

EC DECLARATION OF CONFORMITY

We declare that for the following products of NovaTec Immundiagnostica GmbH (manufacturer),
Waldstraße 23 A6, 63128 Dietzenbach, Germany

have been subjected to a conformity assessment in accordance with Council Directive 98/79/EC
concerning in vitro diagnostic medical devices.

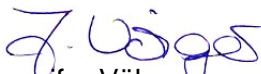
Conformity assessment procedure:

General IVD Directive 98/79/EC, Annex III

Cat. No.	Product name	Classification	GMDN code
AfG096	Aspergillus fumigatus IgG	IVD	52002
AfM096	Aspergillus fumigatus IgM	IVD	52006
BruG96	Brucella IgG	IVD	50619
BruM96	Brucella IgM	IVD	50623
CaA096	Candida albicans IgA	IVD	52052
CaG096	Candida albicans IgG	IVD	52056
CaM096	Candida albicans IgM	IVD	52061
EchG96	Echinococcus IgG	IVD	52219
LpG096	Legionella pneumophila IgG	IVD	51068
LpM096	Legionella pneumophila IgM	IVD	51072
LiG096	Leishmania infantum IgG	IVD	52274
SmG096	Schistosoma mansoni IgG	IVD	52385
SmM096	Schistosoma mansoni IgM	IVD	63902

Dietzenbach

2022-09-02


Jennifer Völger

Quality Management