NovaTec Immundiagnostica GmbH

Declaration of Conformity

We NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

Digitally signed by Petuhova Iuliana
Date: 2019.11.11 16:57:56 EET
Reason: MoldSign Signature
Location: Moldova

herewith declare under our own responsibility, that the product

NovaLisa® Epstein-Barr Virus (VCA) IgM (EBVM0150)

and the following components:

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