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Zentralstelle der Länder
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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 001922 0008 Rev. 03

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. See also notes overleaf.

Report no.: 713158801-03

Valid from: 2020-01-15
Valid until: 2024-05-26

Date, 2020-01-15

Christoph Dicks
Head of Certification/Notified Body

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No. V1 001922 0008 Rev. 03

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 | 3M61-01 |
| ARCHITECT HBsAg Calibrators | 3M61-02 |
| ARCHITECT HBsAg Controls | 6C36-10 |
| ARCHITECT HBsAg Reagent Kit | 6C36-22 |
| ARCHITECT HBsAg Reagent Kit | 6C36-27 |
| ARCHITECT HBsAg Reagent Kit | 6C36-32 |
| 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 HBsAg Reagent Kit | 6C36-41 |
| ARCHITECT HBsAg Reagent Kit | 6C36-42 |
| 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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No. V1 001922 0008 Rev. 03

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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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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No. V1 001922 0008 Rev. 03

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 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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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 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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