

# Declaration of Conformity



<b>Manufacturer Name</b>	<b>SD Biosensor, Inc.</b>	
<b>Manufacturer Address</b>	<u>Head Office</u> C-4th&5th, 16, Deogyong-daero, 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690, KOREA  <u>Manufacturing Site</u> 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do 28161, KOREA	
<b>EC Representative Name</b>	<b>MT Promedt Consulting GmbH</b>	
<b>EC Representative Address</b>	Altenhofstrasse 80 66386 St. Ingbert Germany	
<b>Common Name</b>	<b>Rapid Test Kit</b>	
<b>Product Name</b>	<b>SARS-CoV-2 Rapid Antigen Test</b> <i>*Please refer to "Annex I. Product List" on page 2 in more detail.</i>	
<b>Reference Number</b>	9901-NCOV-01G	
<b>Classification</b>	<b>Others not covered by Annex II and self-testing according to Directive 98/79/EC</b>	
<b>Conformity Assessment Route</b>	Annex III of Directive 98/79/EC (EC Declaration of Conformity)	
<b>Applied Standards</b>	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 23640:2015 EN ISO 17511:2003 EN 13612:2002	EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 15223-1:2016 EN 62366:2008

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentations are retained under the premises of the manufacturer. SD Biosensor, Inc. is exclusively responsible for the declaration of conformity.

**Place: Suwon-si, Republic of Korea**  
**Valid from: August 20, 2020**

Signature

**Hyo-Keun, Lee**  
**CEO / President**

## *Annex I. Product List*

### 9901-NCOV-01G

#### **SARS-CoV-2 Rapid Antigen Test**

- Test Device (individually in a foil pouch with desiccant)
- Extraction buffer tube
- Nozzle cap
- Sterile swab
- Film
- Quick Reference Guide
- Instructions for use

#### **EDMA Code**

15 70 90 90 00

#### **Description of EDMA code**

Other Other Virology Rapid Tests