

EC DECLARATION OF CONFORMITY

According to Art. 9 of 98/79/EC on In Vitro Diagnostic Medical Devices

Manufacturer: Hangzhou Anta Biotechnology Co.,Ltd
Room701 & 702 , Building1, Fuyi Commercial Center, Jianggan
District, Hangzhou City, Zhejiang Province, 310021, China

Trademark: Anitoa

SRN: Not available yet

European Representative: MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 Munich, Germany

SRN: Not available yet

Trade name: Anitoa Maverick qPCR

Product Name: Quantitative Realtime PCR

Product Model: MQ5164, MQ5162, MQ5161, MQ5084, MQ5082, MQ5081
MQ4164, MQ4162, MQ4161, MQ4084, MQ4082, MQ4081
MQ3164, MQ3162, MQ3161, MQ3084, MQ3082, MQ3081
MQ3041, MQ1084, MQ1082, MQ1044, MQ1042

Basic UDI: Not available yet

Classification acc. to IVDD: IVD-Other

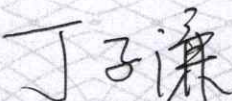
Applied Standard & Common Specification: EN 61010-1: 2018, EN 61010-2-101: 2017,
EN 61326-2-6:2013

Conformity assessment procedure: Annex III of IVDD

CE certificate No.: N.A.

Name and ID of the Notified Body: N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Directive on In Vitro Medical Devices (IVDD). All supporting documentations are retained under the premises of the manufacturer.


Ziqian Ding
General Manager

Hangzhou, 20.10.2020