Declaration of Conformity

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

SG Diagnostics Pte Ltd
Invent Block Level 3
26 Ang Mo Kio Industrial Park 2, Singapore. 569507

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 T

SG Diagnostics Covid-19 Antigen Rapid Test Kit (Colloidal Gold-based)
SG Diagnostics Covid-19 IgG/IgM Rapid Test Kit (Colloidal Gold-based)
SG Diagnostics Covid-19 Triplex RT-qPCR Detection Kit
SG Diagnostics Influenza A/B + Covid-19 Antigen Rapid Test Kit (Colloidal Gold-based)

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:

ISO13485

Corporate Contact Information

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SIGNATURE :

Date : 18 Nov 2020

Stamp

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