

## **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

Manufacturing Site

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. difficile Toxin A/B FIA

STANDARD™ C. difficile Toxin A/B Control

\*Please refer to "Annex I. Product List" on page 2 in more detail.

**Reference Number** F-CDFT-01, C-CDFT-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

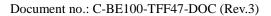
EN 13612:2002

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

<u>F-CDFT-01</u>	EDMA Code	Description of EDMA code
STANDARD™ F C. difficile Toxin A/B FIA	15 01 90 02 00	Clostridium difficile
- Test Device		
(individually in a foil pouch with desiccant)		
- Extraction buffer tube		
- Sterile swab (fecal)		
- Filter cap		
- Instructions for use		
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C-CDFT-01 STANDARD <sup>TM</sup> C. difficile Toxin A/B Control - Positive control: 10 red tablets in each tube (red colored tube)	<b>EDMA Code</b> 15 50 01 01 00	<b>Description of EDMA code</b> Bacteriology Controls - Inf.Imm
- Negative control: 10 blue tablets in each tube (white colored tube)		
- Disposable dropper (100µl)		
- Instructions for use		