

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, under the sole responsibility, declares that the product/the product line

Product Name	Cat. No.	Basic UDI-DI
Elecsys Insulin	12017547122	761333600744AU
Elecsys Insulin	12017547214	761333602084AK
Elecsys Insulin	07027559190	761333600615AG
Elecsys Insulin	07027559214	761333602058AJ
Insulin CalSet	12017504122	761333600743AS

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 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. (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, 27 October 2022

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:

59311CC1CDA8480...

Dr. Christina Schmid
Head of Pre-Market Quality Core Lab

ppa./on behalf of the company

DocuSigned by:

FC5EDEC1054B44C...

Dr. Stefan Scheib
Global Head of Regulatory Affairs, Core Lab

Contact address:

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Abt./Dept. Global Regulatory Affairs
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68305 Mannheim
Germany



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Insulin CalSet	12017504122	761333600743AS

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 B/C/D for Self-Testing – Annex IX
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Conformity Route:

☐ Self-Declaration of Conformity (Class A)
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