

# EU Quality Management System Certificate

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

## IVDR 735494 R000

**Manufacturer:** BioFire Diagnostics, LLC

**Address:**

515 Colorow Drive  
Salt Lake City  
Utah  
84108  
USA

**Single Registration Number:** US-MF-000003311

**EU Authorised Representative:** QbD RepS BV

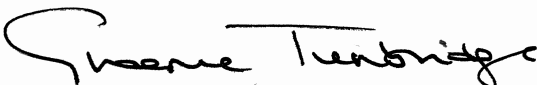
**Address:**

Groenenborgerlaan 16  
2610 Wilrijk  
Belgium

**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: **2021-05-07**

Current Issue Date: **2025-01-13**

Starting Validity Date: **2025-01-13**

Expiry Date: **2026-05-06**

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### Device Schedule: Class D, C and B devices

#### Class C Devices

**W010507** - Multiple Parameters - Infect. Immunology

**IVP3011** - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)

#### Intended purpose

In Vitro Diagnostic PCR devices intended for the detection and identification of infectious agents

#### Class B Devices

**IVR 0503** – devices intended to be used to detect presence of, or exposure to infectious agents

#### Intended purpose

Nucleic acid devices intended to be used for the qualitative detection and identification of an infectious agent

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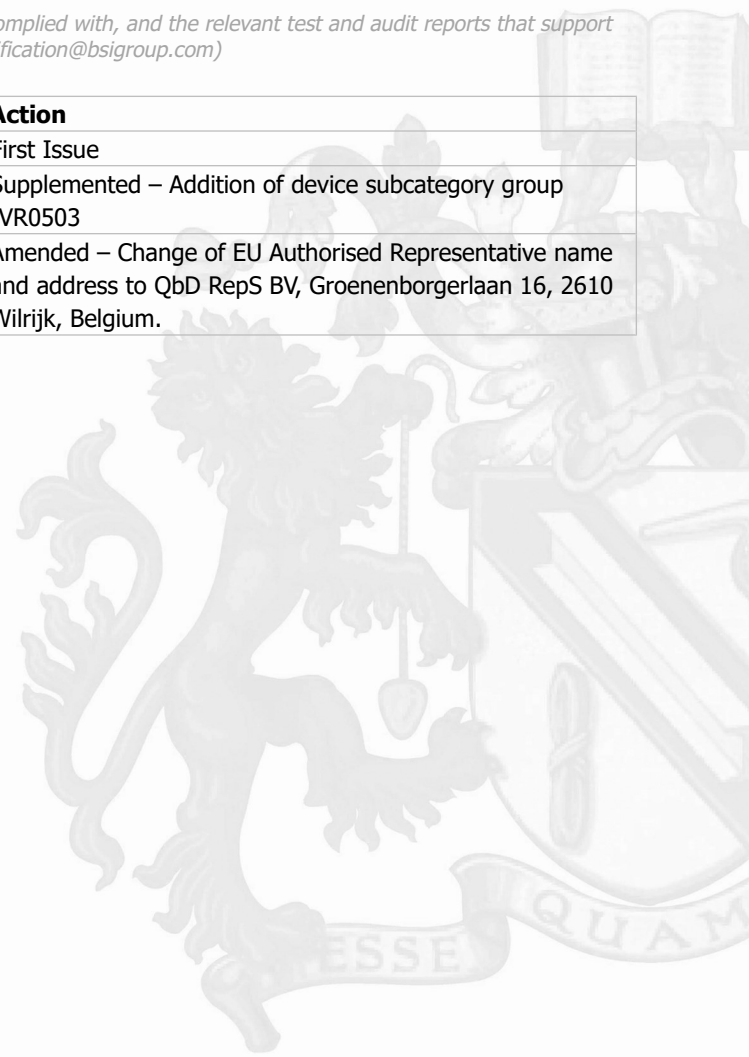
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### Certificate History

*(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
2021-05-07	3281374	First Issue
2023-01-24	3444335	Supplemented – Addition of device subcategory group IVR0503
Current	30336321	Amended – Change of EU Authorised Representative name and address to QbD RepS BV, Groenenborgerlaan 16, 2610 Wilrijk, Belgium.



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