



Xem thông tin sản phẩm tại trang 5

**Bescheinigung
nach § 34 Abs. 1**

der gegenwärtig gültigen Fassung des Medizinproduktegesetzes (MPG) zur Vorlage bei den zuständigen Behörden / Stellen von

Vietnam

Es wird bescheinigt, dass die nachfolgend genannten Medizinprodukte

- in Deutschland,
- in den Mitgliedstaaten der Europäischen Union und
- in den anderen Vertragsstaaten des Abkommens über den Europäischen Wirtschaftsraum

uneingeschränkt verkehrsfähig sind.

Produkt / Produkte:

siehe beigelegte Produktliste

Der für das erstmalige Inverkehrbringen im Europäischen Wirtschaftsraum Verantwortliche nach § 5 MPG:

**Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden
Deutschland**

Es wird auch bescheinigt, dass der Hersteller durch das CE-Kennzeichen zum Ausdruck bringt, dass die Medizinprodukte die Grundlegenden Anforderungen der

Richtlinie 98/79/EG des Rates vom 27.10.1998

in der gegenwärtig gültigen Fassung erfüllen und das vorgeschriebene Konformitätsbewertungsverfahren durchgeführt wurde.

Kassel, 20. April 2020

Im Auftrag

(Weisburd)



Dezernat 56- 53 o 12 (004-02954-21)

**Certificate
according to § 34 (1)**

of the Medical Device Act (MDA) in the current valid version for presentation to the competent authorities / bodies of

Viet Nam

It is certified that the following medical devices can be marketed without restriction within

- Germany,
- the member states of the European Union and
- the other states having a contractual agreement with the European Economic Area.

Product / Products:

see product list attached

Responsible for first placing the product on the European Economic Area market according to § 5 MDA:

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

It is also certified that the manufacturer with the CE-mark confirms that the medical devices fulfil the essential requirements of the

Council Directive 98/79/EC of 27 October 1998

in the current valid version and that the required conformity assessment has been completed.



Produktliste zur Bescheinigung nach § 34 Abs. 1MPG

Attachment to Certificate acc. § 34 (1) MPG

Artikel-Nr. / Article No.	Produktname / Product Name
1A77-38 1A77-48	PRISM HBcore Wash Kit ABBOTT PRISM HBcore Assay Kit
1P31-01 1P31-25	ARCHITECT iGentamicin Calibrators ARCHITECT iGentamicin Reagent Kit
1P36-01 1P36-25	ARCHITECT iCarbamazepine Calibrators ARCHITECT iCarbamazepine Reagent Kit
2K24-10 2K24-11	PRISM Run Control Kit PRISM Positive Run Control Kit
2P25-01 2P25-10 2P25-20 2P25-25 2P25-35	ARCHITECT Chagas Calibrator ARCHITECT Chagas Controls ARCHITECT Chagas Reagent Kit (4x100 tests) ARCHITECT Chagas Reagent Kit (1x100 tests) ARCHITECT Chagas Reagent Kit (1x500 tests)
02R2801 02R2810 02R2822 02R2832	Alinity i HAVAb-IgM Calibrator Alinity i HAVAb-IgM Controls Alinity i HAVAb-IgM Reagent Kit (2 x 100 Tests) Alinity i HAVAb-IgM Reagent Kit (2 x 500 Tests)
3A47-38 3A47-48	PRISM HBsAg Wash Kit PRISM HBsAg Assay Kit
3D34-38 3D34-48	PRISM HIV O Plus Wash Kit PRISM HIV O Plus Assay Kit
3L00-01 3L00-30	PRISM Prime/Purge Accessories PRISM Purge Concentrate
3L27-01 3L27-02 3L27-10	PRISM Activator Diluent PRISM Activator Concentrate PRISM Activator Line Treatment
3P65-01 3P65-10 3P65-25 3P65-35	ARCHITECT EBV VCA IgG Calibrator ARCHITECT EBV VCA IgG Controls ARCHITECT EBV VCA IgG Reagent Kit (1x100 Tests) ARCHITECT EBV VCA IgG Reagent Kit (1x500 Tests)
3P66-01 3P66-10 3P66-25 3P66-35	ARCHITECT EBV VCA IgM Calibrator ARCHITECT EBV VCA IgM Controls ARCHITECT EBV VCA IgM Reagent Kit (1x100 Tests) ARCHITECT EBV VCA IgM Reagent Kit (1x500 Tests)
3P67-01 3P67-10 3P67-25 3P67-35	ARCHITECT EBV EBNA-1 IgG Calibrator ARCHITECT EBV EBNA-1 IgG Controls ARCHITECT EBV EBNA-1 IgG Reagent Kit (1x100 Tests) ARCHITECT EBV EBNA-1 IgG Reagent Kit (1x500 Tests)
4J27-03 4J27-12 4J27-22 4J27-27 4J27-32 4J27-37	ARCHITECT HIV Ag/Ab Combo Calibrator ARCHITECT HIV Ag/Ab Combo Controls ARCHITECT HIV Ag/Ab Combo Reagent Kit (4x100 Tests) ARCHITECT HIV Ag/Ab Combo Reagent Kit (1x100 Tests) ARCHITECT HIV Ag/Ab Combo Reagent Kit (4x500 Tests) ARCHITECT HIV Ag/Ab Combo Reagent Kit (1x500 Tests)
5E22-10 5E22-11	PRISM Run Control Kit PRISM Positive Run Control Kit
6A52-38 6A52-48	PRISM HCV Wash Kit PRISM HCV Assay Kit
6A53-38	PRISM HTLV-I/HTLV-II Wash Kit

