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:	01/06-2021
Valid until:	**26/05-2024**

Product Name:	**Anti-B LB-2**
Product-Code:	B-LB2-0010-01, B-LB2-0010-05, B-LB2-0010-10, B-LB2-0010-50
Clones:	LB-2
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: Identification Number: 0483	mdc medical device certification GmbH Kriegerstraße 6 70191 Stuttgart Germany
Conformity Assessment According to:	Annex IV.4 + 6 Directive 98/79/EC
Certificate No.:	**D1415300017**
Place, Date of Issue:	Neckargemuend, 01/07.2021

Signature of QMB:
(Angela Grajek)

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