# *EC Declaration of Conformity*

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

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|---|---|
| *Manufacturer*: | Roche Diagnostics GmbH |
| *Address:* | Sandhofer Strasse 116<br>68305 Mannheim<br>Germany |
| *Single Registration Number:* | DE-MF-000006260 |

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

| | |
|---|---|
| *Product name*: | **cobas u 411 urine analyzer** |
| *Cat.-No.:* | **04906969001** |
| *Basic UDI-DI:* | **7613336020319W** |
| *Risk Class:* | ☒ *A* ☐ *B* ☐ *C* ☐ *D* |
| *Conformity Route:* | ☒ *Self-Declaration of Conformity (Class A)*<br>☐ *Technical Documentation Assessment Class B/C – Annex IX*<br>☐ *Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX*<br>☐ *Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX*<br>☐ *Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX* |
| *Certificates:* | ☐ *EU QM Certificate No.:*<br>☐ *EU Technical Documentation Assessment Certificate No. (Near-Patient Testing, Self-Testing and Companion Diagnostics):* |
| *Other:* | ☐ *Common Specifications:* |
| *Notified Body (NB) Name:*<br>*NB Address:* | *N/A* |
| *NB Ident. No.:* | *N/A* |

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



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*and*

- *fulfills the requirements of DIRECTIVE 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.*

Mannheim, 8 November 2021

Roche Diagnostics GmbH

ppa./ *on behalf of the company*

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Ralf Zielenski
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Ralf Zielenski
Head Q&R Compliance, PRRC RDG
Centralised and Point of Care Solutions

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

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