EC DECLARATION OF CONFORMITY
EG-KONFORMITÄTSERKLÄRUNG

www.dialab.at

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Date: 2024.03.27 16:20:48 EET
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Location: Moldova

Dialab Produktion und Vertrieb von
chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, A-2351 Wiener Neudorf

REF	**Product Name / Produktname**	**Content / Inhalt**
B06412	Anti-E, monoclonal	*- 1x 5 mL*

Lot Numbers / Lotnummern: *691104-B1, 691104-B3*

Notified Body / Benannte Stelle:
TÜV SÜD Product Service GmbH, code 0123, Ridlerstraße 65, 80339 München, Germany

No. CE Certificate / Nr. CE-Zertifikat: V1 026709 0004 Rev. 03; V7 026709 0007 Rev.02

We declare, on our own responsibility, that our above-mentioned product classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC: **Devices of List A, Annex II**

meets the applicable provisions of the EU Directive 98/79/EC for in-vitro-diagnostic medical devices and the Austrian Medical Product Law.

This Declaration is based on approval according to Annex IV, section 3 and 4 of the aforesaid Directive in cooperation with above mentioned notified body.

Hiermit erklären wir, auf eigene Verantwortung, dass unser oben genanntes Produkt, gemäß der Richtlinie 98/79/EG über In-vitro-Diagnostika klassifiziert als: **Produkte der Liste A, Anhang II**

die anwendbaren Vorschriften der EU-Richtlinie 98/79/EG über in-Vitro-Diagnostika und des Österreichischen Medizinproduktegesetzes erfüllt.

Diese Erklärung basiert auf Freigabe gemäß Anhang IV, Sektion 3 und 4 der oben angeführten Richtlinie in Zusammenarbeit mit oben genannter Benannter Stelle.

Wiener Neudorf, 2023-06-16

Almira Dugic
Qualitätsmanagementbeauftragte
Quality Management Representative

DIALAB
Produktion und Vertrieb von chemisch - technischen
Produkten und Laborinstrumenten Gesellschaft m.b.H.
A - 2351 Wr. Neudorf, IZ-NOE Süd, Hondastr. Obj.M55
Phone: ++43 (0) 2236 660910 - 0 Fax: ++43 (0) 2236 660910 - 30
E-Mail: office@dialab.at Website: www.dialab.at

Benannt durch/Designated by
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 026709 0004 Rev. 03

Manufacturer:

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued
Hondastrasse, Objekt M55
2351 Wr. Neudorf
AUSTRIA

Product Category(ies): Products according to Directive 98/79/EC Annex II

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 026709 0004 Rev. 03

Report no.: 713255766_1_SCN

Valid from: 2022-04-12
Valid until: 2025-05-26

Date, 2022-04-12

Christoph Dicks
Head of Certification/Notified Body

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

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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 026709 0004 Rev. 03

Model(s): **The products detailed below are covered under the scope of this certificate**

Facility(ies): DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf, AUSTRIA

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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 026709 0004 Rev. 03

Products according to Annex II List A Devices:

Product	REF
Anti-A, monoclonal	B05405
Anti-B, monoclonal	B05406
Anti-AB, monoclonal	B05407
Anti-D (IgM/IgG), monoclonal	B05408
Anti-C, monoclonal	B06411
Anti-E, monoclonal	B06412
Anti-c, monoclonal	B06413
Anti-e, monoclonal	B06414
DIAQUICK HIV Plus	H18100
DIAQUICK HIV Plus WB	H18101
DIAQUICK HCV Plus	H18200
DIAQUICK HCV Plus WB	H18201

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

No. V1 026709 0004 Rev. 03

Products according to Annex II List B Devices:

Product	REF
Anti-HG, polyspecific/monoclonal	B05181
DIAQUICK Rubella IgM Cassette	J15020
DIAQUICK Toxoplasma IgM Cassette	J15011
DIAQUICK CMV IgM Cassette	J15030
DIAQUICK Chlamydia Cassette	Z98226CE
PSA	Z00338
DIAQUICK PSA Cassette	Z08010
DiaCheck® Pro Blood Glucose Monitoring System	P13110
DiaCheck® Pro Blood Glucose Test Strips	P13125
DiaCheck® Pro Glucose Control Solution	P13134

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Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 026709 0007 Rev. 02

Manufacturer:

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued
Hondastrasse, Objekt M55
2351 Wr. Neudorf
AUSTRIA

Product:

Reagents and reagent products for blood typing Rhesus (C,c,D,E,e)

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with IVDD Annex IV (4). The design of the devices conforms to the requirements of this Directive. 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:V7 026709 0007 Rev. 02

Report No.: 713255766_2_SCN

Valid from: 2022-05-04
Valid until: 2025-05-26

Date, 2022-05-04

Christoph Dicks
Head of Certification/Notified Body

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

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TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV (4) (List A)

No. V7 026709 0007 Rev. 02

Model(s):

Anti-D (IgM/IgG), monoclonal
Anti-C, monoclonal
Anti-c, monoclonal
Anti-E, monoclonal
Anti-e, monoclonal

Facility(ies):

DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf, AUSTRIA

Parameters:

Model Name:	Model No:
Anti-D (IgM/IgG), monoclonal	B05408
Anti-C, monoclonal	B06411
Anti-c, monoclonal	B06413
Anti-E, monoclonal	B06412
Anti-e, monoclonal	B06414

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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 026709 0009 Rev. 01

Holder of Certificate: **DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.**
IZ-NOE Sued
Hondastrasse, Objekt M55
2351 Wr. Neudorf
AUSTRIA

Certification Mark:

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

Scope of Certificate: **Design, development, production and distribution of in-vitro diagnostic reagents and testkits in the areas of immunological detection of infectious diseases, immunochemistry/immunology/clinical chemistry biomarkers (analytes: enzymes, substrates, electrolytes reagents; controls/standards/calibrators), urinalysis, haematology, haemostasis and immunohaematology (blood grouping).
Distribution of in-vitro diagnostic instruments including accessories for immunology, clinical chemistry, haematology, haemostasis and urinalysis.**

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 026709 0009 Rev. 01

Report No.: 713237224

Valid from: 2022-03-29
Valid until: 2025-03-28

«ECHIP-AMED-PLUS» IDNO 1003600007677

Date, 2022-03-17

Christoph Dicks
Head of Certification/Notified Body

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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 026709 0009 Rev. 01

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): DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.
IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf, AUSTRIA

See Scope of Certificate

Parameters: ./.

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