

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 28641, 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 Stool Pretreatment Kit	
Reference Number	M10-STP-01	
Catalogue Number	11PRT20A	
Basic UDI	088001117IPATDCMA13HB	
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 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 exclusively responsible for the declaration of conformity.

Place: *Suwon-si, Republic of Korea*
Valid from: *May 26, 2023*

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

Signature

Name : Hyo-Keun, Lee

Position : CEO / President

Annex I. Product List

M10-STP-01

STANDARD™ M10 Stool Pretreatment Kit

- Stool Pretreatment solution
- Disposable Sampling Swab
- Tube cap
- STANDARD™ Disposable dropper (1.4ml)
- Stool Pretreatment tool

EMDN Code

W0105900201

Description of EMDN code

BUFFERS (UNASSIGNABLE), SUPPLEM.
REAGENTS, ETC