

EU DECLARATION OF CONFORMITY

Product		
Product name/Trade name	REF	Basic UDI-DI
Citrat Stopplösung/Stopping Solution ELISA STOP	141101	++E654141101V02CV
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
B402E9960D47494...

Signature

Dietzenbach

Issued in

2023-06-22

Date of issue

Marcello Salio

Name

Managing Director

Function