# EC Declaration of Conformity

in accordance with Directive 98/79/EC

## Manufacturer:

***Name:*** [redacted]

| *Product/s* | *Catalogue number* |
|---|---|
| Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) | K511416D |

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

*Conformity assessment route:* Annex III,except Point 6,of Directive

*Applicable Standards:EN ISO 13485:2016;EN ISO 15223-1:2016; EN ISO 14971:2012 ;EN ISO 13612:2002;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.

[redacted] 2020.8.17

(Place and date of issue)

(Signature and position)

Signed for and on behalf of the manufacturer