

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
Product Name	STANDARD™ F β-hCG FIA STANDARD™ F β-hCG Control <i>*Please refer to "Annex I. Product List" on page 2 in more detail.</i>
Reference Number	F-HCG, C-F-HCG
Classification	Others not covered by Annex II and self-testing according to Directive 98/79/EC
Conformity Assessment Route	Annex III of Directive 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: October 7, 2019

Signature



Hyo-Keun, Lee

Annex I. Product List

F-HCG

STANDARD™ F β -hCG FIA

- Test Device
- Extraction buffer
- Disposable dropper (100ul)
- STANDARD™ Ezi tube+ (20ul)

EDMA Code

12 05 02 06 00

Description of EDMA code

b-Human Chorionic Gonadotropin
(incl. subunit)

C-F-HCG

STANDARD™ F β -hCG Control

- STANDARD™ F β -hCG Control – Level 1
- STANDARD™ F β -hCG Control – Level 2

EDMA Code

12 50 01 04 00

Description of EDMA code

Hormone Controls