DiaMed GmbH
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CE Declaration of conformity

MANUFACTURER: ADDRESS:	**DiaMed GmbH** **Pra Rond 23** **1785 Cressier FR** **Switzerland** **Phone: +41(0)26 674 51 11**
EUROPEAN AUTHORIZED REPRESENTATIVE: ADDRESS:	**Bio-Rad** **3, Boulevard Raymond Poincaré** **92430 Marnes-la-Coquette** **FRANCE**
PRODUCT NAME:	**DiaClon ABO/Rh for Patients**
Id-n°:	**50012**
REF:	**001043 / 001044 / 001045 / 001046**

We hereby declare that the above mentioned product meets the provisions of the following Directive(s):

APPLICABLE DIRECTIVE:	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro Diagnostic medical devices
CLASSIFICATION:	Annex II List A
CONFORMITY ROUTE:	Annex IV
GMDN Code:	45308
Generic Device Group Term:	ABO/Rh(D) multiple blood grouping IVD, kit, agglutination
NOTIFIED BODY:	TÜV Product Service GmbH Ridlerstrasse 65-80339 München (Germany) CE-N° 0123
Annex IV.3 Full-Quality system EC Certificate N°:	V1 040330 0182 Rev. 01
EXPIRATION DATE:	26.05.2025
Annex IV.4 Design Examination EC Certificate N°:	V7 040330 0171 Rev. 01
EXPIRATION DATE :	26.05.2025

Name:	*Function:*	*Issued in:*	*Date:*	*Signature*
Galéa Diane	Site Quality Management Representative	Cressier FR	19.05.2022	

Digitally signed by Levința Alexandru
Date: 2025.07.21 12:12:08 EEST
Reason: MoldSign Signature
Location: Moldova

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