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	*Please see "Annex 1. Product List" on Page 2 in more detail.*
Reference Number	F-CRP, C-CRP-1, C-CRP-2
Catalog Number	10CRP10B, 03CCS10
Classification	**Others according to Annex II of 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 980:2008 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 15223-1:2017 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. Manufacturer is exclusively responsible for the declaration of conformity.

Place: Suwon-si, Republic of Korea
Valid from: November 17, 2017

Signature

Hyo-Keun, Lee
CEO / President

Annex I. Product List

F-CRP **STANDARD™ F CRP** - STANDARD™ F CRP Test Device - Spoit (Red) - Extraction Buffer	**EDMA Code** 12.11.01.09.00
C-CRP-1, C-CRP-2 **SDB CRP Control** - SDB CRP Control - Level 1 - SDB CRP Control - Level 2	**EDMA Code** 12.50.01.06.00