Produktliste zur Bescheinigung nach § 34 Abs. 1MPG
Attachment to Certificate acc. § 34 (1) MPG

Artikel-Nr. / Article No.	Produktname / Product Name
6A53-48	PRISM HTLV-I/HTLV-II Assay Kit
6C19-01	ARCHITECT Toxo IgG Calibrators
6C19-10	ARCHITECT Toxo IgG Controls
6C19-25	ARCHITECT Toxo IgG Reagent Kit (1x100 Tests)
6C19-35	ARCHITECT Toxo IgG Reagent Kit (1x500 Tests)
6C20-01	ARCHITECT Toxo IgM Calibrator
6C20-10	ARCHITECT Toxo IgM Controls
6C20-25	ARCHITECT Toxo IgM Reagent Kit (1x100 Tests)
6C20-35	ARCHITECT Toxo IgM Reagent Kit (1x500 Tests)
6C29-01	ARCHITECT HAVAb-IgG Calibrator
6C29-10	ARCHITECT HAVAb-IgG Controls
6C29-22	ARCHITECT HAVAb-IgG Reagent Kit (4x100 Tests)
6C29-27	ARCHITECT HAVAb-IgG Reagent Kit (1x100 Tests)
6C30-02	ARCHITECT HAVAb-IgM Calibrator
6C30-11	ARCHITECT HAVAb-IgM Controls
6C30-22	ARCHITECT HAVAb-IgM Reagent Kit (4x100 Tests)
6C30-27	ARCHITECT HAVAb-IgM Reagent Kit (1x100 Tests)
6C30-01	ARCHITECT HAVAb-IgM Calibrator
6C30-10	ARCHITECT HAVAb-IgM Controls
6C30-20	ARCHITECT HAVAb-IgM Reagent Kit (4x100 Tests)
6C30-25	ARCHITECT HAVAb-IgM Reagent Kit (1x100 Tests)
6C32-01	ARCHITECT HBeAg Calibrators
6C32-10	ARCHITECT HBeAg Controls
6C32-20	ARCHITECT HBeAg Reagent Kit (4x100 Tests)
6C32-25	ARCHITECT HBeAg Reagent Kit (1x100 Tests)
6C32-27	ARCHITECT HBeAg Reagent Kit (1x100 Tests)
6C32-37	ARCHITECT HBeAg Reagent Kit (1x500 Tests)
6C33-02	ARCHITECT Anti-HBc IgM Calibrators
6C33-11	ARCHITECT Anti-HBc IgM Controls
6C33-22	ARCHITECT Anti-HBc IgM Reagent Kit (4x100 Tests)
6C33-27	ARCHITECT Anti-HBc IgM Reagent Kit (1x100 Tests)
6C34-01	ARCHITECT Anti-HBe Calibrator
6C34-10	ARCHITECT Anti-HBe Controls
6C34-20	ARCHITECT Anti-HBe Reagent Kit (4x100 Tests)
6C34-25	ARCHITECT Anti-HBe Reagent Kit (1x100 Tests)
6C34-35	ARCHITECT Anti-HBe Reagent Kit (1x500 Tests)
6C37-01	ARCHITECT Anti-HCV Calibrator
6C37-10	ARCHITECT Anti-HCV Controls
6C37-22	ARCHITECT Anti-HCV Reagent Kit (4x100 Tests)
6C37-27	ARCHITECT Anti-HCV Reagent Kit (1x100 Tests)
6C37-32	ARCHITECT Anti-HCV Reagent Kit (4x500 Tests)
6C37-37	ARCHITECT Anti-HCV Reagent Kit (1x500 Tests)
6C37-02	ARCHITECT Anti-HCV Calibrator
6C37-15	ARCHITECT Anti-HCV Controls
6C37-28	ARCHITECT Anti-HCV Reagent Kit (1x100 Tests)
6C37-33	ARCHITECT Anti-HCV Reagent Kit (4x500 Tests)
6C37-38	ARCHITECT Anti-HCV Reagent Kit (1x500 Tests)
6D16-48	PRISM HBsAg Confirmatory Assay Kit
6L37-11	ARCHITECT Toxo IgG Avidity Calibrator & Controls

