By Royal Charter

EU Quality Management System Certificate

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

IVDR 742163 R000

Manufacturer: Oxoid Limited

Address:
Wade Road
Basingstoke
Hampshire
RG24 8PW
United Kingdom

Single Registration Number: GB-MF-000016914

EU Authorised Representative: Thermo Fisher Diagnostics B.V.

Address:
Scheepsbouwersweg 1B,
1121 PC Landsmeer,
The Netherlands

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 Medical Devices

First Issue Date: **2022-11-29**

Current Issue Date: **2023-02-24**

Starting Validity Date: **2023-02-24**

Expiry Date: **2027-11-28**

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Device Schedule: Class D, C and B devices

Class B devices	Intended purpose
IVR 0505 – Devices intended to be used to grow / isolate / identify and handle infectious agents.	In vitro diagnostic medical devices intended for the determination of antimicrobial agent susceptibility and / or the qualitative identification of infectious agents.
Class C Devices	**Intended Purpose**
W0104 – Microbiology (Culture) IVP 3002 – In vitro diagnostic devices which require knowledge regarding biochemistry	In vitro diagnostic qualitative selective media intended for the screening and identification of bacterial infections.

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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
2022-11-29	3349190	Issued
Current	3854289	Supplemented – addition of Generic Device Group: Class C W0104 IVP 3002

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