Declaration of Conformity

Manufacturer Name	**SD Biosensor, Inc.**
Manufacturer Address	*Head Office* 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, 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 D-dimer FIA** **STANDARD™ F D-dimer Control** **Please refer to "Annex I. Product List" on page 2 in more detail.*
Reference Number	F-DDI-01, C-F-DDI
Catalog Number	10DDI10B, 10DDIC10
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 14971:2012 EN ISO 15197:2015 EN ISO 23640:2015 EN ISO 17511:2003 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 15223-1:2016 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: March 27, 2018

Signature

Hyo-Keun, Lee
CEO / President

Annex I. Product List

F-DDI-01 **STANDARD™ F D-dimer FIA** - STANDARD™ F D-dimer FIA Test Device - STANDARD™ F D-dimer FIA Extraction buffer - STANDARD™ F D-dimer FIA STANDARD™ Ezi tube+ (10ul) - STANDARD™ F D-dimer FIA Disposable dropper (100ul)	**EDMA Code** 13.02.70.03.00	**Description of EMDA code** D-dimer – Rapid Test

C-F-DDI **STANDARD™ F D-dimer Control** - STANDARD™ F D-dimer Control - Level 1 - STANDARD™ F D-dimer Control - Level 2	**EDMA Code** 13.02.50.90.00	**Description of EMDA code** Other Haemostasis Controls