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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 0161 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 0161 Rev. 01

Report No.: 713249325 / 713249325-01

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

Date, 2022-04-22

Christoph Dicks
Head of Certification/Notified Body

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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EC Certificate

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No. V7 040330 0161 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:
45470	DiaClon ABO/Rh + Épreuve Sérique DiaClon Rh-Sousgroupes + K	001397	2 x 24 x 12
45480	DiaClon ABO/Rh + Épreuve Sérique DiaClon Rh-Sousgroupes + K	001398	2 x 60 x 12

consisting of

Id-n°:	Product-Name:	Catalog REF:	Packaging Size:
50411	DiaClon ABO/D + Reverse Grouping	001397E	24 x 12
		001396E	60 x 12
50115	DiaClon Rh-Subgroups + K	002127E	24 x 12
		002126E	60 x 12

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