



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 0153 Rev. 01

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

Product: **Reagents and reagent products for blood typing
for the Rhesus- and Kell-System**

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 0153 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:V7_040330_0153_Rev_01)

Report No.: 713249328

Valid from: 2022-04-22

Valid until: 2025-05-26

Date, 2022-04-22

Christoph Dicks
Head of Certification/Notified Body



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 0153 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:
50110	DiaClon Rh-Subgroups + K		002124	4 x 12
			002127	24 x 12
			002126	60 x 12
			002125	112 x 12
50200	DiaClon Anti-K	002121	1 x 12	
50710	DiaClon Rh + K Pheno II		002224	4 x 12
			002227	24 x 12
			002226	60 x 12
			002225	112 x 12
50850	ID-DiaClon Anti-c		002151	1 x 12
			002154	4 x 12
52000	DiaClon Rh-Subgroups + C ^W + K		002134	4 x 12
			002137	24 x 12
			002136	60 x 12
			002135	112 x 12