

Declaration of Conformity

We NovaTec Immundiagnostica GmbH
Waldstraße 23 A6
63128 Dietzenbach
Germany

herewith declare under our own responsibility, that the product

NovaLisa® Giardia lamblia antigen (GIA0160S)

and the following components:

GMTP	Coated Microplate
GDIL	Sample Diluent
GSOLN STOP	Stop Solution
GWASH BUF 10x	Washing Buffer (10x conc.)
GCONJ	Conjugate
GSUB TMB	TMB Substrate Solution
GCONTROL -	Negative Control
GCONTROL +	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.