

## **Declaration of Conformity**



Manufacturer (SRN) SD Biosensor, Inc. (SRN: KR-MF-000009168)

Manufacturer Address

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)

Ernst-Heckel-Straße 7 66386 St. Ingbert Germany **EC Representative Address** 

**Notified Body** Not Applicable **Notified Body Address** Not Applicable Notified Body No. Not Applicable EC Certificate No. Not Applicable

**Product Name** STANDARD<sup>TM</sup> M10 Sputum Pretreatment Kit

Reference Number M10-SPTP-01 11PRT10A Catalogue Number

Basic UDI 088001117IPATDCMA11H7

Class A (Rule 5(a) applied) according to Annex VIII from Regulation **Classification (Applied Rule)** 

(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 15223-1:2016

> EN ISO 14971:2019 EN ISO 18113-1:2011 EN 13612:2002/AC:2002 EN ISO 18113-2:2011 EN ISO 23640:2015 ISO/TR 20416:2020

Not Applicable **Common Specification** 

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

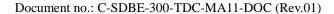
(Signed for and on behalf of SD Biosensors, Inc.) -

Hyo keun lee

Name: Hyo-Keun, Lee

Position: CEO / President

Form: C-SDBE-300-S7-16 Rev.0 (2022.12.05.) **SD BIOSENSOR** 





## Annex I. Product List

## M10-SPTP-01

Form: C-SDBE-300-S7-16

## STANDARD™ M10 Sputum Pretreatment Kit

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

**EMDN Code** W0105900201

**Description of EMDN code** 

BUFFERS (UNASSIGNABLE), SUPPLEM. REAGENTS, ETC

