

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, Chungchungbuk-do 28161, KOREA
EC Representative Name	MT Promedt Consulting GmbH
EC Representative Address	Altenhofstrasse 80 D-66386 St. Ingbert Germany
Common Name	Immunoassay Test Kit
Model Name	STANDARD™ F PCT FIA <i>*Please refer to "Annex I. Product List" on page 2 in more detail.</i>
Reference Number	F-PCT-02, C-F-PCT2
Catalog Number	10PCT20B, 10PCTC20
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 13485:2012 EN ISO 18113-1:2011 EN ISO 14971:2012 EN ISO 18113-2:2011 EN ISO 15197:2015 EN ISO 15223-1:2016 EN ISO 23640:2015 EN 62366:2008 EN ISO 17511:2003 EN 13612:2002 EN 980:2008

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: April 17, 2018

Signature



Hyo-Keun, Lee
CEO / President

Annex I. Product List

F-PCT-02

STANDARD™ F PCT FIA

- STANDARD™ F PCT FIA Test Device
- Extraction Buffer
- Disposable dropper (100µl)
- Fixed volume dropper (100µl)

EDMA Code
12.06.90.16.00

Description of EMDA code
Procalcitonin

C-F-PCT2

STANDARD™ F PCT-02 Control

- STANDARD™ F PCT-02 Control - Level 1
- STANDARD™ F PCT-02 Control - Level 2

EDMA Code
12.50.01.06.00

Description of EMDA code
Specific Protein Controls