



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 PCR Test Kit

Product Name STANDARDTM M10 MDR-TB

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

Reference Number M10-MTB-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

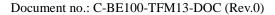
We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentations are retained under the premises of the manufacturer. SD Biosensor, Inc. is exclusively responsible for the declaration of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

Place: Suwon-si, Republic of Korea

Valid from: May 20, 2022

Signature

Hyo-Keun, Lee CEO / President





Annex I. Product List

$\frac{M10\text{-}MTB\text{-}01}{\text{STANDARD}^{\text{TM}}\,\text{M10 MDR-TB}}$

- Cartridge
- Quick Reference Instructions

EDMA Code 15 01 07 40 00

Description of EDMA code

Mycobacterial Detection by NA Reagents