ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 18 06 40330 153

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

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

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

Parameters: see attachment

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. See also notes overleaf.

Report No.: 713127462

Valid from: 2018-07-18
Valid until: 2023-07-17

Date, 2018-07-11

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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A1 / 04.11

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Attachment to Certificate no V7 18 06 40330 153
dated 2018-07-11

Product Service

Id-n°:	Product-Name	Catalog REF:	Packaging 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

Munich, CRT2, 2018-07-11

Stefan Preiß

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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