Declaration of Conformity

CE IVD

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	**Immunoassay Test Kit**
Product Name	**STANDARD™ F COVID/Flu Ag Combo FIA** **Please refer to "Annex I. Product List" on page 2 in more detail.*
Reference Number	F-CVFL-01C
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: April 1, 2022

Signature

Hyo-Keun, Lee
CEO / President

Annex I. Product List

	EDMA Code	Description of EDMA code
F-CVFL-01C **STANDARD™ F COVID/Flu Ag Combo FIA** - Test device (individually in a foil pouch with desiccant) - Extraction buffer tube - Nozzle cap - Sterile swab - Instructions for Use	15 04 90 90 00	Other Other Virology Reagents