

Declaration of Conformity



Manufacturer Name SD Biosensor, Inc.

Manufacturer Address <u>Head Office</u>

C-4th&5th, 16, Deogyeong-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 STANDARDTM Q COVID-19 Ag Test /

STANDARDTM COVID-19 Ag Control / STANDARDTM COVID-19 Ag Control swab

*Please refer to "Annex I. Product List" on page 2 in more detail.

Reference Number Q-NCOV-01G / C-NCOV-01G / C-NCOV-02G

Catalog Number 09COV30D, 09COV31D, 09COV32D, 09COV33D, 10COVC10,

10COVC11

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 17511:2003 EN 62366:2008

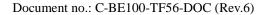
EN 13612:2002

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: December 08, 2020

Signature

Hyo-Keun, Lee CEO / President





Annex I. Product List

O-NCOV-01G STANDARD TM Q COVID-19 Ag Test (Catalog no. 09COV30D) - Test Device (individually in a foil pouch with desiccant) - Extraction buffer tube - Nozzle cap - Sterile swab (np specimen) - Film	EDMA Code 15 70 90 90 00	Description of EDMA code Other Other Virology Rapid Tests
Q-NCOV-01G STANDARD TM Q COVID-19 Ag Test (Catalog no. 09COV31D) - Test Device (individually in a foil pouch with desiccant) - Extraction buffer tube - Nozzle cap - Sterile swab (nasal specimen) - Film	EDMA Code 15 70 90 90 00	Description of EDMA code Other Other Virology Rapid Tests
O-NCOV-01G STANDARD TM Q COVID-19 Ag Test (Catalog no. 09COV32D) - Test Device (individually in a foil pouch with desiccant) - Extraction buffer tube - Nozzle cap - Sterile swab (np specimen) - Positive Control swab - Negative Control swab - Film	EDMA Code 15 70 90 90 00	Description of EDMA code Other Other Virology Rapid Tests
O-NCOV-01G STANDARD TM Q COVID-19 Ag Test (Catalog no. 09COV33D) - Test Device (individually in a foil pouch with desiccant) - Extraction buffer tube - Nozzle cap - Sterile swab (nasal specimen) - Positive Control swab - Negative Control swab - Film	EDMA Code 15 70 90 90 00	Description of EDMA code Other Other Virology Rapid Tests
C-NCOV-01G STANDARD TM COVID-19 Ag Control (Catalog no. 10COVC10) - Positive control (tablet type) - Negative control (tablet type)	EDMA Code 15 50 01 04 00	Description of EDMA code Other Virology Controls - Inf.Imm.
C-NCOV-02G STANDARD TM COVID-19 Ag Control swab (Catalog no. 10COVC11) - Positive control swab - Negative control swab	EDMA Code 15 50 01 04 00	Description of EDMA code Other Virology Controls - Inf.Imm.