

# Declaration of Conformity



<b>Manufacturer Name</b>	<b>SD Biosensor, Inc.</b>	
<b>Manufacturer Address</b>	<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	
<b>EC Representative Name</b>	<b>MT Promedt Consulting GmbH</b>	
<b>EC Representative Address</b>	Altenhofstrasse 80 66386 St. Ingbert Germany	
<b>Common Name</b>	<b>Immunoassay Test Kit</b>	
<b>Model Name</b>	<b>STANDARD™ F iFOB FIA</b> <b>STANDARD™ F iFOB Control</b> <i>*Please refer to "Annex I. Product List" on page 2 in more detail.</i>	
<b>Reference Number</b>	F-FOB-01, C-F-FOB	
<b>Classification</b>	<b>Others not covered by Annex II and self-testing according to Directive 98/79/EC</b>	
<b>Conformity Assessment Route</b>	Annex III of IVDD 98/79/EC (EC Declaration of Conformity)	
<b>Applied Standards</b>	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 23640:2015 EN ISO 17511:2003	EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 15223-1:2016 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: May 03, 2022***

Signature



**Hyo-Keun, Lee**  
**CEO / President**

## ***Annex I. Product List***

### **F-FOB-01**

#### **STANDARD™ F iFOB FIA**

- Test Device  
(individually in a foil pouch with desiccant)
- Sample collection tube with assay diluent
- Instructions for use

#### **EDMA Code**

11 70 03 01 00

#### **Description of EDMA code**

Faecal Occult Blood (CC)

### **C-F-FOB**

#### **STANDARD™ F iFOB Control**

- STANDARD™ F iFOB Control - Level 1
- STANDARD™ F iFOB Control - Level 2
- Instructions for use

#### **EDMA Code**

12 50 01 90 00

#### **Description of EDMA code**

Other Controls Immunochemistry