Affimedix
Discovering Health Diagnostics for Life®

DECLARATION OF CONFORMITY

1) Manufacturer *(Name, department)*: **AFFIMEDIX, INC.**
Address: **3556 Investment Blvd., Hayward, California 94545, USA**

and

2) European authorized representative: **Qarad EC-REP BV**
Address: **Pas 257, 2440 Geel, Belgium**

3) Product(s) *(name, type or model/ batch number, etc.)*

- ***Rapi-D***™ *Quantitative Vitamin D Test*
- *See Appendix*

4) The Manufacturer declares that products described above are in conformity with:

Document No.	Title
98/79/EC	**European Directive for In Vitro Diagnostic Medical Devices**

5) Additional information (conformity procedure, Notified Body, CE certificate, etc.):

Conformity assessment procedure for CE marking: IVD Directive, Annex III

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe.

AFFIMEDIX, INC.
California, USA

Hayward, California, USA
November 16, 2020

(Place & date of issue)

Dr. Kevin Wang
Director – R & D, Quality System & IVD Compliance
Affimedix, Inc.

(name, function and signature of manufacturer)

Appendix A

Date: November 16, 2020

List of devices

Device Group: Rapid Tests		
Device name	**Type/ model/ ref number**	**First date of CE-marking**
Rapi-D™ Quantitative Vitamin D Test	1155Q-10	
Rapi-D™ Quantitative Vitamin D Test	1155Q-25	