



Declaration of conformity

MANUFACTURER: **DiaMed GmbH**
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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

Name:
Galéa Diane

Function:
Site Quality Management
Representative

Issued in:
Cressier FR

Date:
12.12.2017

Signature