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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

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

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

Digitally signed by Iurchevici Valeriu
Date: 2023.02.22 20:31:21 EET
Reason: MoldSign Signature
Location: Moldova

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

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

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-245.10.07

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

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

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

TÜV®

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

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. 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 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. 02

Report no.: 713205839

Valid from: 2021-04-23
Valid until: 2024-05-26

Date, 2021-04-22

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

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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 026709 0004 Rev. 02

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

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
Anti-D Negative Control	B09936
DIAQUICK HIV Plus	H18100
DIAQUICK HIV Plus WB	H18101
DIAQUICK HCV Plus	H18200
DIAQUICK HCV Plus WB	H18201

MOLDOVA mun.CHIŞINĂU, SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TECHIPAMED-PLUS" IDNO 1003600077677 REPUBLICA

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

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

TÜV®

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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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 026709 0004 Rev. 02

Products according to Annex II List B Devices:

Product	REF
Anti-HG, polyspecific/monoclonal	B05181
Rubella IgG	V00045
Rubella IgM	V05061
DIAQUICK Rubella IgM Cassette	J15020
Toxoplasma IgG	V00064
Toxoplasma IgM	V05079
DIAQUICK Toxoplasma IgM Cassette	J15011
CMV IgG	V00004
CMV IgM	V00012
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

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

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

TÜV®