Sugentech

721-26,Jeongjungyeonje-ro, Osong-eup,
Heungdeok-gu, Cheongju-si
Chungcheongbuk-do, 28161, Republic of Korea
Phone: +82-43-710-2836, Fax: +82-43-710-2870
Email: info@sugentech.com , Website: www.sugentech.com

DECLARATION OF CONFORMITY

MANUFACTURER:	*SUGENTECH, INC.* *721-26, JEONGJUNGYEONJE-RO, OSONG-EUP,* *HEUNGDEOK-GU, CHEONGJU-SI,* *CHUNGCHEONGBUK-DO 28161,* *REPUBLIC OF KOREA*
EUROPEAN REPRESENTATIVE:	*MT PROMEDT CONSULTING GMBH* *ALTENHOFSTR. 80, 66386 ST.INGBERT GERMANY*
PRODUCT:	SGTi-flex COVID-19 IgM/IgG
CLASSIFICATION:	*GENERAL IVDS*
EDMA CODE	15 70 90 90 00 (OTHER OTHER VIROLOGY RAPID TESTS)
CONFORMITY ASSESSMENT ROUTE:	*ANNEX III*

WE HERE WITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER AND MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED: *LIST OF (HARMONIZED) STANDARDS FOR WHICH DOCUMENTED EVIDENCE FOR COMPLIANCE CAN BE PROVIDED (ATTACHMENT 1)*

START OF CE-MARKING: *MARCH 12, 2020*

PLACE, DATE OF ISSUE: *CHEONGJU-SI, MARCH 12, 2020*

SIGNATURE:

MIJIN SOHN / PRESIDENT

HC Solutions