

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.

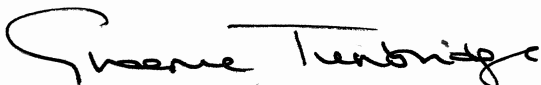
Address:

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

IVR 0505 – Devices intended to be used to grow / isolate / identify and handle infectious agents.

Intended purpose

In vitro diagnostic medical devices intended for the determination of antimicrobial agent susceptibility and / or the qualitative identification of infectious agents.

Class C Devices

W0104 – Microbiology (Culture)

IVP 3002 – In vitro diagnostic devices which require knowledge regarding biochemistry

Intended Purpose

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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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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