

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 Ag RAPID
INIST COVID-19 Ag Rapid**

MODEL NAME

**ABCAR-020, MD4000201220, ABCAR-005,
MD4000201205, ABCAR-001, MD4000201201**

EDMA CODE / TERM

15 70 90 90 00 / Other Other Virology Rapid Tests

CLASSIFICATION

Other IVD according to IVDD 98/79/EC

**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**

**PLACE,
DATE OF ISSUE**

Anyang-Si, Korea, 2020-12-16

SIGNATURE

A handwritten signature in black ink, appearing to read "Han Sang Jo".

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