



## Declaration of conformity

MANUFACTURER: **DiaMed GmbH**  
ADDRESS: **Pra Rond 23**  
**1785 Cressier FR**  
**Switzerland**  
**Phone: +41(0)26 674 51 11**

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 Directives:

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

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Name:	Function:	Issued in:	Date:	Signature
Galéa Diane	Site Quality Management Representative	Cressier FR	12.12.2017	

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