

# EU DECLARATION OF CONFORMITY

## Product

| Product name/ Trade name  | REF  | Basic UDI-DI |     |          |                    |
|---|------|--------------|-----|----------|--------------------|
| IgG Konjugat/Conjugate (anti-human) LINE<br><table border="1"> <tr> <td>CONJ</td> <td>100x</td> <td>IgG</td> </tr> </table> | CONJ | 100x         | IgG | WE400.62 | ++E654WE40002V01KJ |
| CONJ  | 100x | IgG          |     |          |                    |
| IgM Konjugat/Conjugate (anti-human) LINE<br><table border="1"> <tr> <td>CONJ</td> <td>100x</td> <td>IgM</td> </tr> </table> | CONJ | 100x         | IgM | WE400.82 |                    |
| CONJ  | 100x | IgM          |     |          |                    |
| IgA Konjugat/Conjugate (anti-human) LINE<br><table border="1"> <tr> <td>CONJ</td> <td>100x</td> <td>IgA</td> </tr> </table> | CONJ | 100x         | IgA | WE400.42 |                    |
| CONJ  | 100x | IgA          |     |          |                    |

## Intended purpose

|                            |   |
|----------------------------|---|
| Detection/Measurement      | For use with LINE products from Virotech Diagnostic   |
| Function                   | Reagent contains an enzyme conjugate that binds to the immune complex of antibody and antigen fixed on the NC |
| 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**

|                       |          |
|-----------------------|----------|
| <b>CLASSIFICATION</b> | <b>A</b> |
|-----------------------|----------|

| Conformity Assessment Procedure |       |
|---------------------------------|-------|
| ANNEX II+III                    | apply |
| Common Specifications           | n/a   |

Valid from lot:

|      |      |     |
|------|------|-----|
| CONJ | 100x | IgX |
|------|------|-----|

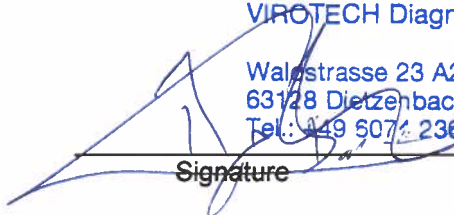
X: **G**:13161; **M**: 20111; **A**: 20591

Valid until: 2023-08-31

VIROTECH Diagnostics GmbH

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Dietzenbach
2022-08-31  
 Signature Issued in Date of issue

Rodrigo Berlie
Managing Director  
 Name Function