



**CELL ID PTE LTD**  
*Shaping your future health*  
**源鉴定 塑造您的未来健康**

## EC Declaration of Conformity

Manufacturer:

Name: Cell ID Pte Ltd

Address: 3 Gambas Crescent, Nordcom One, #09-08 Singapore 757088

European Representative:

Name: MedNet GmbH / MedNet EC-REP GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name:

(i) Smart COVID-19 IgM/IgG Rapid Diagnostic Test

Model:

(i) Test device (Laminated)

Classification: Other Device of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III

We, Cell ID Pte Ltd, herewith declare that the mentioned products meet the transposition into national law, the provision of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We take exclusively responsible for this declaration of conformity

### DIRECTIVES

General applicable directives:

DIRECTIVE 98/78/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices

Standard applied:

EN ISO 13485:2016      EN 13612:2002  
EN ISO 14971:2012      EN ISO 23640:2015  
EN ISO 18113-1:2011      EN ISO 18113-3:2011  
EN ISO 15223-1:2016      EN 13641:2002

Place and Date of Issue: Singapore on 07/04/2020

Signature: \_\_\_\_\_

Name: Dr Neo Siak Peng (Position: CEO)



Cell ID Pte Ltd

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### ***Authorized contacts for the manufacturer***

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Name of second authorized contact	SHARIFAH ANNOR ARAFAH	
Authorized contact postal address	Department: REGULATORY AFFAIRS	
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DR NEO SIAK PENG  
CEO



SHARIFAH ANNOR ARAFAH  
RA Officer