

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: DE-MF-000006260

Authorized Representative: N/A
Address:

Single Registration Number: N/A

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

Product name: **Precinorm PUC**
Cat.-No.: **03121313122**
Basic UDI-DI: **761333600582AS**
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, 8 June 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

i.V./on behalf of the company

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