



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 02 40330 150

Manufacturer:**DiaMed GmbH**

Pra Rond 23
1785 Cressier FR
SWITZERLAND

**Product:****Reagents and reagent products for blood typing****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.:

713118826

Valid from:

2018-06-04

Valid until:

2023-06-03

**Date,** 2018-05-28

Stefan Preiß

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

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Product Service

Id-n°:	Product-Name	Catalog REF:	Packaging 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
50492	DiaClon ABO/D + DAT	001344 001347 001346 001345	4 x 12 24 x 12 60 x 12 112 x 12
50601	DiaClon Complete Crossmatch	004614 004617 004616 004615	4 x 12 24 x 12 60 x 12 112 x 12
50682	DiaClon Type + Screen	002437 002431 002439 002438	4 x 12 24 x 12 60 x 12 112 x 12
50961	DiaClon ABO/Rh for Newborns DVI+	001047 001048 001049 001050	4 x 12 24 x 12 60 x 12 112 x 12

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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

Munich, CRT2, 2018-05-28

S. Preiß

Stefan Preiß