

EU DECLARATION OF CONFORMITY

Product					
Product name/Trade name	REF	Basic UDI-DI			
IgA Konjugat/Conjugate (anti-human) LINE	WE400.42	++E654WE40002V01KJ			
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CONJ	100x	IgA			
IgG Konjugat/Conjugate (anti-human) LINE	WE400.62				
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CONJ	100x	IgG			
IgM Konjugat/Conjugate (anti-human) LINE	WE400.82				
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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

- | | |
|---|---|
| <input type="checkbox"/> ANNEX IX Technical Documentation Examination | <p>EU CERTIFICATE #:
 Name of Notified Body: mdc medical device certification GmbH
 Notified Body Identification: 0483</p> |
| <input type="checkbox"/> ANNEX IX Full Quality System | <p>EU CERTIFICATE #:
 Name of Notified Body: mdc medical device certification GmbH
 Notified Body Identification: 0483</p> |
| <input type="checkbox"/> ANNEX X Type Examination | <p>EU CERTIFICATE #:
 Name of Notified Body: mdc medical device certification GmbH
 Notified Body Identification: 0483</p> |
| <input type="checkbox"/> ANNEX XI Production Quality System | <p>EU CERTIFICATE #:
 Name of Notified Body: mdc medical device certification GmbH
 Notified Body Identification: 0483</p> |
| <input checked="" type="checkbox"/> ANNEX II+III | |

Common Specifications (CS): n/a

Common Specifications have not been issued for this product.

DocuSigned by:

 Signature

Dietzenbach
 Issued in

2023-06-22
 Date of issue

Marcello Salio
 Name

Managing Director
 Function