

DECLARATION OF CONFORMITY

MANUFACTURER



: 1drop Inc.

A-203, Keumkang Pentarium IT Tower, 215,
Galmachi-ro, Jungwon-gu, Seongnam-si,
Gyeonggi-do, 13217, REPUBLIC OF KOREA

EUROPEAN
REPRESENTATIVE



: MT Promedt Consulting GmbH

Altenhofstr. 80
66386 St. Ingbert, Germany

PRODUCT

: 1copy™ COVID-19 qPCR Multi Kit

CATALOG NO.

: M22MD100M

EDMA code/ Term

: 16 90 90 01 90 Other Other Genetic Tests

Registration
Number

: DE/CA70/40838-154617

CLASSIFICATION

: Others (Neither listed in Annex II of IVDD Nor self-testing)

CONFORMITY

: IVDD ANNEX III

ASSESSMENT ROUTE

We here with declare that the above mentioned products meet the provisions of the council directive 98/79/EC for In Vitro diagnostic medical device. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED

: EN ISO 13485:2016, EN 15223-1:2016, EN 13612:2002/AC:2002, EN 13975:2003, EN ISO 14971:2012, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 23640:2015

START DATE OF CE MARKING: 2020-03-27

PLACE, DATE OF ISSUE : Seongnam-si, 2020-03-27

SIGNATURE

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