

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 TB-Feron FIA (IFN-gamma) STANDARD™ F TB-Feron FIA (IFN-gamma) IGRA STANDARD™ F TB-Feron Control TB-Feron Tubes 100 TB-Feron Tubes 200 TB-Feron Tubes 300 STANDARD™ TB-Feron SPP <i>*Please refer to "Annex I. Product List" on page 2 in more detail.</i>
Reference Number	F-TBF-01, F-TBF-02, C-F-TBF-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: May 19, 2022

Signature



Hyo-Keun, Lee
CEO / President

Annex I. Product List

F-TBF-01

STANDARD™ F TB-Feron FIA (IFN-gamma)

- Test Device
(individually in a foil pouch with desiccant)
- Conjugate Tablet
- Instructions for use

EDMA Code

13 06 01 01 00

Description of EDMA code

Interferons (a,b,y)

F-TBF-02

STANDARD™ F TB-Feron FIA (IFN-gamma) IGRA

- Test Device
- Conjugate Tablet
- TB-Feron Mitogen Tubes
- TB-Feron TB Antigen Tubes
- TB-Feron Nil tubes
- Instructions for use

EDMA Code

13 06 01 01 00

Description of EDMA code

Interferons (a,b,y)

C-F-TBF-01

STANDARD™ F TB-Feron Control

- STANDARD™ F TB-Feron Control - Level 1
- STANDARD™ F TB-Feron Control - Level 2
- STANDARD™ F TB-Feron Control - Level 3

EDMA Code

12 50 01 06 00

Description of EDMA code

Specific Protein Controls

07TBFA10

TB-Feron Tubes 100

- TB-Feron Mitogen Tube
- Instructions for use

EDMA Code

13 02 80 80 00

Description of EDMA code

Coated tubes (Citrate, Heparin etc.)

07TBFA20

TB-Feron Tubes 200

- TB-Feron TB Antigen Tube
- TB-Feron Nil Tube
- Instructions for use

EDMA Code

13 02 80 80 00

Description of EDMA code

Coated tubes (Citrate, Heparin etc.)

07TBFA30

TB-Feron Tubes 300

- TB-Feron Mitogen Tube
- TB-Feron TB Antigen Tube
- TB-Feron Nil Tube
- Instructions for use

EDMA Code

13 02 80 80 00

Description of EDMA code

Coated tubes (Citrate, Heparin etc.)

07TBFA40

STANDARD™ TB-Feron SPP

- TB-Feron Mitogen Tube
- TB-Feron TB Antigen Tube
- TB-Feron Nil Tube
- Instructions for use

EDMA Code

13 02 80 80 00

Description of EDMA code

Coated tubes (Citrate, Heparin etc.)