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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 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

List of Harmonized Standards

Standard No.	Title of the standard
EN ISO 13485:2016 EN ISO 13485:2016 / AC:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN 13612:2002 EN 13612:2002/AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 23640:2015	*In vitro* diagnostic medical devices — Evaluation of stability of *in vitro* diagnostic reagents
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
EN ISO 17511:2003	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)
EN 62366:2008	Medical devices - Application of usability engineering to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
CLSI Guideline, EP07-A2	Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition
CLSI Guideline, EP12-A	User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline
CLSI Guideline, EP14-A2	Evaluation of Matrix Effects; Approved Guideline-Second Edition
CLSI Guideline, EP17-A	Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline
CLSI Guideline, I/LA21-P	Clinical Evaluation of Immunoassays, Approved Guideline