Declaration of Conformity

CE

Manufacturer Name	**SD Biosensor, Inc.**
Manufacturer Address	*Head Office* 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	**STANDARD™ Q COVID-19 Ag Test /** **STANDARD™ COVID-19 Ag Control /** **STANDARD™ 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 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: December 08, 2020

Signature

Hyo-Keun, Lee
CEO / President

Annex I. Product List

Q-NCOV-01G **STANDARD™ 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™ 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
Q-NCOV-01G **STANDARD™ 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
Q-NCOV-01G **STANDARD™ 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™ 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™ 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.