



## Document Information:

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Signed By:	deichfub (Beate Deichfuss {DQRDB})
Role:	Approver
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Signed Date:	15-Sep-2023 11:17:03 (UTC)

## **EU 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:** DE-MF-000006260

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

Product Name	Cat. No.	Basic UDI-DI
ECO-D	05422485190	761333601366AR

**Intended Use:**

EcoTergent is an additive to the reaction bath to reduce surface tension on cobas c 311 systems.

Product Name	Cat. No.	Basic UDI-DI
ECO-D	05907543190	761333601389B5
ECO-D	05907543214	761333601390AN
ECO-D	06544410190	761333601435AK
ECO-D	08063354190	761333601533AL

**Intended Use:**

EcoTergent is an additive to the reaction bath to reduce surface tension on cobas c systems.

**Risk Class:**  A  B  C  D

**Conformity Route:**  Self-Declaration of Conformity (Class A)  
 Self-Declaration of Conformity after Notified Body involvement for sterile manufacturing conditions acc. Art. 48 (10) (Class A sterile)  
 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.:  
 EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):

**Other:**  Common Specifications:

Notified Body (NB) Name: N/A  
NB Address:

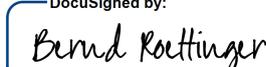
NB Ident. No.: N/A

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

Mannheim, 11 September 2023

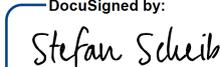
Roche Diagnostics GmbH

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