

# EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

## IVDR 759872 R000

**Manufacturer:** RECIPE Chemicals + Instruments GmbH

**Address:**

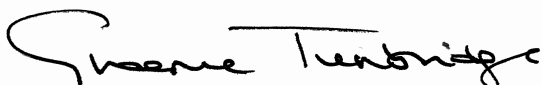
Dessauerstraße 3  
80992 München  
Germany

**Single Registration Number:** DE-MF-000032553

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-03-25**

Current Issue Date: **2025-11-18**

Starting Validity Date: **2025-11-18**

Expiry Date: **2030-03-24**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

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### Device Schedule: Class D, C and B devices

#### Class C Devices

W0101 – Clinical Chemistry

IVP 3003 – In vitro diagnostic devices which require knowledge regarding chromatography

#### Intended purpose

In vitro diagnostic medical devices intended for newborn screening and therapeutic drug monitoring

#### Class B Devices

IVR 0605 – Devices intended to be used for monitoring of levels of medicinal products, substances or biological components

IVR 0608 – Devices intended to be used for screening, determination or monitoring of physiological markers

#### Intended purpose

In vitro diagnostic medical devices intended for the monitoring of levels of medicinal products, substances or biological components

In vitro diagnostic medical devices intended to be used for screening, determination, or monitoring of physiological markers

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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.  
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### Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
2025-03-25	3559920	Issued
Current	30584287	Amended – Class B IVR 0605 intended purpose aligned to device category description. Class C W0102 + IVP 3003 EMDN code corrected to W0101 and combined with existing group.



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