Declaration of Conformity

CE

Manufacturer (SRN)	SD Biosensor, Inc. (SRN : KR-MF-000009168)
Manufacturer Address	*Head Office* C-4th&5th, 16, Deogyeong-daero, 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do 16690, REPUBLIC OF KOREA *Manufacturing Site* 14, Jeungpyeongsandan-ro, Jeungpyeong-eup, Jeungpyeong-gun, Chungcheongbuk-do 27915, REPUBLIC OF KOREA
EC Representative (SRN)	MT Promedt Consulting GmbH (SRN: DE-AR-000000085)
EC Representative Address	Ernst-Heckel-Straße 7 66386 St. Ingbert Germany
Notified Body	TÜV SÜD PRODUCT SERVICE GmbH
Notified Body Address	Ridlerstr. 65, 80339 München, Germany
Notified Body No.	0123
Certificate No.	EU Technical Documentation Assessment Certificate (IVDR) : TBD EU QMS Certificate (IVDR): TBD
Product Name	STANDARD™ M10 Flu/RSV/SARS-CoV-2 Fast
Reference Number	M10-CVFR-02
Catalogue Number	11FLU30A
Basic UDI-DI	88001117IPBA01MA03WR
Classification (Applied Rule)	Class B (Rule 6) according to Annex VIII from Regulation (EU) IVDR 2017/746
Conformity Assessment Route	Annex IX (Chapter I, II, III) of Regulation (EU) 2017/746 (IVDR)
Common Specification	N/A

We herewith declare that the above mentioned products meet the provisions of the following Regulations/Directives:

Regulation (EU) 2017 /746 for *in vitro* diagnostic medical devices
EN ISO 13485:2016
EN ISO 14971:2019
EN ISO 23640:2015
EN ISO 17511:2021
EN ISO 15223-1:2021
EN ISO 15223-1:2021
EN ISO 20916:2024
EN ISO 13612:2002 / AC:2002
EN ISO 18113-1:2024
EN ISO 18113-2:2024
IEC 62366-1:2015
ASTM D4169-22

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: June 2, 2025

(Signed for and on behalf of SD Biosensor, Inc.) _____

Signature

Name : Hyo-Keun, Lee
Position : CEO