

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										
Model Name	STANDARD™ F Strep A Ag FIA STANDARD™ Strep A Ag Control <i>*Please refer to "Annex I. Product List" on page 2 in more detail.</i>										
Reference Number	FSRA01G C-SRA01G										
Classification	Others not covered by Annex II and self-testing according to Directive 98/79/EC										
Conformity Assessment Route	Annex III of IVDD 98/79/EC (EC Declaration of Conformity)										
Applied Standards	<table> <tr> <td>EN ISO 13485:2016</td><td>EN ISO 18113-1:2011</td></tr> <tr> <td>EN ISO 14971:2012</td><td>EN ISO 18113-2:2011</td></tr> <tr> <td>EN ISO 23640:2015</td><td>EN ISO 15223-1:2016</td></tr> <tr> <td>EN ISO 17511:2003</td><td>EN 62366:2008</td></tr> <tr> <td>EN 13612:2002</td><td></td></tr> </table>	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	
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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: April 24, 2019

Signature



Hyo-Keun, Lee
CEO / President

Annex I. Product List

FSRA01G**STANDARD™ F Strep A Ag FIA**

- Test device
- Extraction buffer 1
- Extraction buffer 2
- Fixed volume dropper
- Sterile swab
- Positive control swab
- Negative control swab

EDMA Code

15.70.01.03.00

Description of EDMA Code

Strep A – Rapid Test

C-SRA01G**STANDARD™ Strep A Ag Control**

- Positive control
- Negative control

EDMA Code

15.50.01.04.00

Description of EDMA Code

Other Virology Controls-Inf.Imm.