EU Quality Management System Certificate

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

IVDR 735494 R001

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: **2026-04-20**

Starting Validity Date: **2026-05-07**

Expiry Date: **2031-05-06**

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Device Schedule: Class D, C and B devices

Class C Devices	Intended purpose
W010507 - Multiple Parameters - Infect. Immunology/NAT **IVP3011** - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	In Vitro Diagnostic PCR devices intended for the detection and identification of infectious agents
Class B near-patient and professional use test devices	**Intended purpose**
BIOFIRE® SPOTFIRE® Respiratory/Sore Throat plus (R/STplus) Panel	See IVDR 832356
BIOFIRE® SPOTFIRE® Respiratory/Sore Throat plus (R/STplus) Panel Mini	See IVDR 832361
Class B Devices	**Intended purpose**
IVR 0503 – devices intended to be used to detect presence of, or exposure to infectious agents	Nucleic acid devices intended to be used for the qualitative detection and identification of an infectious agent

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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
2025-01-13	30336321	Amended – Change of EU Authorised Representative name and address to QbD RepS BV, Groenenborgerlaan 16, 2610 Wilrijk, Belgium.
2026-03-03	30657526	Supplemented – Addition of two Class B near-patient and professional use test devices, BIOFIRE® SPOTFIRE® Respiratory/Sore Throat plus (R/STplus) Panel and BIOFIRE® SPOTFIRE® Respiratory/Sore Throat plus (R/STplus) Panel Mini Amended – Added updated description to EMDN scope for W010507
Current	30564062	Re-Issued – Certificate Renewal.

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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.

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