EU DECLARATION OF CONFORMITY

Product		
Product name/Trade name	**REF**	**Basic UDI-DI**
RF-SorboTech – 2ml RFSORBO	161101	++E65416110V01N6
RF-SorboTech – 10ml RFSORBO	161102	
RF-SorboTech – 80x RFSORBO	B/300.00	

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
B462E9060D47494...

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

Name	Function
Marcello Salio	Managing Director