

# Declaration of Conformity

**Manufacturer Name** SD Biosensor, Inc.

**Manufacturer Address** Head Office  
C-4th&5th, 16, Deogyong-daero, 1556beon-gil, Yeongtong-gu,  
Suwon-si, Gyeonggi-do 16690, KOREA

Manufacturing Site  
74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu,  
Cheongju-si, Chungcheongbuk-do 28161, KOREA

**EC Representative Name** MT Promedt Consulting GmbH

**EC Representative Address** Altenhofstrasse 80 66386 St. Ingbert Germany

**Common Name** Rapid Test Kit

**Product Name** STANDARD™ Q COVID-19 Ag Test  
*\*Please refer to "Annex I. Product List" on page 2 in more detail.*

**Reference Number** Q-NCOV-01G

**Classification** Others not covered by Annex II and self-testing according to  
Directive 98/79/EC

**Conformity Assessment Route** Annex III of Directive 98/79/EC (EC Declaration of Conformity)

**Applied Standards**

EN ISO 13485:2016	EN ISO 18113-1:2011
EN ISO 14971:2012	EN ISO 18113-2:2011
EN ISO 23640:2015	EN ISO 15223-1:2016
EN ISO 17511:2003	EN 62366:2008
EN 13612:2002	

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: March 03, 2020*

Signature



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

# *Annex I. Product List*

## **Q-NCOV-01G**

### **STANDARD™ Q COVID-19 Ag Test**

- Test Device (individually in a foil pouch with desiccant)
- extraction buffer tube
- Filter cap
- Sterile swab A
- Sterile swab B (option)

## **EDMA Code**

15 70 90 90 00

## **Description of EMDA code**

Other Other Virology Rapid Tests