EU DECLARATION OF CONFORMITY

Product		
Product name/Trade name	**REF**	**Basic UDI-DI**
TMB-Substrat/ Substrate ELISA SUBS | TMB | RTU	151101	++E654151101V02DG
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
B462E9960D47494...

Signature	Issued in	Date of issue
	Dietzenbach	2023-06-22

Name	Function
Marcello Salio	Managing Director