

Attachment I. Non-significant Change History

(After 26 May 2022)

Manufacturer Name SD Biosensor, Inc.
Manufacturer Address Head Office
C-4th&5th, 16, Deogyong-daero, 1556beon-gil, Yeongtong-gu,
Suwon-si, Gyeonggi-do 16690, KOREA

EC Representative Name MT Promedt Consulting GmbH
Ernst-Heckel-Straße 7 66386 St. Ingbert Germany

Product Name STANDARD™ M10 MDR-TB
Reference Number M10-MTB-01

#	Change No.	Change Date	Change History	Remark
1	M-22-022	7 February 2023	Manufacturing site Address Change - As is: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do 28161, REPUBLIC OF KOREA - To be: 14, Jeungpyeongsandan-ro, Jeungpyeong-eup, Jeungpyeong-gun, Chungcheongbuk-do, 27915, REPUBLIC OF KOREA	STANDARD™ M10 MDR-TB
2	O-22-003	18 April 2023	EAR (EC-REP) Address Change - As is: Altenhofstrasse 80 66386 St. Ingbert Germany - To be: Ernst-Heckel-Straße 7 66386 St. Ingbert Germany	STANDARD™ M10 MDR-TB
3	NC23-06-10	23 June 2023	Updated interpretation of results and note in detail. Updated handling condition in detail.	STANDARD™ M10 MDR-TB

In accordance with the MDCG 2022-6 guidance, we herewith declare that the above mentioned changes are non-significant.

This attachment belongs to the DoC [C-BE100- TFM13-DOC (Rev.0)], which was issued on May 20, 2022.

Place: Suwon-si, Republic of Korea
Date of issue: July 28, 2023

Signature



Hyo-Keun, Lee
CEO / President