

EU DECLARATION OF CONFORMITY

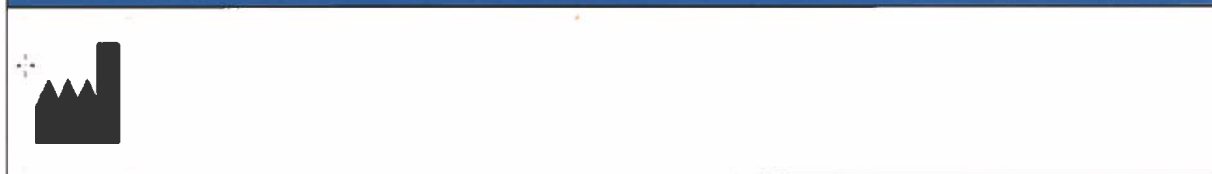
Product

Product name/ Trade name	REF	Basic UDI-DI
IgG Konjugat/Conjugate (anti-human) ELISA <div style="border: 1px solid black; display: inline-block; padding: 2px;">CONJ</div> <div style="border: 1px solid black; display: inline-block; padding: 2px;">IgG</div>	131101	++E654131001V01BT
IgM Konjugat/Conjugate (anti-human) ELISA <div style="border: 1px solid black; display: inline-block; padding: 2px;">CONJ</div> <div style="border: 1px solid black; display: inline-block; padding: 2px;">IgM</div>	131201	
IgA Konjugat/Conjugate (anti-human) ELISA <div style="border: 1px solid black; display: inline-block; padding: 2px;">CONJ</div> <div style="border: 1px solid black; display: inline-block; padding: 2px;">IgA</div>	131301	
IgA 2 Konjugat/Conjugate (anti-human) ELISA <div style="border: 1px solid black; display: inline-block; padding: 2px;">CONJ</div> <div style="border: 1px solid black; display: inline-block; padding: 2px;">IgA2</div>	131601	

Intended purpose

Detection/Measurement	For use with ELISA products from Virotech Diagnostic
Function	Reagent contains an enzyme conjugate that binds to the immune complex of antibody and antigen fixed in the MTP
Specific information about	n/a
Automated	n/a
Type	n/a
Specimen	Human Serum or Plasma/CSF
Testing population	n/a
Intended user	Specialised personnel in laboratories

Manufacturer



Virotech Diagnostics GmbH
Waldstrasse 23 A2
63128 Dietzenbach
Germany

SRN: DE-MF-000025733

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Regulation:

Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices

CLASSIFICATION A

Conformity Assessment Procedure

ANNEX II+III apply

Common Specifications n/a

Valid from lot:

CONJ IgX

X: IgG: 20661; IgM: 20132; IgA: 21531; IgA2: 12512

Valid until: 2023-08-31

VIROTECH Diagnostics GmbH

Waldstrasse 23 A2

63128 Dietzenbach

Tel.: +49 6074 94699-0

Signature



Dietzenbach

Issued in

2022-08-31

Date of issue

Rodrigo Berlie

Name

Managing Director

Function