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 040330 0171 Rev. 01

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

Product: **Reagents and reagent products for blood typing**

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 040330 0171 Rev. 01

Report No.: 713229332

Valid from: 2022-04-22
Valid until: 2025-05-26

Date, 2022-04-22

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Levința Alexandru
Date: 2025.07.21 12:13:51 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

REPUBLICA MOLDOVA, mun. CHIȘINĂU
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

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No. V7 040330 0171 Rev. 01

Model(s): **DiaMed-ID Micro Typing System ID-Cards (monoclonal Reagents)**

Facility(ies): DiaMed GmbH
Pra Rond 23, 1785 Cressier FR, SWITZERLAND

Parameters:

Id-n°:	Product-Name	Catalog REF:	Packaging Size:
--			
50012	DiaClon ABO/Rh for Patients	001044	4 x 12
		001043	24 x 12
		001046	60 x 12
		001045	112 x 12
50053	DiaClon ABD-Confirmation for Patients	001254	4 x 12
		001257	24 x 12
		001256	60 x 12
		001255	112 x 12
50053	DiaClon ABD-Confirmation	001255VC	112 x 12
50057	DiaClon ABD (DVI-) Confirmation for Patients	001284	4 x 12
		001287	24 x 12
		001286	60 x 12
		001285	112 x 12
50092	DiaClon ABO/D + Reverse Grouping	001234	4 x 12
		001237	24 x 12
		001236	60 x 12
		001235	112 x 12
50481	DiaClon ABO/D	001324	4 x 12
		001323	24 x 12
		001326	60 x 12
		001325	112 x 12

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No. V7 040330 0171 Rev. 01

50492	DiaClon ABO/D + DAT	001344	4 x 12
		001347	24 x 12
		001346	60 x 12
		001345	112 x 12
50601	DiaClon Complete	004614	4 x 12
	Crossmatch	004617	24 x 12
		004616	60 x 12
		004615	112 x 12
50682	DiaClon Type + Screen	002437	4 x 12
		002431	24 x 12
		002439	60 x 12
		002438	112 x 12
50961	DiaClon ABO/Rh	001047	4 x 12
	for Newborns DVI+	001048	24 x 12
		001049	60 x 12
		001050	112 x 12
51011	DiaClon ABO/Rh	001037	4 x 12
	for Donors	001033	24 x 12
		001039	60 x 12
		001038	112 x 12
51051	DiaClon ABD-	001134	4 x 12
	Confirmation for Donors	001133	24 x 12
		001136	60 x 12
		001135	112 x 12

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