



## **Declaration of Conformity**



Manufacturer Name SD Biosensor, Inc.

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

74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu,

Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

EC Representative Name MT Promedt Consulting GmbH

EC Representative Address Altenhofstrasse 80 66386 St. Ingbert Germany

Common Name Real Time RT-PCR Test Kit

Product Name STANDARD<sup>TM</sup> M10 Arbovirus Panel

\*Please refer to "Annex I. Product List" on page 2 in more detail.

**Reference Number** M10-AB5-01

Classification Others not covered by Annex II and self-testing according to

Directive 98/79/EC

Conformity Assessment Route Annex III of Directive 98/79/EC (EC Declaration of Conformity)

Applied Standards EN ISO 13485:2016 EN ISO 14971:2012

EN ISO 17511:2003 EN 13612:2002 EN ISO 15223-1:2016 EN ISO 23640:2015 EN ISO 18113-1:2011 EN 62366:2008

EN ISO 18113-2:2011

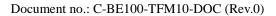
We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentations are retained under the premises of the manufacturer. SD Biosensor, Inc. is exclusively responsible for the declaration of conformity.

Place: Suwon-si, Republic of Korea

Valid from: May 20, 2022

Signature

Hyo-Keun, Lee CEO / President





## Annex I. Product List

## $\frac{M10\text{-}AB5\text{-}01}{\text{STANDARD}^{\text{TM}}\,\text{M10 Arbovirus Panel}}$

- Cartridge
- Quick Reference Instructions

EDMA Code
15 04 40 90 00
15 04 40 11 00

## **Description of EDMA code**Other Virology – NA Reagents Dengue Virus – NA reagent