


EU DECLARATION OF CONFORMITY

Product		
Product name/Trade name Verd.-/ Waschpuffer Dilution- /Washbuffer LINE <div style="display: flex; justify-content: space-between; margin-top: 5px;"> DWBUF 10x </div>	<div style="border: 2px solid black; padding: 2px; width: fit-content; margin: 0 auto;">REF</div> WE200.08	Basic UDI-DI ++E654WE20008V02KQ
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 | EU CERTIFICATE #:
Name of Notified Body: mdc medical device certification GmbH
Notified Body Identification: 0483 |
| <input type="checkbox"/> ANNEX IX Full Quality System | EU CERTIFICATE #:
Name of Notified Body: mdc medical device certification GmbH
Notified Body Identification: 0483 |
| <input type="checkbox"/> ANNEX X Type Examination | EU CERTIFICATE #:
Name of Notified Body: mdc medical device certification GmbH
Notified Body Identification: 0483 |
| <input type="checkbox"/> ANNEX XI Production Quality System | EU CERTIFICATE #:
Name of Notified Body: mdc medical device certification GmbH
Notified Body Identification: 0483 |
| <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