


# 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 for self-testing</b>	
<b>Product Name</b>	<b>SARS-CoV-2 Antigen Self Test Nasal</b> <i>*Please refer to "Annex I. Product List" on page 2 in more detail.</i>	
<b>Reference Number</b>	9901-NCOV-06G	
<b>Classification</b>	<b>Self-Testing Device according to Directive 98/79/EC</b>	
<b>Conformity Assessment Route</b>	Annex IV without section 4 and 6 of Directive 98/79/EC (Full Quality Assurance)	
<b>Notified Body</b>	<b>TÜV SÜD PRODUCT SERVICE GmbH</b>	
<b>Notified Body Address</b>	Ridlerstr. 65, 80339 München, Germany	
<b>ID Number of NB</b>	0123	
<b>Number of EC-Certificate</b>	V1 075369 0058 Rev.01	
<b>Applied Standards</b>	EN ISO 13485:2016	EN ISO 18113-1:2011
	EN ISO 14971:2012	EN ISO 18113-4:2011
	EN ISO 23640:2015	EN 13532:2002
	EN ISO 17511:2003	EN ISO 15223-1:2016
	EN 13612:2002	EN 62366:2008
	EN 13641:2002	

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: June 7, 2021**

Signature   
**Hyo-Keun Lee**  
**Vice President**

## *Annex I. Product List*

**9901-NCOV-06G**

**SARS-CoV-2 Antigen Self Test Nasal**

- Test Device (packaged in foil pouch 1 including desiccant package)
- Tube with liquid and nozzle cap (packaged in foil pouch 2)
- Sterile swab
- Buffer holder
- Quick Reference Guide
- Instructions for Use

**EDMA Code**

15 70 90 90 00

**Description of EDMA code**

Other Other Virology Rapid  
Tests