

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	
	<u>Manufacturing Site</u> 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungchungbuk-do 28161, KOREA	
EC Representative Name	MT Promedt Consulting GmbH	
EC Representative Address	Altenhofstrasse 80 D-66386 St. Ingbert Germany	
Common Name	Immunoassay Test Kit	
Model Name	STANDARD™ F Influenza A/B FIA <i>*Please refer to "Annex I. Product List" on page 2 in more detail.</i>	
Reference Number	FINF01G	
Catalog Number	10INF10B, 10INF10D	
EDMA Code	15.04.80.04.00	
Classification	Others according to Annex II of Directive 98/79/EC	
Conformity Assessment Route	Annex III of IVDD 98/79/EC (EC Declaration of Conformity)	
Applied Standards	EN ISO 13485:2012	EN ISO 18113-1:2011
	EN ISO 14971:2012	EN ISO 18113-2:2011
	EN ISO 15197:2015	EN ISO 15223-1:2016
	EN ISO 23640:2015	EN 62366:2008
	EN ISO 17511:2003	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: November 22, 2017

Signature



Hyo-Keun, Lee
CEO / President

Annex I. Product List

FINF01G**STANDARD™ F Influenza A/B FIA**

- Test device
- Extraction buffer
- Filter cap □
- Fixed volume dropper
- Sterile swab
- Positive control swab
- Negative control swab

EDMA Code

15.04.80.04.00