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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 Ag REF: CAGT010E0 CAGT020E0 CAGT025E0 REF: CAGT010E1 CAGT020E1 CAGT025E1 REF: CAGT010E2 CAGT020E2 CAGT025E2 SGTi-flex COVID-19 Ag Control REF: CAGC001E
CLASSIFICATION:	*GENERAL IVDS*
EDMA CODE	15 70 90 90 00 (OTHER OTHER VIROLOGY RAPID TESTS) 12 50 01 06 00 (SPECIFIC PROTEIN CONTROLS)
CONFORMITY ASSESSMENT ROUTE:	*ANNEX III*

Sugentech

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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)*

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SIGNATURE:

MIJIN SOHN / PRESIDENT