



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 0157 Rev. 02

Manufacturer: **DiaMed GmbH**

Pra Rond 23
1785 Cressier FR
SWITZERLAND

Product: **Reagents for determining
the ABO blood group-system
Test cells for the ID-Micro Typing 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_0157_Rev_02

Report No.: 713249418

Valid from: 2022-04-25

Valid until: 2025-05-26

Date, 2022-04-25

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 0157 Rev. 02

Model(s): ID-DiaCell ABO
ID-DiaCell ABO/I, II
ID-DiaCell ABO/I, II, III

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

Parameters:	Id-n°:	Product-Name	Catalog	Packaging
			REF:	Size:
	--			
	06012	ID-DiaCell ABO A1	003620	1 x 10 ml
	06022	ID-DiaCell ABO A2	003621	1 x 10 ml
	06032	ID-DiaCell ABO B	003622	1 x 10 ml
	06042	ID-DiaCell ABO O	003623	1 x 10 ml
	45002	ID-DiaCell ABO / I-II *	003610	6 x 10 ml
	45012	ID-DiaCell ABO / I-II-III *	003618	6 x 10 ml
	45022	ID-DiaCell ABO A1, A2, B, O	003619	4 x 10 ml
	45082	ID-DiaCell ABO A1, A2, B	003617	3 x 10 ml
	45092	ID-DiaCell ABO A1, B	003624	2 x 10 ml
	45352	ID-DiaCell ABO A1, B, O	003615	3 x 10 ml

* These variants include cells for detection of irregular antibodies.