

EC DECLARATION OF CONFORMITY

SolGent Co., Ltd.

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Declares that the medical device(s) described hereafter
Other Virology – NA Reagents, 15 04 40 90 00 (EDMA code)

Model Name: DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit

Catalogue Number: SQD52-K100, SQD52-K020

Has been classified as Others not covered by Annex II and self-testing according to Directive 98/79/EC.

Is in conformity with the applicable requirements of the following documents

Ref. No.
EN ISO 15223-1 : 2016
ISO 13485 : 2016
EN 13612 : 2002
EN ISO 17511 : 2003
EN 23640 : 2015
EN 13641 : 2002
EN ISO 14971 : 2012
EN ISO 18113-1 : 2011
EN ISO 18113-2 : 2011
IEC 62366-1:2015
IEC 62366-2:2016

Is subject to the conformity assessment procedure set out in Annex III of Directive 98/79/EC

26th, February, 2020 Signature: *Chameejong*

