

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 IgG*

Product Code (Catalog No.) *COGT005E, COGT010E, COGT020E
COGT025E, COGT030E, COGT050E,
COGT100E*

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: *AUGUST 19, 2020*

PLACE, DATE OF ISSUE: *CHEONGJU-SI, AUGUST 19, 2020*

SIGNATURE:


MIJIN SOHN / PRESIDENT