

## **EC Declaration of Conformity**

as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices

**Manufacturer:** Roche Diagnostics GmbH  
**Address:** Sandhofer Strasse 116  
 68305 Mannheim  
 Germany

**Single Registration Number:** TBD (application filed; confirmation pending)

**Authorized Representative:** N/A  
**Address:**

**Single Registration Number:** N/A

Roche Diagnostics GmbH declares, under the sole responsibility, that the product/the product line

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
BILD2	05168384190	7613336003309V
BILD2	05168384214	7613336003319X
BILD2	05589061190	761333600343A6
BILD2	05589134190	761333600344A8
BILD2	08056951190	7613336005109Z

**Risk Class:**  A  B  C  D

**Conformity Route:**

- Self-Declaration of Conformity (Class A)
- Technical Documentation Assessment Class B/C – Annex IX
- Technical Documentation Assessment Class D – Annex IX
- Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX
- Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX
- Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX

**Certificates:**

- EU QM Certificate No.: V12 010283 0639
- EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):

**Other:**  Common Specifications:

**Notified Body (NB) Name:** TÜV Süd Product Service GmbH  
**NB Address:** Ridlerstraße 65  
 80339 Munich  
 Germany  
**NB Ident. No.:** 0123

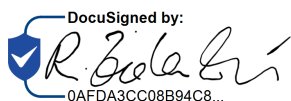
*to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.*

Mannheim, 20 April 2021

Roche Diagnostics GmbH

*ppa./on behalf of the company*

*i.V./on behalf of the company*

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Ralf Zielenski  
Head of Quality  
Centralised and Point of Care Solutions

DocuSigned by:  
  
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Dr. Joachim Hoch  
Director Global Regulatory Affairs  
Centralised and Point of Care Solutions

*Contact address:*

Roche Diagnostics GmbH  
Abt./Dept. Global Regulatory Affairs  
Sandhofer Strasse 116  
D-68305 Mannheim

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Product Name	Cat. No.	Basic UDI-DI
BILT3	05795397190	761333600348AG
BILT3	05795419190	761333600349AJ
BILT3	05795648190	761333600350A3
BILT3	08056960190	761333600511A3

**Risk Class:**  A  B  C  D

**Conformity Route:**

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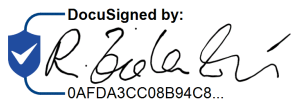
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 23 April 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

i.V./on behalf of the company

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