

# 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™ M C. *difficile*  
**Reference Number** M10-CDF-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 C. <i>difficile</i>
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 C. <i>difficile</i>

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-TFM16-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