

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	<i>Please see "Annex 1. Product List" on Page 2 in more detail.</i>	
Reference Number	F-A1C, C-A1C	
Catalog Number	10A1C10B, 03ACS10	
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 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-A1C

STANDARD™ F HbA1c Test

- STANDARD™ F HbA1c Test Device
- Spoit (Blue)
- Extraction Buffer

EDMA Code

11.70.01.07.00

C-A1C

SDB HbA1c Control

- SDB HbA1c Control - Level 1
- SDB HbA1c Control - Level 2

EDMA Code

11.50.02.90.00