

Declaration of Conformity



Manufacturer Name	SD Biosensor, Inc.	
Manufacturer Address	<u>Head Office</u>	
	5.1.2e	
	<u>Manufacturing Site</u>	
	5.1.2e	
EC Representative Name	MT Promedt Consulting GmbH	
EC Representative Address	Altenhofstrasse 80 66386 St. Ingbert Germany	
Common Name	Rapid Test Kit	
Product Name	SARS-CoV-2 Rapid Antigen Test	
	<i>*Please refer to "Annex I. Product List" on page 2 in more detail.</i>	
Reference Number	9901-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: August 20, 2020

Signature

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Annex I. Product List

9901-NCOV-01G

SARS-CoV-2 Rapid Antigen Test

- Test Device (individually in a foil pouch with desiccant)
- Extraction buffer tube
- Nozzle cap
- Sterile swab
- Film
- Quick Reference Guide
- Instructions for use

EDMA Code

15 70 90 90 00

Description of EDMA code

Other Other Virology Rapid Tests