

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

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

Product name: Sodium Electrode Conditioner

Cat.-No.: 03110362180

Basic UDI-DI: 761333601127A5

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, 23 May 2022

Roche Diagnostics GmbH

ppa./on behalf of the company

i.V./on behalf of the company

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

Dr. Thomas Mall
Speciality Sub-Chapter Lead,
Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

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Sandhofer Strasse 116
D-68305 Mannheim

EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang III der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998
as per Annex III of Directive 98/79/EC of the European Parliament and Council of 27 October 1998

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: Roche Professional Diagnostics
Sandhofer Strasse 116
68305 Mannheim
Germany

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie (bei rezepturgleichen Produkten)
Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)

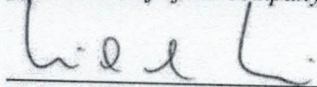
Produktname/Product name: **Cleaning Solution**
Art.-Nr./Id. No.: 03111555180

Beschreibung/Description: The Cleaning Solution is intended to be used for cleaning of the
9180 Electrolyte Analyzer..

auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom
27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt
vermarktet werden soll) über In-vitro-Diagnostica entspricht.
*to which this declaration relates fulfils the requirements of EC Directive 98/79/EC of the Council of 27 October
1998 (and its relevant transposition into the national laws of the Member States in which the device is intended to
be placed on the market) concerning in-vitro diagnostic devices.*

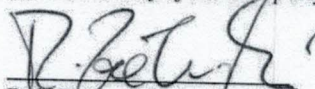
Mannheim, 01. Sep. 2014

Roche Diagnostics GmbH
ppa./on behalf of the company



Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

Roche Diagnostics International Ltd
ppa./on behalf of the company



Ralf Zielenski
Head of Quality GPS and RDI
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Product Name	Cat. No.	Basic UDI-DI
Deproteinizer	03110435180	761333602965BU

Intended Use:

The Deproteinizer (Mat. No. 03110435180) is intended to be used by professional users in near-patient testing and laboratory environment with the cobas b 221 system, the 9180 Electrolyte Analyzer and the cobas ISE neo Analyzer for the periodic external cleaning or decontamination of the measuring system in manual or automatic workflows. For the 9180 Electrolyte Analyzer, the Deproteinizer is used for the regular decontamination of surfaces of the analyzer, including the front door and the areas around the measuring chamber window. Additionally, it is used for the cobas b 221 system for the decontamination of the waste separator, T&D disk, tubing paths and after emptying the W Waste Container to wipe the exterior, as well as for decontamination of the measuring chamber when this is contaminated (protein deposits) or when sample path components have to be exchanged.

Furthermore, the Deproteinizer is intended to be used with the cobas ISE neo Analyzer for cleaning the ISE flow path.

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, 5 April 2024

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

Dr. Bernd Röttinger
Head of Pre-Market Quality Point of Care

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

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