

Declaration of Conformity



Manufacturer Name	SD Biosensor, Inc.	
Manufacturer Address	<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	
EC Representative Name	MT Promedt Consulting GmbH	
EC Representative Address	Altenhofstrasse 80 66386 St. Ingbert Germany	
Common Name	Immunoassay Test Kit	
Product Name	STANDARD™ F COVID-19 Ag FIA STANDARD™ COVID-19 Ag Control <i>*Please refer to "Annex I. Product List" on page 2 in more detail.</i>	
Reference Number	F-NCOV-01G, C-NCOV-01G	
Catalog Number	10COV30D, 10COV31D, 10COVC10	
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: September 23, 2021

Signature

Hyo-Keun, Lee
CEO / President

Annex I. Product List

F-NCOV-01G

STANDARD™ F COVID-19 Ag FIA

(Catalog No. 10COV30D)

- Test Device (individually in a foil pouch with desiccant)
- Extraction buffer tube
- Nozzle cap
- Sterile swab – (Nasopharyngeal)

EDMA Code

15 04 90 90 00

Description of EDMA code

Other Other Virology Reagents

F-NCOV-01G

STANDARD™ F COVID-19 Ag FIA

(Catalog No. 10COV31D)

- Test Device (individually in a foil pouch with desiccant)
- Extraction buffer tube
- Nozzle cap
- Sterile swab – (Nasal)

EDMA Code

15 04 90 90 00

Description of EDMA code

Other Other Virology Reagents

C-NCOV-01G

STANDARD™ COVID-19 Ag Control

(Catalog No. 10COVC10)

- STANDARD™ COVID-19 Ag Control - Positive
- STANDARD™ COVID-19 Ag Control - Negative

EDMA Code

15 50 01 04 00

Description of EDMA code

Other Virology Controls -
Inf.Imm.