Produktliste zur Bescheinigung nach § 34 Abs. 1MPG
Attachment to Certificate acc. § 34 (1) MPG

Artikel-Nr. / Article No.	Produktname / Product Name
6L37-25	ARCHITECT Toxo IgG Avidity Reagent Kit
6L61-01	ARCHITECT rHTLV-I/II Calibrator
6L61-10	ARCHITECT rHTLV-I/II Controls
6L61-25	ARCHITECT rHTLV-I/II Reagent Kit (1x100 Tests)
6L61-30	ARCHITECT rHTLV-I/II Reagent Kit (4x500 Tests)
6L61-35	ARCHITECT rHTLV-I/II Reagent Kit (1x500 Tests)
7G46-38	PRISM HIV Ag/Ab Combo Wash Kit
7G46-48	PRISM HIV Ag/Ab Combo Assay Kit
7P24-01	ARCHITECT HBeAg Quantitative Calibrators
7P24-10	ARCHITECT HBeAg Quantitative Controls
07P4501	Alinity i Toxo IgG Calibrators
07P4510	Alinity i Toxo IgG Controls
07P4522	Alinity i Toxo IgG Reagent Kit (2 x 100 Tests)
07P4532	Alinity i Toxo IgG Reagent Kit (2 x 500 Tests)
07P4610	Alinity i Toxo IgG Avidity Controls
07P4622	Alinity i Toxo IgG Avidity Reagent Kit
07P4701	Alinity i Toxo IgM Calibrator
07P4710	Alinity i Toxo IgM Controls
07P4722	Alinity i Toxo IgM Reagent Kit (2 x 100 Tests)
07P4732	Alinity i Toxo IgM Reagent Kit (2 x 500 Tests)
07P6001	Alinity i Syphilis TP Calibrator
07P6010	Alinity i Syphilis TP Controls
07P6022	Alinity i Syphilis TP Reagent Kit (2 x 100 Tests)
07P6032	Alinity i Syphilis TP Reagent Kit (2 x 600 Tests)
07P6101	Alinity i rHTLV-I/II Calibrator
07P6110	Alinity i rHTLV-I/II Controls
07P6122	Alinity i rHTLV-I/II Reagent Kit (2 x 100 Tests)
07P6132	Alinity i rHTLV-I/II Reagent Kit (2 x 500 Tests)
07P6301	Alinity i Anti-HBe Calibrator
07P6310	Alinity i Anti-HBe Controls
07P6322	Alinity i Anti-HBe Reagent Kit (2 x 100 Tests)
07P6401	Alinity i HBeAg Calibrators
07P6410	Alinity i HBeAg Controls
07P6422	Alinity i HBeAg Reagent Kit (2 x 100 Tests)
07P8601	Alinity i Anti-HBc IgM Calibrators
07P8610	Alinity i Anti-HBc IgM Controls
07P8622	Alinity i Anti-HBc IgM Reagent Kit (2 x 100 Tests)
07P8701	Alinity i Anti-HBc II Calibrator
07P8710	Alinity i Anti-HBc II Controls
07P8722	Alinity i Anti-HBc II Reagent Kit (2 x 100 Tests)
07P8732	Alinity i Anti-HBc II Reagent Kit (2 x 600 Tests)
8D06-04	ARCHITECT Syphilis TP Calibrator
8D06-13	ARCHITECT Syphilis TP Controls
8D06-32	ARCHITECT Syphilis TP Reagent Kit (1x100 Tests)
8D06-42	ARCHITECT Syphilis TP Reagent Kit (1x500 Tests)
8D06-29	ARCHITECT Syphilis TP Reagent Kit (1x100 Tests)
8D06-39	ARCHITECT Syphilis TP Reagent Kit (1x500 Tests)
8D07-01	ARCHITECT Pepsinogen I Calibrators
8D07-10	ARCHITECT Pepsinogen I Controls

Produktliste zur Bescheinigung nach § 34 Abs. 1MPG
Attachment to Certificate acc. § 34 (1) MPG

