

# 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 C. <i>difficile</i> GDH FIA STANDARD™ C. <i>difficile</i> GDH Control <i>*Please refer to "Annex I. Product List" on page 2 in more detail.</i>
Reference Number	F-CDFG-01, C-CDFG-01
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	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: January 13, 2022**

Signature

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

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

**F-CDFG-01****STANDARD™ F *C. difficile* GDH FIA**

- Test Device  
(individually in a foil pouch with desiccant)
- Extraction buffer tube
- Sterile swab (fecal)
- Filter cap
- Instructions for use

**EDMA Code**  
15 01 90 02 00**Description of EDMA code**  
Clostridium difficile**C-CDFG-01****STANDARD™ C. *difficile* GDH Control**

- Positive control
- Negative control
- Disposable dropper (100µl)
- Instructions for use

**EDMA Code**  
15 50 01 01 00**Description of EDMA code**  
Bacteriology Controls - Inf.Imm.