ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 010051 0139 Rev. 01

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

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Manufacture and Warehousing of In-vitro Diagnostic Reagents for Clinical Chemistry, Immunochemistry, Hematology and Infectious Immunology. The provision of Warehousing and Distribution services of In-vitro Diagnostic medical devices and medical devices.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 010051 0139 Rev. 01

Report No.: 713332354_IVDR

Valid from: 2024-10-01
Valid until: 2027-09-30

Date, 2024-07-11

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Ceaicovschi Tudor
Date: 2025.02.19 15:09:50 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 010051 0139 Rev. 01

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

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

Design and Development, Manufacture and Warehousing of In-vitro Diagnostic Reagents for Clinical Chemistry, Immunochemistry, Hematology and Infectious Immunology.

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

The provision of Warehousing and Distribution services of In-vitro Diagnostic medical devices and medical devices.

./.

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 054869 0011 Rev. 02

Holder of Certificate: **Abbott Ireland Diagnostics Division**
Lisnamuck
Longford
Co. Longford
IRELAND

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Reagents for Clinical Chemistry and Immunochemistry.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 054869 0011 Rev. 02

Report No.: 713280794

Valid from: 2023-09-01
Valid until: 2026-08-31

Date, 2023-07-14

Christoph Dicks
Head of Certification/Notified Body

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 054869 0011 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Abbott Ireland Diagnostics Division
Lisnamuck, Longford, Co. Longford, IRELAND

See Scope of Certificate

./.

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Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden
Germany

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
010051	713318978-21	medical_devices@tuvsud.com	NA	2024-12-19	1 of 9

TÜV SÜD Product Service GmbH
Confirmation Letter
CLI 010051 0165 Rev. 01

Reference: **713198378 | 713227883 | 713273267 | 713276863 | 713279612 | 713281083-09 | 713281083-13 | 713281083-18 | 713281855 | 713296312-CN | 713297671 | 713302431 | 713312272 | 713312280 | 713312285 | 713312286 | 713312292 | 713318978-04 | 713318978-05 | 713354680**

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2024/1860 amending Regulations (EU) 2017/746 (in the following referenced as IVDR) as regards the transitional provisions for certain in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under IVDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR with the above stated manufacturer with the following Single Registration Number (SRN)

Single Registration Number: DE-MF-000009455

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an IVDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.

- Table 2 identifies the devices for which an IVDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive or these devices did not require a Notified Body certificate under Directives.

If devices covered by certificates issued under Directive Directive 98/79/EC (IVDD) that expired after 26. May 2022 and before 09. July 2024, without having been withdrawn, this letter also confirms that

- the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 54(1) of IVDR or Article 92(1) of the IVDR respectively.

The transition timelines in accordance Article 110 (3) of IVDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110 (3c) of IVDR, are shown below:

- 31. December 2027, for devices certified under IVDD
- 31. December 2027, for class D devices;
- 31. December 2028, for class C devices;
- 31. December 2029, for class B devices and for class A devices placed on the market in sterile condition

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CLI 010051 0165

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-12-19

TÜV SÜD Product Service GmbH
Medical and Health Services

jana neumann (Dec 19, 2024 15:33 GMT+1)

Jana Neumann
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Michael Mauermeir (Dec 19, 2024 14:54 GMT+1)

Michael Mauermeir
Application Reviewer

Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
ARCHITECT HBeAg / HBeAg 038074ARC0632K6	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0120 Rev. 04 NB# 0123
Alinity i HBeAg / HBeAg 038074AIP0764LJ	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0109 Rev. 05 NB# 0123
ARCHITECT Anti-HBe / Anti-HBe 038074ARC0634KA	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0124 Rev. 03 NB# 0123
Alinity i Anti- HBe / Anti-HBe 038074AIP0763LG	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0108 Rev. 05 NB# 0123
ARCHITECT HIV Ag/Ab Combo 038074ARJ0427MG	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0118 Rev. 04 NB# 0123
HIV Ag/Ab Combo 038074WIE0009T4	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0118 Rev. 04 NB# 0123
Alinity i HIV Ag/Ab Combo 038074AIP0807LB	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0113 Rev. 05 NB# 0123
HIV Ag/Ab Combo 038074WIE0010SM	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0113 Rev. 05 NB# 0123
ARCHITECT Anti-HCV 038074ARC0637KG	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0132 Rev. 04 NB# 0123
ARCHITECT Anti-HCV / Anti-HCV 038074WIE0014SV	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0132 Rev. 04 NB# 0123
Alinity i Anti-HCV 038074AIP0806L9	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0112 Rev. 05 NB# 0123
Alinity i Anti-HCV / Anti-HCV 038074WIE0013ST	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0112 Rev. 05 NB# 0123