Artikel-Nr. / Article No.	Produktname / Product Name
8D07-26	ARCHITECT Pepsinogen I Reagent Kit (1 x 100 Tests)
8D07-36	ARCHITECT Pepsinogen I Reagent Kit (1 x 500 Tests)
8L44-01	ARCHITECT Anti-HBc II Calibrator
8L44-10	ARCHITECT Anti-HBc II Controls
8L44-25	ARCHITECT Anti-HBc II Reagent Kit (1x100 Tests)
8L44-30	ARCHITECT Anti-HBc II Reagent Kit (4x500 Tests)
8L44-35	ARCHITECT Anti-HBc II Reagent Kit (1x500 Tests)
08P0601	Alinity i Anti-HCV Calibrator
08P0610	Alinity i Anti-HCV Controls
08P0622	Alinity i Anti-HCV Reagent Kit (2 x 100 Tests)
08P0632	Alinity i Anti-HCV Reagent Kit (2 x 500 Tests)
08P0701	Alinity i HIV Ag/Ab Combo Calibrator
08P0710	Alinity i HIV Ag/Ab Combo Controls
08P0722	Alinity i HIV Ag/Ab Combo Reagent Kit (2 x 100 Tests)
08P0732	Alinity i HIV Ag/Ab Combo Reagent Kit (2 x 600 Tests)
08P2601	Alinity i HAVAb-IgG Calibrator
08P2610	Alinity i HAVAb-IgG Controls
08P2622	Alinity i HAVAb-IgG Reagent Kit (2 x 100 Tests)
08P2632	Alinity i HAVAb-IgG Reagent Kit (2 x 500 Tests)
9D65-01	ARCHITECT Pepsinogen II Calibrators
9D65-10	ARCHITECT Pepsinogen II Controls
9D65-26	ARCHITECT Pepsinogen II Reagent Kit (1 x 100 Tests)
9D65-36	ARCHITECT Pepsinogen II Reagent Kit (1 x 500 Tests)
09P1001	Alinity i HBeAg Quantitative Calibrators
09P1010	Alinity i HBeAg Quantitative Controls
09P1922	Alinity i Chagas Reagent Kit (2 x 100 Tests)
09P1932	Alinity i Chagas Reagent Kit (2 x 500 Tests)
09P1901	Alinity i Chagas Calibrator
09P1910	Alinity i Chagas Controls
09P2022	Alinity i EBV EBNA-1 IgG Reagent Kit (2 x 100 Tests)
09P2032	Alinity i EBV EBNA-1 IgG Reagent Kit (2 x 500 Tests)
09P2001	Alinity i EBV EBNA-1 IgG Calibrator
09P2010	Alinity i EBV EBNA-1 IgG Controls
09P2122	Alinity i EBV VCA IgG Reagent Kit (2 x 100 Tests)
09P2132	Alinity i EBV VCA IgG Reagent Kit (2 x 500 Tests)
09P2101	Alinity i EBV VCA IgG Calibrator
09P2110	Alinity i EBV VCA IgG Controls
09P2222	Alinity i EBV VCA IgM Reagent Kit (2 x 100 Tests)
09P2232	Alinity i EBV VCA IgM Reagent Kit (2 x 500 Tests)
09P2201	Alinity i EBV VCA IgM Calibrator
09P2210	Alinity i EBV VCA IgM Controls
09P2422	Alinity i Pepsinogen I Reagent Kit (2 x 100 Tests)
09P2432	Alinity i Pepsinogen I Reagent Kit (2 x 500 Tests)
09P2401	Alinity i Pepsinogen I Calibrators
09P2410	Alinity i Pepsinogen I Controls
09P2522	Alinity i Pepsinogen II Reagent Kit (2 x 100 Tests)
09P2532	Alinity i Pepsinogen II Reagent Kit (2 x 500 Tests)
09P2501	Alinity i Pepsinogen II Calibrators
09P2510	Alinity i Pepsinogen II Controls





TỔNG LÃNH SỰ QUÁN NƯỚC CHXHCN VIỆT NAM
tại Frankfurt am Main, CHLB Đức

1. Quốc gia: **Việt Nam**
Country:
- Giấy tờ, tài liệu này**
This public document
2. do Ông (Bà): **Weisburd** ký
has been signed by:
3. với chức danh: **Cán bộ phụ trách**
acting in the capacity of:
4. và con dấu của: **Chính quyền Tp. Kassel**
bears the seal/stamp of:
- được chứng nhận / hợp pháp hóa lãnh sự**
Certified
5. tại: **Frankfurt** 6. ngày: **04/05/2020**
at: *the:*
7. Cơ quan cấp: **Tổng lãnh sự quán Việt Nam tại Frankfurt/Main**
by:
8. Số: **612/2020/CN-HPHLS**
No:

Tổng Lãnh sự/ Consul General



Phạm Trường Giang