



Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device
We,

*Reszon Diagnostics International Sdn. Bhd.
Revongen Corporation Center, Level 17, Top Glove Tower, No. 16, Persiaran Setia
Dagang, Setia Alam, Seksyen U13, 40170 Shah Alam, Selangor Darul Ehsan, Malaysia.*

Declare under our sole responsibility that the following in vitro diagnostic medical devices
other than those covered by annex II and devices for performance evaluation

| No. | Catalogue reference number | Commercial name |
|-----|----------------------------|--|
| 1 | RCV-RD0101 | Reszon COVID-19 Rapid IgG/IgM Test Kit |
| 2 | RCV-RD0201 | Reszon COVID-19 Rapid Antigen Test Kit |

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which
apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- **ISO 13485:2016**

Corporate Contact Information

Reszon Diagnostics International Sdn. Bhd.

(HQ)

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(Manufacturing)

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RESPONSIBLE PERSON'S name: Mr. LAW ENG LIM

Position: CEO



SIGNATURE:

Date: 1st June 2020

Stamp:



European Authorized Representative:

Registered Address:

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