

# 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):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-12-16**

Date: **2021-12-16**

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

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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.  
A Member of the BSI Group of Companies.

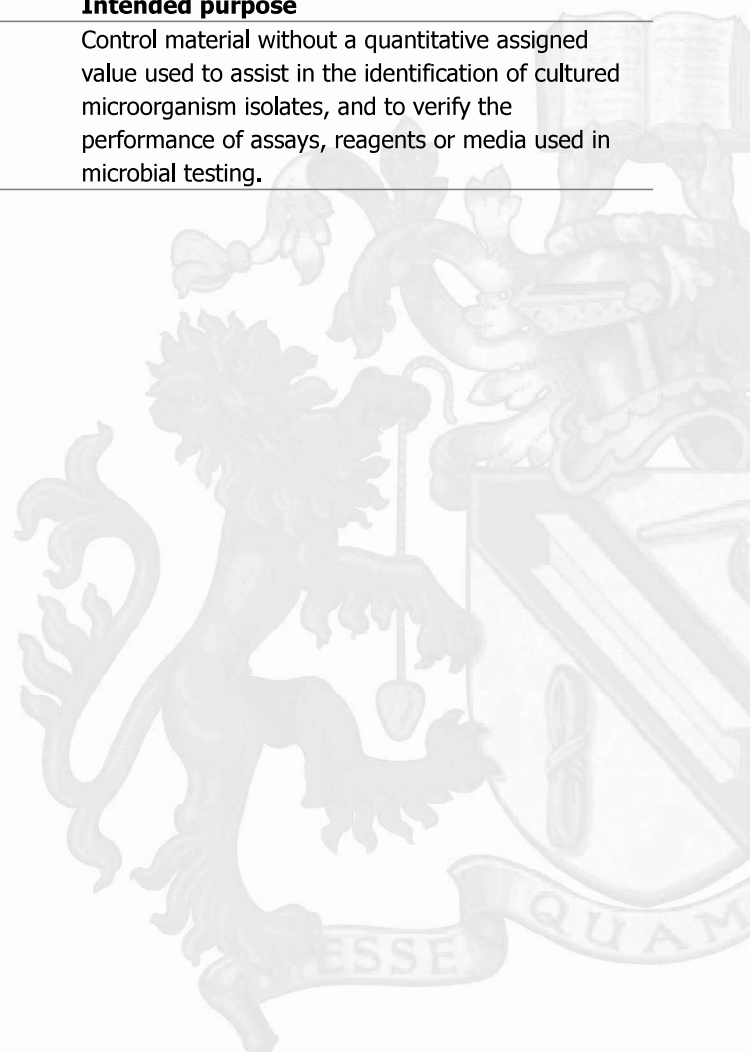
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## Device Schedule:

Class B devices	Intended purpose
IVR 0701	Control material without a quantitative assigned value used to assist in the identification of cultured microorganism isolates, and to verify the performance of assays, reagents or media used in microbial testing.



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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	3277524	Issued



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