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 040330 0182 Rev. 01

Manufacturer: **DiaMed GmbH**
Pra Rond 23
1785 Cressier FR
SWITZERLAND

Product Category(ies): **Products for blood typing**
ABO, Rh, Kell, Duffy, Kidd, irregular and RBC antibodies

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 040330 0182 Rev. 01

Report no.: 713249257-03_SCN

Valid from: 2022-04-13
Valid until: 2025-05-26

REPUBLICA MOLDOVA, mun. CHISINAU
DIALAB SOLUTIONS S.R.L.
IDNO 1022600026511
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Date, 2022-04-13

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Levința Alexandru
Date: 2025.07.21 12:12:53 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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 040330 0182 Rev. 01

Model(s):

ID System
(cards, reagents, cells)
DiaMed MP-Test
(microplates, sera, cells)
Products for conventional testing
(sera, reagents, cells)

For details on the Annex II List A-products see respective Design-Examination Certificates

For details on the Annex II List B-products see the device list below

Facility(ies):

DiaMed GmbH
Pra Rond 23, 1785 Cressier FR, SWITZERLAND

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

TÜV®

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

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 040330 0182 Rev. 01

Several Annex II List A devices as specified in the corresponding design examination certificates and the following Annex II list B devices:

ID-System cards:

Id-n° 50531: LISS/Coombs
Id-n° 50270: DiaClon Anti-Jk^a
Id-n° 50280: DiaClon Anti-Jk^b
Id-n° 51250: DiaClon Anti-Jk^a/Jk^b
Id-n° 51270: ID-Card Anti-Fy^a / -Fy^b
Id-n° 50350: ID-Card Anti-Fy^a
Id-n° 50360: ID-Card Anti-Fy^b
Id-n° 50380: ID-Antigen Profile II
Id-n° 50390: ID-Antigen Profile III
Id-n° 50510: Reverse Grouping with Antibody Screening
Id-n° 50571: DiaScreen
Id-n° 50581: LISS/Coombs + Enzyme Test
Id-n° 50550: Reverse Grouping with Antibody Screening 4/2
Id-n° 50540: Coombs Anti-IgG

Reagents and test sera for the ID-System:

Id-n° 09210: ID-Anti Fy^a
Id-n° 09310: ID-Anti Fy^b
Id-n° 45140: ID-Antigen Profile III (ID-Testsera Anti-M,-N,-S,-s,-Fy^a,-Fy^b (6x1,4ml))
Id-n° 45460: ID-Antigen Profile III (ID-Testsera Anti-M,-N,-S,-s,-Fy^a,-Fy^b (6x5,0ml))
Id-n° 46180: ID-Anti-Fy^a/Fy^b

REPUBLICA MOLDOVA, mun. CHISINAU
DIALAB SOLUTIONS S.R.L.
IDNO 1022600026511
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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®

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 040330 0182 Rev. 01

Test cells for the ID-System:

Id-n° 45184: ID-DiaCell I-II-III
Id-n° 45330: ID-DiaCell I-II-III Asia
Id-n° 45194: ID-DiaCell IP-IIP-IIIP
Id-n° 45151: ID-DiaCell I-II
Id-n° 06070: ID-DiaCell Pool
Id-n° 45161: ID-DiaPanel
Id-n° 45171: ID-DiaPanel-P
Id-n° 05980: ID-Di^{a} (Diego) positive
Id-n° 06291: ID-I Negative Cell
Id-n° 45070: ID-DiaScreen I-II-III-IV-VP-VIP
Id-n° 45200: ID-DiaScreen I-II-III-IV
Id-n° 45210: ID-DiaScreen VP-VIP
Id-n° 45660 ID-DiaScreen Prophylax
Id-n° 45670 ID-DiaPanel Plus 6

DiaClon blood grouping reagents:

Id-n° 17620: DiaClon Anti-Jk^{a}
Id-n° 17720: DiaClon Anti-Jk^{b}
Id-n° 14070: DiaClon Coombs-Serum Uncolored
Id-n° 14060: DiaClon Coombs-Serum Green

Polyclonal blood grouping reagents:

Id-n° 14710: Coombs-Serum IgG
Id-n° 16070: Coombs-Control IgG
Id-n° 17610: Anti-Jk^{a}
Id-n° 17710: Anti-Jk^{b}
Id-n° 19210: Anti-Fy^{a}
Id-n° 19310: Anti-Fy^{b}

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

TÜV®

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 040330 0182 Rev. 01

Test cells:

Id-n° 16080:	DiaCell Di^a (Diego) positive
Id-n° 45220:	DiaCell I+II
Id-n° 45230:	DiaCell I+II+III
Id-n° 45241:	DiaPanel
Id-n° 06060:	ID-DiaCell SF
Id-n° 08770:	IH-QC7
Id-n° 08780:	IH-QC8

REPUBLICA MOLDOVA, MUN. CHISINAU
DIALAB SOLUTIONS S.R.L.
IDNO 1022600026511
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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®