



Certificate of EU product notification

Herewith we confirm that

MT Promedt Consulting GmbH
Altenhofstraße 80
66386 St. Ingbert
Germany

has taken over the function of an European Authorized Representative according to the requirements of Article 10 of the IVDD 98/79/EC for

SD Biosensor, Inc.
Head Office: C-4th&5th, 16, Deogyong-daero, 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, Republic of Korea
Manufacturing Site: 74, Osongsaengmyeong 4-ro, Osong-eup, Cheongwon-gun, Chungcheongbuk-do, 28161, Republic of Korea

MT Promedt Consulting GmbH has made the product notification at the relevant competent authority according to Article 10(3).
The in vitro diagnostic medical devices of the manufacturer, covered by the notification, are listed in Annex I of this certificate.

18 March 2020

Dr. Michael Rinck
- Managing Director -

Enclosure
Annex I



SD Biosensor, Inc.

Annex I
to "Certificate of EU Product Notification"
(List of CE marked Products)

Reference number	Product Name (Model name)	Registration Number (at the German CA/DIMDI) DE/CA70/40838/	Product Category (EDMS)	EDMS Code Description	Classific. Annex
Q-NCOV-01D	STANDARD™ Q COVID-19 IgM/IgG Duo Test	153967	15 70 90 90 00	Other Other Virology Rapid Tests	III
Q-NCOV-01G	STANDARD™ Q COVID-19 Ag Test	153967	15 70 90 90 00	Other Other Virology Rapid Tests	III
M-NCOV-01	STANDARD™ M nCoV Real-Time Detection kit	154022	15 04 90 90 00	Other Other Virology Reagents	III
F-NCOV-01G	STANDARD™ F COVID-19 Ag FIA	154022	15 04 90 90 00	Other Other Virology Reagents	III

18 March 2020

Dr. Michael Rinck
- Managing Director -