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: **2025-03-25**

Starting Validity Date: **2025-03-25**

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

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Device Schedule: Class D, C and B devices

Class C Devices	Intended purpose
W0102 – Immunochemistry (Immunology) IVP 3003 – In vitro diagnostic devices which require knowledge regarding chromatography	Chromatography in vitro diagnostic medical devices intended for therapeutic drug monitoring.
W0101- Clinical Chemistry IVP 3003 – In vitro diagnostic devices which require knowledge regarding chromatography	Chromatography/spectrometry in vitro diagnostic medical devices intended for newborn screening for amino acids and acylcarnitines from dried blood spots

Class B Devices	Intended purpose
IVR 0605 – Devices intended to be used for monitoring of levels of medicinal products, substances or biological components	Chromatography/spectrometry in vitro diagnostic medical devices intended for the monitoring of benzodiazepines.
IVR 0608 – Devices intended to be used for screening, determination or monitoring of physiological markers	Chromatography/spectroscopy in vitro diagnostic medical devices intended to be used for screening, determination or monitoring of physiological markers.

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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)

Date	Reference Number	Action
Current	3559920	Issued

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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.

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 389 Chiswick High Road, London, W4 4AL, UK.
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