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
ARCHITECT Anti-HBc II / Anti-HBc II 038074ARL0844NS	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0130 Rev. 04 NB# 0123
Alinity i Anti-HBc II / Anti-HBc II 038074AIP0787LW	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0111 Rev. 04 NB# 0123
ARCHITECT Anti-HBc IgM / Anti-HBc IgM 038074ARC0633K8	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0121 Rev. 05 NB# 0123
Alinity i Anti-HBc IgM / Anti-HBc IgM 038074AIP0786LU	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0110 Rev. 04 NB# 0123
ARCHITECT rHTLV I/II 038074ARL0661NG	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0128 Rev. 03 NB# 0123
Alinity i rHTLV-I/II 038074AIP0761LC	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0107 Rev. 03 NB# 0123
ARCHITECT HCV Ag 038074ARL0647NN	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0127 Rev. 04 NB# 0123
Alinity s Anti-HCV II 038074ASW0456SK	Class D incl. ST/NPT	Alinity s Anti-HCV II 038074ASW0456SK Ref IDs: 04W5655	V1 010051 0103 Rev. 13 V7 010051 0135 Rev. 02 NB# 0123
Alinity s HIV Ag/Ab Combo 038074ASP0601PP	Class D incl. ST/NPT	Alinity s HIV Ag/Ab Combo 038074ASP0601PP Ref IDs: 06P0109, 06P0118, 06P0119, 06P0177	V1 010051 0103 Rev. 13 V7 010051 0102 Rev. 05 NB# 0123
Alinity s HIV Ag/Ab Combo 038074WIE0007SY	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0102 Rev. 05 NB# 0123
Alinity s Anti-HBc 038074ASP0606PZ	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0105 Rev. 03 NB# 0123
Alinity s HTLV I/II 038074ASP0607Q3	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0106 Rev. 03 NB# 0123

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
ARCHITECT Toxo IgG **038074ARC0619KE**	Class C for professional use	N/A	V1 010051 0103 Rev. 13 NB# 0123
Alinity i Toxo IgG **038074AIP0745LE**	Class C for professional use	N/A	V1 010051 0103 Rev. 13 NB# 0123
ARCHITECT Toxo IgM **038074ARC0620JX**	Class C for professional use	N/A	V1 010051 0103 Rev. 13 NB# 0123
Alinity i Toxo IgM **038074AIP0747LJ**	Class C for professional use	N/A	V1 010051 0103 Rev. 13 NB# 0123
Alinity i HCV Ag **038074AIP0923LE**	Class D incl. ST/NPT	N/A	V1 010051 0103 Rev. 13 V7 010051 0133 Rev. 02 NB# 0123

Legend: ST – self-testing; NPT – near-patient testing; CDx – companion diagnostics

Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
ARCHITECT EBV VCA IgG / EBV VCA IgG **038074ARP0365PM**	Class D incl. ST/NPT	N/A	N/A - Device did not require a Notified Body certificate under Directives
Alinity i EBV VCA IgG / EBV VCA IgG **038074AIP0921LA**	Class D incl. ST/NPT	N/A	N/A - Device did not require a Notified Body certificate under Directives
ARCHITECT EBV VCA IgM / EBV VCA IgM **038074ARP0366PP**	Class D incl. ST/NPT	N/A	N/A - Device did not require a Notified Body certificate under Directives
Alinity i EBV VCA IgM / EBC VCA IgM **038074AIP0922LC**	Class D incl. ST/NPT	N/A	N/A - Device did not require a Notified Body certificate under Directives
ARCHITECT EBV EBNA-1 IgG / **EBV EBNA-1 IgG** **038074ARP0367PR**	Class D incl. ST/NPT	N/A	N/A - Device did not require a Notified Body certificate under Directives

