



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 Rh-Subgroups + K**
Id-n°: **50110**
REF: **002124 / 002127 / 002126 / 002125**

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: 45309

Generic Device Group Term: Rhesus (Rh) phenotype (CcDEe)/Kell phenotype 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 0153 Rev. 01

EXPIRATION DATE : 26.05.2025

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