


# EU DECLARATION OF CONFORMITY

Product		
<b>Product name/Trade name</b>	<b>REF</b>	<b>Basic UDI-DI</b>
PBS-Waschlösung/ Washing Solution ELISA <span style="border: 1px solid black; padding: 2px;">WASHBUF</span> <span style="border: 1px solid black; padding: 2px;">20x</span>	141201	++E654141201V02DA
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**

- |   |   |
|---|---|
| <input type="checkbox"/> ANNEX IX Technical Documentation Examination | <p><b>EU CERTIFICATE #:</b><br/>                 Name of Notified Body: mdc medical device certification GmbH<br/>                 Notified Body Identification: 0483</p> |
| <input type="checkbox"/> ANNEX IX Full Quality System                 | <p><b>EU CERTIFICATE #:</b><br/>                 Name of Notified Body: mdc medical device certification GmbH<br/>                 Notified Body Identification: 0483</p> |
| <input type="checkbox"/> ANNEX X Type Examination                     | <p><b>EU CERTIFICATE #:</b><br/>                 Name of Notified Body: mdc medical device certification GmbH<br/>                 Notified Body Identification: 0483</p> |
| <input type="checkbox"/> ANNEX XI Production Quality System           | <p><b>EU CERTIFICATE #:</b><br/>                 Name of Notified Body: mdc medical device certification GmbH<br/>                 Notified Body Identification: 0483</p> |
| <input checked="" type="checkbox"/> ANNEX II+III                      |   |

Common Specifications (CS): n/a  
 Common Specifications have not been issued for this product.

DocuSigned by:  
  
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Signature	Dietzenbach Issued in	2023-06-22 Date of issue
Marcello Salio Name	Managing Director Function	