

## **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 28641, REPUBLIC OF KOREA

MT Promedt Consulting GmbH (SRN: DE-AR-00000085) EC Representative (SRN)

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

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

STANDARDTM M10 Stool Pretreatment Kit **Product Name** 

M10-STP-01 Reference Number 11PRT20A Catalogue Number

088001117IPATDCMA13HB **Basic UDI** 

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

(EU) IVDR 2017/746

Article 48 (10), Annex II and Annex III(Regulation (EU) IVDR **Conformity Assessment Route** 

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.

EN ISO 13485:2016 **Applied Standards** 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 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.) –

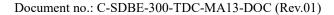
Hyo keun lee

Name: Hvo-Keun, Lee

Position: CEO / President

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

😂 SD BIOSENSOR





Form: C-SDBE-300-S7-16

## 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 BUFFERS (UNASSIGNABLE), SUPPLEM. REAGENTS, ETC

