

Declaration of Conformity



Manufacturer (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> 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	Not Applicable	
Notified Body Address	Not Applicable	
Notified Body No.	Not Applicable	
EC Certificate No.	Not Applicable	
Product Name	STANDARD™ M10 Sputum Pretreatment Kit	
Reference Number	M10-SPTP-01	
Catalogue Number	11PRT10A	
Basic UDI	088001117IPATDCMA11H7	
Classification (Applied Rule)	Class A (Rule 5(a) 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) The conformity assessment procedure for class A devices should be carried out, as a general rule, under the sole responsibility of manufacturers, since such devices pose a low risk to patients. EU declaration of conformity is issued under the sole responsibility of the manufacturer.	
Applied Standards	EN ISO 13485:2016 EN ISO 14971:2019 EN 13612:2002/AC:2002 EN ISO 23640:2015	EN ISO 15223-1:2016 EN ISO 18113-1:2011 EN ISO 18113-2:2011 ISO/TR 20416:2020
Common Specification	Not Applicable	

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 [solely](#) responsible for the declaration of conformity.

Place: Suwon-si, Republic of Korea

Valid from: May 04, 2023

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

Signature

Name : Hyo-Keun, Lee

Position : CEO / President

Annex I. Product List

M10-SPTP-01**STANDARD™ M10 Sputum Pretreatment Kit**

- Sputum Pretreatment solution
- STANDARD™ Disposable dropper (1.4ml)
- Sputum Pretreatment tool

EMDN Code

W0105900201

Description of EMDN codeBUFFERS (UNASSIGNABLE), SUPPLEM.
REAGENTS, ETC