By Royal Charter

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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Device Schedule: Class D, C and B devices

Class C Devices	Intended purpose
W0101 – Clinical Chemistry IVP 3003 – In vitro diagnostic devices which require knowledge regarding chromatography	In vitro diagnostic medical devices intended for newborn screening and therapeutic drug monitoring

Class B Devices	Intended purpose
IVR 0605 – Devices intended to be used for monitoring of levels of medicinal products, substances or biological components	In vitro diagnostic medical devices intended for the 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	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
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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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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