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	

Intended purpose

Detection/Measurement	For use with ELISA products from Virotech Diagnostic
Function	Accessories for all VIROTECH IgM ELISA products and for the VIROTECH Bordetella pertussis Toxin (PT) IgA ELISA in sample preparation
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: 2 ml RFSORBO : 20471; 10 ml RFSORBO : 20191; 80x RFSORBO: 20302-01

Valid until: 2023-08-31

VIROTECH Diagnostics GmbH
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GOLD STANDARD DIAGNOSTICS

Signature	Dietzenbach	2022-08-31
	Issued in	Date of issue

Rodrigo Berlie	Managing Director
Name	Function