

DECLARATION OF CONFORMITY

MANUFACTURER



Absology Co., Ltd.

#1303, Digital Empire "B", Simin-daero 383,
Dongan-Gu, Anyang-Si, Gyeonggi-Do, 14057,
Republic of Korea

**EUROPEAN
AUTHORIZED
REPRESENTATIVE**



MT Promedt Consulting GmbH

Altenhofstrasse 80, 66386 St. Ingbert, Germany
(DIMDI Code: DE/0000040838)

PRODUCT NAME

Absoludy COVID-19 IgM / IgG RAPID

INIST COVID-19 IgM / IgG RAPID

MODEL NAME

ABCVR-025

EDMA CODE / TERM

15 70 90 90 00 Other Other Virology Rapid Tests

CLASSIFICATION

**"Other IVD" according to IVDD 98/79/EC,
No Annex II, No List A+B product, No self-testing product**

CONFORMITY

ASSESSMENT ROUTE

IVDD Annex III EC Declaration of Conformity

We herewith declare that the above mentioned products meet the provisions of the council directive 98/79/EC for in vitro diagnostic 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

**EN ISO13485:2016, EN13612:2002, EN ISO
23640:2015, EN ISO14971:2012, EN ISO 18113-1
:2011, EN ISO18113-2:2011, EN13641:2002, EN
ISO15223-1:2016, EN 62366:2008, EN ISO17511:2003**

EC CERTIFICATE No.

N/A

NOTIFY BODY PLACE,

N/A

DATE OF ISSUE

Anyang-Si, Korea, 2020-05-20

SIGNATURE

**Han Sang Jo, Ph.D.
CEO of Absology Co., Ltd.**