

DiaMed GmbH Pra Rond 23

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Declaration of conformity

MANUFACTURER: DiaMed GmbH

ADDRESS:

Pra Rond 23

1785 Cressier FR

Switzerland

Phone: +41(0)26 674 51 11

PRODUCT NAME:

DiaClon ABO/Rh for Patients

ld-n°:

50012

REF:

001043 / 001044 / 001045 / 001046

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:

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

Name:

Function:

Issued in:

Date:

Sianature

Galéa Diane

Representative

Site Quality Management

Cressier FR

29.03.2017