



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

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





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

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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

50492	DiaClon ABO/D + DAT	001344	4 x 12
		001347	24 x 12
		001346	60 x 12
		001345	112 x 12
50601	DiaClon Complete Crossmatch	004614	4 x 12
		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 for Newborns DVI+	001047	4 x 12
		001048	24 x 12
		001049	60 x 12
		001050	112 x 12
51011	DiaClon ABO/Rh for Donors	001037	4 x 12
		001033	24 x 12
		001039	60 x 12
		001038	112 x 12
51051	DiaClon ABD- Confirmation for Donors	001134	4 x 12
		001133	24 x 12
		001136	60 x 12
		001135	112 x 12

