



EC Declaration of Conformity



in accordance with Directive 98/79/EC

Manufacturer:

Name: Hangzhou Realy Tech Co., Ltd.

Address: #2 Building, No. 763, Yuansha Village, Xinjie Street, Xiaoshan District, 311200 Hangzhou City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Tel: +0571-56050793

E-mail: info@realytech.com

EU-Representative:

Name: CMC Medical Devices & Drugs S.L

Address: C/Horacio Lengo No 18 CP 29006, Málaga-Spain

Tel: +34951214054

E-mail: info@cmcmedicaldevices.com

Product/s

M.Pneumonia IgG/IgM Rapid Test Device

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

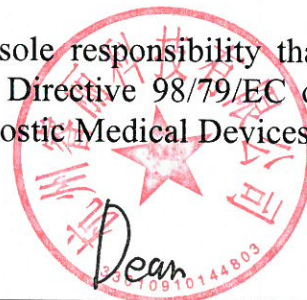
Conformity assessment route: Annex III (except Point 6) of the Directive

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.

Hang Zhan 2022.4.29

(Place and date of issue)



(Signature and position)

Signed for and on behalf of the manufacturer