

Declaration of Conformity



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

Manufacturer Address <u>Head Office</u>

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

Product Name STANDARD™ M10 STI Sample Pretreatment Kit

Reference Number M10-STIP-01
Catalogue Number 11PRT30A

Basic UDI 088001117IPATDCMA12H9

Classification (Applied Rule)

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

(EU) IVDR 2017/746

Conformity Assessment Route Article 48(10), 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 ISO/TR 20416:2020

EN ISO 23640:2015

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 soley exclusively responsible for the declaration of conformity.

Place: Suwon-si, Republic of Korea Valid from: May 30, 2023

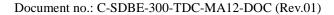
(Signed for and on behalf of SD Biosensors, Inc.) -

Signature

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

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

SD BIOSENSOR





Annex I. Product List

<u>M10-STIP-01</u>		EMDN Code	Description of EMDN code			
STANDARD TM M10 STI Sample Pret	reatment	W0580	IVD	GENERAL	USE	CONSUMABLES
Kit			DEVICES - OTHER ACCESSORIES			
 STI Pretreatment tool 						
- STANDARD™ Disposable dropper ((1.4ml)					

Form: C-SDBE-300-S7-16