



DiaMed GmbH
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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: **LISS/Coombs**
Id-n°: **50531**
REF: **004014 / 004017 / 004016 / 004015**

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 B

CONFORMITY ROUTE: Annex IV


GMDN Code: 52731

Generic Device Group Term: Polyspecific antihuman globulin/complement IVD, antibody, 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

| Name: | Function: | Issued in: | Date: | Signature |
|-------------|--|-------------|------------|---|
| Galéa Diane | Site Quality Management Representative | Cressier FR | 12.05.2022 |  |