EU 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): N/A EU QMS Certificate (IVDR): V13 075369 0072
Product Name	STANDARD™ M10 MRSA/SA
Reference Number	M10-MRSA-01
Catalogue Number	11MSS10A
Basic UDI-DI	88001117IPCA01MA22XG
Classification (Applied Rule)	Class C (Rule 3(C) applied) 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	Not Applicable

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

The EU declaration of conformity is issued under the sole responsibility of the manufacturer. All supporting documentations are retained under the premises of the manufacturer. SD Biosensor, Inc. is sole responsibility for the declaration of conformity.

Place: ***Suwon-si, Republic of Korea***
Valid from: ***March 25, 2026***

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

Signature

Name : Hyo-Keun, Lee
Position : CEO / President