

EU Declaration of Conformity

Manufacturer/ Supplier Information:	BioFire Defense, LLC 79 West 4500 South, Suite 14 Salt Lake City, Utah 84107, USA Phone: 801-262-3592 info@biofiredefense.com www.BioFireDefense.com
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This declaration of conformity is issued under the sole responsibility of the manufacturer, BioFire Defense, LLC.

Object of Declaration	
Product Name:	RAZOR Mk II
Description:	Bio-Detection instrument using real time PCR.

The object of the declaration described above is in conformity with the relevant Union harmonization legislation: European Directive 2014/35/EU on low voltage equipment safety, and 2014/30/EU on the harmonization of the laws of the Member States relating to electromagnetic compatibility.

The following relevant standards have been met:

EN 61010-1: 2016 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
EN 61010-2-10: 2014 Particular requirements for laboratory equipment for the heating of materials
EN 61326-1: 2013 Electrical equipment for measurement, control and laboratory use. EMC requirements. General requirements, referring to the standards listed below.
CISPR 11+A1:2010 Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement
EN 61000-3-2+A2:2009 Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤ 16A per phase)
EN 61000-3-3:2008 Electromagnetic compatibility (EMC) – Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
EN 61000-4-2:2009 Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques – Section 2 Electrostatic Discharge immunity test.
EN 61000-4-3+A2:2010 Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques – Section 3 Radiated, radio frequency, electromagnetic field immunity test.



EN 61000-4-4+A1:2010

Electromagnetic compatibility (EMC) – Part 4: Testing and measurement techniques – Section 4 Electrical fast transient/burst immunity test.

EN 61000-4-5:2006

Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques – Section 5 Surge immunity test.

EN 61000-4-6:2009

Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques – Section 6 Immunity to conducted disturbances, induced by radio frequency field immunity test.

EN 61000-4-8:2010

Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Section 8 Power frequency magnetic field immunity test.

EN 61000-4-11:2004

Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques – Section 11 Voltage dips, short interruptions and voltage variations immunity test.

This declaration of conformity and technical documentation demonstrating compliance as described in Annex III of the European Directive 2014/35/EU is kept by the manufacturer and can be made available at the disposal of national market surveillance authorities for 10 years after the electrical equipment has been placed on the market.

4/9/2020

Salt Lake City, UT, USA
(Place and date of issue)



Robert Lollini
President

