

Declaration of Conformity

We NovaTec Immundiagnostica GmbH
 Waldstraße 23 A6
 63128 Dietzenbach
 Germany

herewith declare under our own responsibility, that the product

NovaLisa[®] Anti-TG (ATG1010)

and the following components:

MTP	TG Coated Microplate (IgG)
DIL G	IgG Sample Diluent
SOLN STOP	Stop Solution
WASH BUF 20x	Washing Buffer (20x conc.)
CONJ	TG anti-IgG Conjugate
SUB TMB	TMB Substrate Solution
CONTROL L	Avidity Cytomegalovirus (CMV) Virus IgG Control Low
CONTROL H	Avidity Cytomegalovirus (CMV) Virus IgG Control High
CAL A - F	Anti-TG Standards

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.