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified during application review)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Alinity i EBV EBNA-1 IgG / EBV EBNA-1 038074AIP0920L8	Class D incl. ST/NPT	N/A	N/A - Device did not require a Notified Body certificate under Directives
ARCHITECT Syphilis TP / Syphilis TP 038074ARD0806KS	Class D incl. ST/NPT	N/A	N/A - Device did not require a Notified Body certificate under Directives
Alinity i Syphilis TP / Syphilis TP 038074AIP0760LA	Class D incl. ST/NPT	N/A	N/A - Device did not require a Notified Body certificate under Directives
Alinity s Chagas 038074ASP0608Q5	Class D incl. ST/NPT	N/A	N/A - Device did not require a Notified Body certificate under Directives
Alinity s Chagas 038074WIE0006SW	Class D incl. ST/NPT	N/A	N/A - Device did not require a Notified Body certificate under Directives
Alinity s Syphilis 038074ASP0609Q7	Class D incl. ST/NPT	N/A	N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-08-20	713318978-21	Initial issue
2024-12-19	713354680	Revision 01: Addition of Device: Alinity i HCV Ag (Basic UDI-DI: 038074AIP0923LE) to Table 1

Attachment

Additional Information for the devices listed in the table(s) above:

Device name **Basic UDI-DI** **(under IVDR application)**	**REF ID**
ARCHITECT HBeAg / HBeAg 038074ARC0632K6	6C32-01, 6C32-10, 6C32-27, 6C32-37, 6C32-74, 6C32-77, 6C32-09, 6C32-19, 7P24-01, 7P24-10, 7P24-09, 7P24-19
Alinity i HBeAg / HBeAg 038074AIP0764LJ	07P6401, 07P6410, 09P1001, 09P1009, 09P1010, 09P1019, 07P6422, 07P6432, 07P6409, 07P6419, 07P6474, 07P6477
ARCHITECT Anti-HBe / Anti-HBe 038074ARC0634KA	6C34-01, 6C34-10, 6C34-25, 6C34-35, 6C34-09, 6C34-19, 6C34-74, 6C34-77
Alinity i Anti- HBe / Anti-HBe 038074AIP0763LG	07P6301, 07P6310, 07P6322, 07P6332, 07P6309, 07P6319, 07P6374, 07P6377
ARCHITECT HIV Ag/Ab Combo 038074ARJ0427MG	4J27-03, 4J27-12, 4J27-27, 4J27-32, 4J27-37
HIV Ag/Ab Combo 038074WIE0009T4	4J27-09, 4J27-17, 4J27-84, 4J27-87, 4J27-89
Alinity i HIV Ag/Ab Combo 038074AIP0807LB	08P0701, 08P0710, 08P0722, 08P0732
HIV Ag/Ab Combo 038074WIE0010SM	08P0709, 08P0717, 08P0784, 08P0787
ARCHITECT Anti-HCV 038074ARC0637KG	6C37-02, 6C37-15, 6C37-28, 6C37-33, 6C37-38
ARCHITECT Anti-HCV / Anti-HCV 038074WIE0014SV	6C37-10, 6C37-27, 6C37-32, 6C37-37, 6C37-74, 6C37-77, 6C37-78, 6C37-09, 6C37-19
Alinity i Anti-HCV 038074AIP0806L9	08P0602, 08P0611, 08P0623, 08P0633
Alinity i Anti-HCV / Anti-HCV 038074WIE0013ST	08P0601, 08P0610, 08P0622, 08P0609, 08P0619, 08P0674
ARCHITECT Anti-HBc II / Anti-HBc II 038074ARL0844NS	8L44-01, 8L44-10, 8L44-25, 8L44-30, 8L44-35, 8L44-09, 8L44-19, 8L44-74, 8L44-77, 8L44-78
Alinity i Anti-HBc II / Anti-HBc II 038074AIP0787LW	07P8701, 07P8710, 07P8722, 07P8732, 07P8709, 07P8719, 07P8774, 07P8777

