EU DECLARATION OF CONFORMITY

Product		
Product name/Trade name	**REF**	**Basic UDI-DI**
IgG Konjugat/Conjugate (anti-human) ELISA CONJ | IgG	131101	
IgM Konjugat/Conjugate (anti-human) ELISA CONJ | IgM	131201	
IgA Konjugat/Conjugate (anti-human) ELISA CONJ | IgA	131301	++E654131001V01BT
IgA 2 Konjugat/Conjugate (anti-human) ELISA CONJ | IgA2	131601	

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

RISK CLASS

☒ A ☐ B ☐ C ☐ D

CONFORMITY ROUTE

☐ ANNEX IX Technical Documentation Examination — **EU CERTIFICATE #:**
Name of Notified Body: mdc medical device certification GmbH
Notified Body Identification: 0483

☐ ANNEX IX Full Quality System — **EU CERTIFICATE #:**
Name of Notified Body: mdc medical device certification GmbH
Notified Body Identification: 0483

☐ ANNEX X Type Examination — **EU CERTIFICATE #:**
Name of Notified Body: mdc medical device certification GmbH
Notified Body Identification: 0483

☐ ANNEX XI Production Quality System — **EU CERTIFICATE #:**
Name of Notified Body: mdc medical device certification GmbH
Notified Body Identification: 0483

☒ ANNEX II+III

Common Specifications (CS): n/a
Common Specifications have not been issued for this product.

DocuSigned by:
Marcello Salio
B462E9960D47494...

Signature	Issued in	Date of issue
	Dietzenbach	2023-06-22

Name	Function
Marcello Salio	Managing Director