yra parengta vadovaujantis IVD reglamentu ir yra išduodama tik gamintojo atsakomybe.
NO	Vi, undertegnede, erklærer herved at utstyret til <i>in vitro</i> -diagnostikk som er anført ovenfor, er i samsvar med gjeldende bestemmelser i Europaparlaments- og rådsforordning (EU) 2017/746 av 5. april 2017 om medisinsk utstyr til <i>in vitro</i> -diagnostikk. Denne erklæringen er utarbeidet i overensstemmelse med vedlegg IV i IVD-forordningen og er utstedt under produsentens eneansvar.
PL	My, niżej podpisani, niniejszym oświadczamy, że wymieniony(-e) powyżej wyrób(wyroby) medyczny(-e) do diagnostyki <i>in vitro</i> spełnia(-ją) odpowiednie wymagania Rozporządzenia (UE) 2017/746 Parlamentu Europejskiego i Rady z dnia 5 kwietnia 2017 r. w sprawie wyrobów medycznych do diagnostyki <i>in vitro</i> . Niniejsza deklaracja została sporządzona zgodnie z Załącznikiem IV Rozporządzenia IVDR i wydana na wyłączną odpowiedzialność producenta.
PT	Nós, abaixo assinados, declaramos que os dispositivos médicos para diagnóstico <i>in vitro</i> descritos acima estão em conformidade com as disposições aplicáveis do Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho, de 5 de abril de 2017, relativo aos dispositivos médicos para diagnóstico <i>in vitro</i> . Esta declaração é feita em conformidade com o anexo IV do Regulamento IVD e é emitida sob a exclusiva responsabilidade do fabricante.
RO	Subsemnatii, declaram că dispozitivul (dispozitivele) medical(e) pentru diagnostic <i>in vitro</i> descrise mai sus sunt conforme cu dispozitiile aplicabile din Regulamentul (UE) 2017/746 al Parlamentului European și al Consiliului din 5 aprilie 2017 privind Dispozitivele medicale pentru diagnosticul <i>in vitro</i> . Prezenta declarație este emisă în conformitate cu anexa IV la Regulamentul IVD și este emisă sub responsabilitatea exclusivă a producătorului.
SK	My, dolupodpisaní, týmto vyhlasujeme, že diagnostická(-é) zdravotnícka(-e) pomôcka(-y) uvedená(-é) vyššie je (sú) v zhode s príslušnými ustanoveniami Nariadenia Európskeho parlamentu a Rady (EÚ) 2017/746 z 5. apríla 2017 o diagnostických zdravotníckych pomôckach <i>in vitro</i> . Toto vyhlásenie je v súlade s Prílohou IV k Nariadeniu IVD a vydáva sa na výhradnú zodpovednosť výrobcu.
SV	Vi, undertecknade, försäkrar härmed att den eller de medicintekniska produkter för <i>in vitro</i> -diagnostik som beskrivs ovan överensstämmer med de tillämpliga bestämmelserna i Europaparlamentets och rådets förordning (EU) 2017/746 av den 5 april 2017 om medicintekniska produkter för <i>in vitro</i> -diagnostik. Denna försäkran görs i enlighet med bilaga IV till IVD-förordningen och utfärdas under tillverkarens enskilda ansvar.
TR	Biz, aşağıda imzaları bulunan, yukarıda belirtilen <i>in vitro</i> diagnostik tıbbi cihazların, 2017/746 sayılı Avrupa Parlamentosu (AB) Yönetmeliği ile 5 Nisan 2017 tarihli <i>In Vitro</i> Diagnostik Tıbbi Cihazlar Konseyinin ilgili hükümlerine uygun olduğunu beyan ederiz. Bu beyan IVD Yönetmeliği Ek IV uyarınca yapılmıştır ve üreticinin münhasır sorumluluğu altındadır.