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

Product/s	*Catalogue number*
CRP Rapid Test Device(Whole blood/Serum/ Plasma)	A020201D

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 15223-1:2016; EN ISO 14971:2019; EN 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.

We hereby explicitly appoint Luxus Lebenswelt GmbH, located at Kochstr.1,47877, Willich, Germany to act as our European Authorised Representative as defined in the aforementioned Directive.

Hang Zhou 2021.3.2

(Place and date of issue)

Ding Pengfei
General manager

(Signature and position)

Signed for and on behalf of the manufacturer