NovaTec Immundiagnostica GmbH

Declaration of Conformity

We NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product

NovaLisa® Candida albicans IgG (CANG0060)

and the following components:

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

Digitally signed by Munteanu Iuliana
Date: 2019.06.19 16:06:16 EEST
Reason: MoldSign Signature
Location: Moldova

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.