



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

Page 1 of 3

Attachment to Certificate no V7 18 02 40330 150
dated 2018-05-28



Product Service

Id-n°:	Product-Name	Catalog REF:	Packaging Size
50012	DiaClon ABO/Rh for Patients	001044	4 x 12
		001043	24 x 12
		001046	60 x 12
		001045	112 x 12
50053	DiaClon ABD-Confirmation for Patients	001254	4 x 12
		001257	24 x 12
		001256	60 x 12
		001255	112 x 12
50053	DiaClon ABD-Confirmation	001255VC	112 x 12
50057	DiaClon ABD (DVI-) Confirmation for Patients	001284	4 x 12
		001287	24 x 12
		001286	60 x 12
		001285	112 x 12
50092	DiaClon ABO/D + Reverse Grouping	001234	4 x 12
		001237	24 x 12
		001236	60 x 12
		001235	112 x 12
50481	DiaClon ABO/D	001324	4 x 12
		001323	24 x 12
		001326	60 x 12
		001325	112 x 12
50492	DiaClon ABO/D + DAT	001344	4 x 12
		001347	24 x 12
		001346	60 x 12
		001345	112 x 12
50601	DiaClon Complete Crossmatch	004614	4 x 12
		004617	24 x 12
		004616	60 x 12
		004615	112 x 12
50682	DiaClon Type + Screen	002437	4 x 12
		002431	24 x 12
		002439	60 x 12
		002438	112 x 12
50961	DiaClon ABO/Rh for Newborns DVI+	001047	4 x 12
		001048	24 x 12
		001049	60 x 12
		001050	112 x 12

Attachment to Certificate no V7 18 02 40330 150
dated 2018-05-28



Product Service

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

Stefan Preiß