Device name Basic UDI-DI (under IVDR application)	REF ID
ARCHITECT Anti-HBc IgM / Anti-HBc IgM 038074ARC0633K8	6C33-02, 6C33-11, 6C33-22, 6C33-27, 6C33-09, 6C33-19, 6C33-74, 6C33-75
Alinity i Anti-HBc IgM / Anti-HBc IgM 038074AIP0786LU	07P8601, 07P8610, 07P8622, 07P8674, 07P8609, 07P8619
ARCHITECT rHTLV I/II 038074ARL0661NG	6L61-01, 6L61-10, 6L61-25, 6L61-30, 6L61-35
Alinity i rHTLV-I/II 038074AIP0761LC	07P6101, 07P6110, 07P6122, 07P6132
ARCHITECT HCV Ag 038074ARL0647NN	6L47-02, 6L47-11, 6L47-29
Alinity s Anti-HCV II 038074ASW0456SK	04W5602, 04W5610, 04W5612, 04W5656
Alinity s HIV Ag/Ab Combo 038074ASP0601PP	06P0102, 06P0110, 06P0112, 06P0155
Alinity s HIV Ag/Ab Combo 038074WIE0007SY	06P0103, 06P0120, 06P0124, 06P0160
Alinity s Anti-HBc 038074ASP0606PZ	06P0602, 06P0610, 06P0612, 06P0655
Alinity s HTLV I/II 038074ASP0607Q3	06P0702, 06P0710, 06P0712, 06P0755
ARCHITECT Toxo IgG 038074ARC0619KE	6C19-01, 6C19-10, 6C19-25, 6C19-35, 6C19-09, 6C19-19, 6C19-74, 6C19-77
Alinity i Toxo IgG 038074AIP0745LE	07P4501, 07P4510, 07P4522, 07P4532, 07P4509, 07P4519, 07P4574, 07P4577
ARCHITECT Toxo IgM 038074ARC0620JX	6C20-01, 6C20-10, 6C20-25, 6C20-35, 6C20-09, 6C20-19, 6C20-74, 6C20-77
Alinity i Toxo IgM 038074AIP0747LJ	07P4701, 07P4710, 07P4722, 07P4732, 07P4709, 07P4719, 07P4774, 07P4777
ARCHITECT EBV VCA IgG / EBV VCA IgG 038074ARP0365PM	3P65-01, 3P65-10, 3P65-25, 3P65-35, 3P65-09, 3P65-19, 3P65-74, 3P65-77
Alinity i EBV VCA IgG / EBV VCA IgG 038074AIP0921LA	09P2101, 09P2110, 09P2122, 09P2132, 09P2109, 09P2119, 09P2174, 09P2177
ARCHITECT EBV VCA IgM / EBV VCA IgM 038074ARP0366PP	3P66-01, 3P66-10, 3P66-25, 3P66-35, 3P66-09, 3P66-19, 3P66-74, 3P66-77

Device name Basic UDI-DI (under IVDR application)	REF ID
Alinity i EBV VCA IgM / EBC VCA IgM 038074AIP0922LC	09P2201, 09P2210, 09P2219, 09P2222, 09P2232, 09P2209, 09P2274, 09P2277
ARCHITECT EBV EBNA-1 IgG / EBV EBNA-1 IgG 038074ARP0367PR	3P67-01, 3P67-10, 3P67-25, 3P67-35, 3P67-09, 3P67-19, 3P67-74, 3P67-77
Alinity i EBV EBNA-1 IgG / EBV EBNA-1 038074AIP0920L8	09P2001, 09P2009, 09P2010, 09P2019, 09P2022, 09P2032, 09P2074, 09P2077
ARCHITECT Syphilis TP / Syphilis TP 038074ARD0806KS	8D06-04 , 8D06-09 , 8D06-13 , 8D06-19, 8D06-32, 8D06-42, 8D06-84, 8D06-87
Alinity i Syphilis TP / Syphilis TP 038074AIP0760LA	07P6001, 07P6009, 07P6010, 07P6019, 07P6022, 07P6032, 07P6074, 07P6077
Alinity s Chagas 038074ASP0608Q5	06P0802, 06P0810, 06P0812, 06P0845
Alinity s Chagas 038074WIE0006SW	06P0803, 06P0820, 06P0824, 06P0850
Alinity s Syphilis 038074ASP0609Q7	06P0902, 06P0910, 06P0912, 06P0955
Alinity i HCV Ag 038074AIP0923LE	09P2322, 09P2301, 09P2310

2024-12-19

TÜV SÜD Product Service GmbH
Medical and Health Services

jana neumann (Dec 19, 2024 15:33 GMT+1)

Jana Neumann
Conformity Assessment Responsible (CARE)

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

Product Service

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

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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZLG-BS-245.10.07

TÜV SÜD Product Service

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

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

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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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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

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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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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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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

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Product Service

Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 010051 0149 Rev. 00

Manufacturer:

Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden
GERMANY

This Confirmation Statement is only valid in combination with the following EC Certificate (IVDD): **V1 010051 0103 Rev. 13**

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (IVDD). It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2022 or later.
The conditions laid down in Article 110 (3) of Regulation (EU) 2017/746 on in vitro diagnostic medical devices for placing devices on the market and putting into service apply. For details and confirmation statement validity see: www.tuvsud.com/ps-cert?q=cert:VCQ 010051 0149 Rev. 00

