

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 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 solely 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

Annex I. Product List

M10-STIP-01

STANDARD™ M10 STI Sample Pretreatment Kit

- STI Pretreatment tool
- STANDARD™ Disposable dropper (1.4mℓ)

EMDN Code

W0580

Description of EMDN code

IVD GENERAL USE CONSUMABLES
DEVICES - OTHER ACCESSORIES