



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.

This certificate does not attest the conformity of the medical devices with the above mentioned directive. The conformity is stated in the respective product-related Declarations of Conformity signed under the sole responsibility of the manufacturer.

8 May 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)

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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	154896	15 70 90 90 00	Other Other Virology Rapid Tests	III
Q-NCOV-01G	STANDARD™ Q COVID-19 Ag Test	154896	15 70 90 90 00	Other Other Virology Rapid Tests	III
M-NCOV-01	STANDARD™ M nCoV Real-Time Detection kit	155230	15 04 90 90 00	Other Other Virology Reagents	III
F-NCOV-01G	STANDARD™ F COVID-19 Ag FIA	155230	15 04 90 90 00	Other Other Virology Reagents	III
F-NCOV-01D	STANDARD™ F COVID-19 IgM/IgG Duo FIA	155230	15 04 90 90 00	Other Other Virology Reagents	III
C-NCOV-01G	STANDARD™ Q COVID-19 Ag Control	154682	15 50 01 04 00	Other Virology Controls-Inf.Imm	III
C-NCOV-01D	STANDARD™ COVID-19 IgM/IgG Control	154682	15 50 01 04 00	Other Virology Controls-Inf.Imm	III
Q-NCOV-01C	STANDARD™ Q COVID-19 IgM/IgG Combo Test	154896	15 70 90 90 00	Other Other Virology Rapid Tests	III
F-NCOV-01C	STANDARD™ F COVID-19 IgM/IgG Combo FIA	155230	15 04 90 90 00	Other Other Virology Reagents	III

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