

EU DECLARATION OF CONFORMITY

Product

Product name/ Trade name	REF	Basic UDI-DI
Citrat Stopplösung/Stopping Solution ELISA STOP	141101	++E654141101V02CV

Intended purpose

Detection/Measurement	For use with ELISA products from Virotech Diagnostic
Function	Reagent for stopping the colour development of the ELISA test sample by enzyme activity
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
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Conformity Assessment Procedure

ANNEX II+III	apply
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Common Specifications	n/a
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Valid from lot: 13401

Valid until: 2023-08-31

DocuSigned by:

Marcello Salio

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Signature

Dietzenbach

Issued in

2022-12-15

Date of issue

Marcello Salio

Name

Managing Director

Function