Report No.: 713283413-03

Valid until: 2025-05-26

Issue Date: 2023-07-11

Marta Carnielli
Head of Notified Body IVD

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Product Service

Confirmation Statement on validity of EC Certificate (IVDD)

pursuant to Directive 98/79/EC concerning in vitro diagnostic medical devices

No. VCQ 010051 0149 Rev. 00

Product Category(ies): **Products for the determination of infection markers for HIV, Hepatitis B, Hepatitis C, HTLV, toxoplasmosis**

Description of Change: **Removal of Products according to Annex II List A Devices:**

Product Name	REF N°
Abbott PRISM HBcore Assay Kit	1A77-48
Abbott PRISM Run Control Kit	2K24-10
Abbott PRISM Run Control Kit	5E22-10
Abbott PRISM HBsAg Assay Kit	3A47-48
Abbott PRISM HIV O Plus Assay Kit	3D34-48
Abbott PRISM HTLV-I/HTLV-II Assay Kit	6A53-48
Abbott PRISM HCV Assay Kit	6A52-48
Abbott PRISM HBsAg Confirmatory Assay Kit	6D16-48
Abbott PRISM HIV Ag/Ab Combo Assay Kit	7G46-48
Abbott PRISM Positive Run Control Kit	2K24-11
Abbott PRISM Positive Run Control Kit	5E22-11

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(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

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(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

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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°
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

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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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(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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(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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Management Service

CERTIFICATE

Certificate Registration No.: **12 100 64551/02 TMS** / Order No.: **707151799**

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that the organization

Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden
Germany

at the site

Abbott

Abbott Diagnostics GmbH
Max-Planck-Ring 2
65205 Wiesbaden
Germany

for the scope

The provision of Warehousing and Distribution services of In-Vitro Diagnostic Medical Devices and Medical Devices

has established and applies a Quality Management System.

An audit was performed and has furnished proof
that the requirements according to

DIN EN ISO 9001:2015

are fulfilled.

The certificate is valid in conjunction
with the main certificate from **2024-10-01** until **2027-09-30**.

Fred Wenke
Head of Certification Body
Munich, 2024-07-16

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

MS/01-07/2023

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 010051 0139 Rev. 01

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

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Manufacture and Warehousing of In-vitro Diagnostic Reagents for Clinical Chemistry, Immunochemistry, Hematology and Infectious Immunology. The provision of Warehousing and Distribution services of In-vitro Diagnostic medical devices and medical devices.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 010051 0139 Rev. 01

Report No.: 713332354_IVDR

Valid from: 2024-10-01
Valid until: 2027-09-30

Date, 2024-07-11

Christoph Dicks
Head of Certification/Notified Body

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 010051 0139 Rev. 01

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

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

Design and Development, Manufacture and Warehousing of In-vitro Diagnostic Reagents for Clinical Chemistry, Immunochemistry, Hematology and Infectious Immunology.

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

The provision of Warehousing and Distribution services of In-vitro Diagnostic medical devices and medical devices.

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Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 054869 0013 Rev. 01

Manufacturer: **Abbott Ireland Diagnostics Division**
Lisnamuck
Longford
Co. Longford
IRELAND

SRN Manufacturer: IE-MF-000010070

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 054869 0013 Rev. 01

Report No.: 713235160-02

Preceding Certificate No.: V12 054869 0013 Rev. 00

Valid from: 2021-12-03

Valid until: 2026-11-25

Date of Initial Issuance: 2021-11-26

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-12-03

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EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 054869 0013 Rev. 01

Classification:	B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0504 - Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging

Classification:	B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0607 - Devices intended to be used for detection of pregnancy or fertility testing

Classification:	B
Device Group:	W0101 - CLINICAL CHEMISTRY
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

Classification:	B
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
Intended Purpose:	IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

Classification:	C
Device Group:	W0101 - CLINICAL CHEMISTRY
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0301 - Devices intended to be used in screening, diagnosis, staging or monitoring of cancer

Classification:	C
Device Group:	W0101 - CLINICAL CHEMISTRY
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

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EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 054869 0013 Rev. 01

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose:	IVR 0602 - Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease

Classification:	C
Device Group:	W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0504 - Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging

The validity of this certificate depends on conditions and/or is limited to the following: -none-

Revision History:

Rev.	Dated	Report
00	2021-11-26	713198595

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