EU Quality Management System Certificate

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

IVDR 781169 R000

Manufacturer: Promise Proteomics

Address:
7 Parvis louis neel
BHT 52A - CS20050
Grenoble CEDEX 9
38040
France

Single Registration Number: FR-MF-000027377

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: **2024-10-23**

Current Issue Date: **2024-10-23**

Starting Validity Date: **2024-10-23**

Expiry Date: **2029-10-22**

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Device Schedule: Class D, C and B devices

Class B devices	Intended purpose
IVR0605- Devices intended to be used for monitoring levels of medicinal products, substances or biological components.	Kit for preparation of liquid chromatography mass spectrometry (LC-MS) assays, including calibrators and controls, intended to be used for monitoring of therapeutic monoclonal antibodies (mAbs), therapeutic proteins or Anti-Drug-Antibodies (ADA) against therapeutic monoclonal antibodies.

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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	3792336	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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