EC Declaration of Conformity

in accordance with Directive 98/79/EC

Manufacturer:

Name: *Hangzhou Realy Tech Co., Ltd.*
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EU-Representative:

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Product/s
M.Pneumonia IgG/IgM Rapid Test Device

Category: Other Devices (All devices except Annex II and self-testing devices)

Conformity assessment route: Annex III (except Point 6) of the Directive

Applicable Standards: EN ISO 13485:2016; EN ISO 15223-1:2021, EN ISO 14971:2019, EN ISO 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 23640:2015

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Hangzhou 2022.4.29

(Place and date of issue)

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(Signature and position)
Signed for and on behalf of the manufacturer