

Declaration of Conformity



Manufacturer Name (SRN)	SD Biosensor, Inc. (SRN : KR-MF-000009168)	
Manufacturer Address	<u>Head Office</u> C-4th&5th, 16, Deogyong-daero, 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690, REPUBLIC OF KOREA <u>Manufacturing Site</u> 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do 28161, REPUBLIC OF KOREA	
EC Representative Name (SRN)	MT Promedt Consulting GmbH (SRN: DE-AR-000000085)	
EC Representative Address	Altenhofstrasse 80 66386 St. Ingbert Germany	
Common Name	Immunoassay Analyzer (Semi-automated I.A. System)	
Product Name	STANDARD™ F200 / STANDARD™ F Calibration Kit <i>*Please refer to "Annex I. Product List" on page 2 in more detail.</i>	
Reference Number	F200 / FCAL-10	
Basic UDI	088001117IPATDCFA02FM	
Classification (Applied Rule)	Class A (Rule 5 applied) according to Annex VIII from Regulation (EU) IVDR 2017/746	
Conformity Assessment Route	Article 48, Annex II and Annex III(Regulation (EU) IVDR 2017/746)	
Applied Standards	EN ISO 13485:2016 EN ISO 14971:2019 EN ISO 23640:2015 EN ISO 17511:2003 EN 13612:2002 EN 62304:2006/AC:2008 IEC 60068-2-64:2008+A1:2019 EN 55011:2009+A1:2010 EN 61000-3-3:2014 EN 61010-2-101:2017	EN ISO 18113-1:2011 EN ISO 18113-3:2011 EN ISO 15223-1:2016 EN 62366:2008 IEC 61010-1:2010/AMD1:2016 IEC 61010-2-101:2018 EN 61326-1:2013 EN 61326-2-6:2013 EN 61010-1:2010

We herewith declare that the above mentioned products meet the provisions of the Regulation (EU) 2017 /746 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: May 26, 2022

Signature

Hyo-Keun, Lee
CEO / President

Annex I. Product List

F200**STANDARD™ F200**

- STANDARD™ F200 Analyzer
- STANDARD™ F Calibration Set (FCAL)

EMDN Code

W02010690

Description of EMDN Code

Various rapid test chemistry /
immunochemistry instruments
("point of care" and/or emergency)

FCAL-10**STANDARD™ F Calibration Kit****EMDN Code**

W0101050302

Description of EMDN Code

Calibrators single component (cc)