

# EC Declaration of Conformity

<b>Manufacturer/ Supplier Information:</b>	<b>Maine Molecular Quality Controls, Inc.</b> 23 Mill Brook Road Saco, Maine 04072 USA Phone: 1-207-885-1072 Email: <a href="mailto:info@mmqci.com">info@mmqci.com</a> Website: <a href="http://www.mmqci.com">www.mmqci.com</a>
<b>European Representative</b>	<b>QARAD EC-REP BV</b> Pas 257 2440 Geel, Belgium

We, Maine Molecular Quality Controls Inc., declare under our sole responsibility, that the product:

**BioFire® JI Control Panel M420**

**Catalog #: M420**

meets the provisions of the European Directive 98/79/EC for *in vitro* Diagnostic Medical Devices. The device is classified as a General In Vitro Diagnostic (IVD) Device. The MMQCI quality system is registered to EN ISO 13485:2016. Conformity Assessment Method: General IVD Annex III.

The undersigned declares that the device listed above conforms to the essential requirements described in ANNEX I of the European Directive 98/79/EC. Technical documentation demonstrating compliance as described in Annex I is kept by the manufacturer and can be made available by the authorized representative in Europe - QARAD EC-REP BV, Pas 257, 2440 Geel, Belgium.

Saco, Maine USA / 03/15/2022

(Place and date of Issue)

*Nutchen D. Wright*  
Manager, QARA  
(Signature and Title)





	<b>Document No:</b> N/A	<b>Rev:</b> 01	Page 1 of 1
	<b>Title:</b> Addendum to Approved DoC		

**1. Purpose**

To provide recent changes to the original Declaration of Conformity (DoC) signed on 03/15/2022.

**2. Scope**

This memo covers BioFire® JI Control Panel M420 Catalog#: M420

**3. Background**

As per Article 110, **Maine Molecular Quality Controls, Inc.** can benefit from the transitional provisions if the Declaration of Conformity has been drawn up prior to May 26, 2022. Since **Maine Molecular Quality Controls, Inc.** is updating the DoC after this date, this addendum is provided to show the non-significant changes have been made to the original DoC. These changes do not impact the conformity status of the product; therefore, the original DoC issued before May 26, 2022, is still effective.

**4. List of Changes**

**4.1. Name Change of European Authorized Representative (AR)**

The AR for **Maine Molecular Quality Controls, Inc.** has changed their name and address from:

QARAD EC-REP BV  
Pas 257  
2440 Geel  
Belgium

To:  
QbD RepS BV  
Groenenborgerlaan 16  
2610 Wilrijk  
Belgium

Approved By:

Saco, Maine USA / 2025-11-07

(Place and date of Issue)

Gretchen D. Wright  
Manager QARA, PPRC  
(Signature and Title)