

EU Quality Management System Certificate

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

IVDR 803746 R002

Manufacturer: Radox Laboratories Limited

Address:

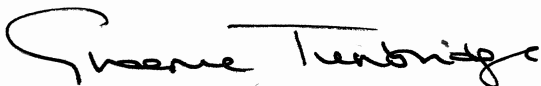
55 Diamond Road
Crumlin
County Antrim
BT29 4QY
United Kingdom

Single Registration Number: XI-MF-000028410

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: **2024-12-12**

Current Issue Date: **2026-10-01**

Starting Validity Date: **2026-10-01**

Expiry Date: **2029-12-11**

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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 B Devices	Intended purpose
IVR 0701 – Devices which are controls without a quantitative assigned value	In vitro diagnostic controls without a quantitative assigned value to be used for immunoassays and biochemistry assays for the detection of physiological markers.
IVR 0608 – Devices intended to be used for screening, determination or monitoring of physiological markers	In vitro diagnostic immunoassays, calibrators and controls intended for the determination of physiological markers.
Class C Devices	Intended purpose
W0102 – Immunochemistry (Immunology) IVP 3007 – In vitro diagnostic devices which require knowledge regarding immunoassays	In vitro diagnostic immunoassays and controls intended for the determination of physiological markers and medicinal products and immunoassay controls for cancer markers.
W0106 – Genetic testing IVP 3011 – In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	In vitro diagnostic device for qualitative genotyping intended for the prediction of genetic disease.
W0102 – Immunochemistry (Immunology) IVP 3002 – In vitro diagnostic devices which require knowledge regarding biochemistry	In vitro diagnostic calibrators and controls intended for the determination of physiological markers, medicinal products and cancer 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
2024-12-12	30096562	Issued
2025-02-14	30366865	Supplemented – Addition of: Device Category: Class B IVR 0608 Generic Device Group: Class C W0102, IVP 3007
2025-10-16	30522581	Supplemented – Addition of Generic Device Group: Class C W0106 IVP 3011
2026-09-04	30787913	Supplemented – Addition of Generic Device Group Class C W0102 IVP 3002
Current	30817997	Amended – Removal of EU Authorised Representative

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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.
A Member of the BSI Group of Companies.