EU DECLARATION OF CONFORMITY

Product

Product name/ Trade name	REF	Basic UDI-DI
TMB-Substrat/ Substrate ELISA SUBS TMB RTU	151101	++E654151101V02DG

Intended purpose

Detection/Measurement	For use with ELISA products from Virotech Diagnostic
Function	Reagent for 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**

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

Valid from lot: 13401

Valid until: 2023-08-31

DocuSigned by:
Marcello Salio
B462E9960D47494...

Signature	Issued in	Date of issue
	Dietzenbach	2022-12-15

Name	Function
Marcello Salio	Managing Director