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® Brucella IgM (BRUM0050)

and the following components:

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

is 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 III (2-5)

Dietzenbach 2019-02-18

Britta-Maria Duchmann Berlie
Chief Operations Officer

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