

DECLARATION OF CONFORMITY

Manufacturer:

CE-IMMUNDIAGNOSTIKA GmbH
Karl-Landsteiner-Straße 6, D-69151 Neckargemuend
Tel. +49 6223-80094 00 Fax +49 6223-80094 99

Revision: 02/06-2021

Valid until: **26/05-2024**

Product Name:

Anti-D

Product-Code:

D-RUM-0010-01, D-RUM-0010-05, D-RUM-0010-05, D-RUM-0010-10, D-RUM-0010-20, D-RUM-0010-50

Clone:

Klon RUM-1

EU-Classification:

List A or List B

(Annex II Directive 98/79/EC)

List A

As exclusively responsible manufacturer we herewith declare that the above-mentioned products meet the provisions of the Council Directive Annex I 98/79/EC on in vitro diagnostic Medical Devices. All supporting documentation is retained under the Premises of the Manufacturer.

Supervising authority :

Regierungspräsidium Karlsruhe

Notified Body:

mdc medical device certification GmbH

Identification Number: 0483

Kriegerstraße 6
70191 Stuttgart
Germany

Conformity Assessment According to:

Annex IV.4 + 6 Directive 98/79/EC

Certificate No.:

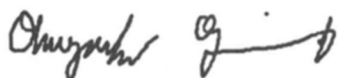
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Place, Date of Issue:

Neckargemuend, 27.09.2021

Signature of QMB:

(Angela Grajek)



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