NovaTec Immundiagnostica GmbH

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Declaration of Conformity

We NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product

NovaLisa® Cytomegalovirus (CMV) IgM (CMVM0110)

and the following components:

MTP	Microtiterplate
DIL M	IgM Sample Dilution Buffer
SOLN STOP	Stop Solution
WASH BUF 20x	Washing Buffer (20x conc.)
CONJ	Conjugate
SUB TMB	TMB Substrate Solution
CONTROL -	Negative Control
CUT OFF	Cut-off Control
CONTROL +	Positive Control

of annex II list B are in accordance with the requirements of the IVD Directive 98/79/EC of the European Parliament and Council of Oct.27, 1998 in regard to in vitro diagnostic medical devices (IVDs).

The accordance was shown by conformity assessment procedures in

Annex IV.3

by participation of the notified body:

mdc medical device certification GmbH (0483)
Kriegerstrasse 6
70191 Stuttgart.

valid until: 2023-12-03

Dietzenbach 2020.07.22

Jennifer Völger
Quality Management Representative

The conformity of the above mentioned product is checked at least every 3 years. This is documented by rechecking and signing the general requirements.