

EU Quality Management System Certificate

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

IVDR 734881 R000

Manufacturer: Microbiologics, Inc

Address:

200 Cooper Avenue North
St.Cloud
Minnesota
56303
USA

Single Registration Number: US-MF-000000466

EU Authorised Representative: MediMark Europe Sarl

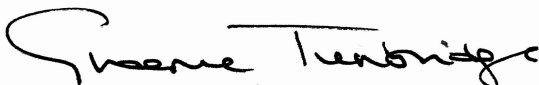
Address:

11 rue Emile Zola - BP 2332
38033 Grenoble Cedex 2
France

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: **2021-12-16**

Current Issue Date: **2023-08-30**

Starting Validity Date: **2023-08-30**

Expiry Date: **2026-12-15**

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Device Schedule: Class D, C and B devices

Class B devices

IVR 0701

Intended purpose

Control material without a quantitative assigned value used to assist in the identification of cultured microorganism isolates, and to verify the performance of assays including nucleic acid amplification testing, reagents or media used in microbial testing.

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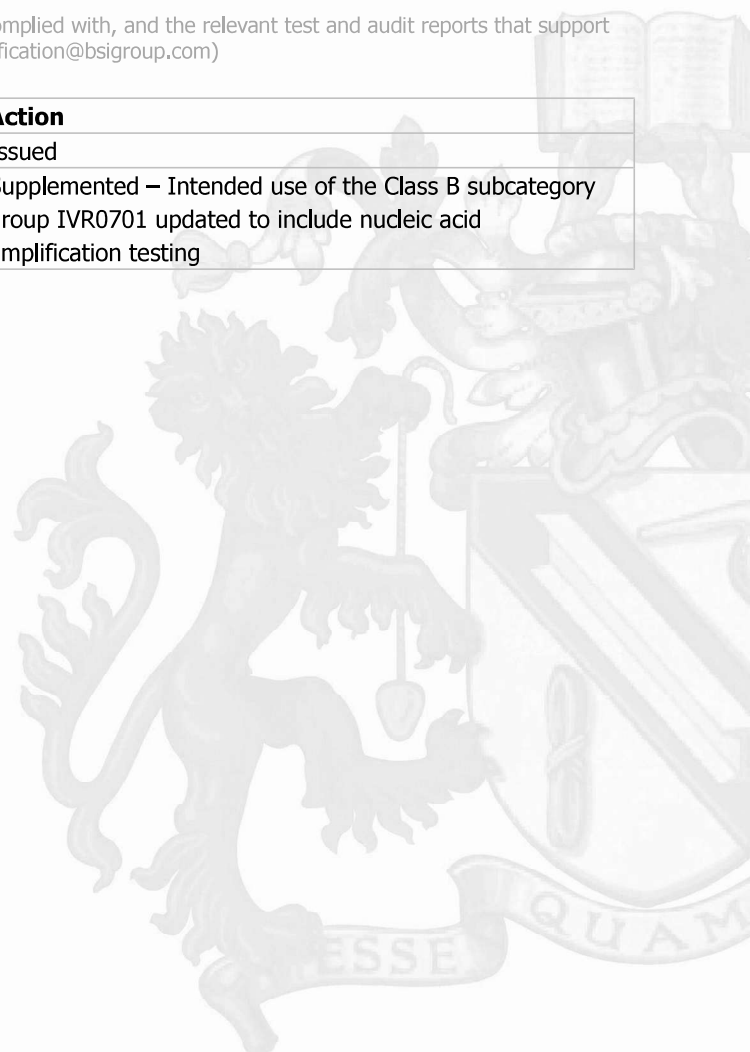
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Certificate History

(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
2021-12-16	3277524	Issued
Current	30005572	Supplemented – Intended use of the Class B subcategory group IVR0701 updated to include nucleic acid amplification testing



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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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