EC Declaration of Conformity

In accordance with Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

WE HEREWITH DECLARE EXCLUSIVELY UNDER SOLE RESPONSIBILITY THAT THE BELOW MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product name:	Rapid detection kit for SARS-CoV-2 antigens
Model Name:	Asan Easy Test® COVID-19 Ag
Catalogue Number:	AM3474-K (20T) / AM3476-K (25T)

Applied Directive : 98/79/EC

Classification : other IVD according to Annex III of the IVD Directive 98/79/EC

Conformity Assessment Route : Annex III of the Directive 98/79/EC
(No Annex II, List A or B product, no self-testing product)

Manufacturer : **ASAN PHARMACEUTICAL CO., LTD.**

Address : 122-26, Gieopdanji-ro, Gongdo-eup, Anseong-si, Gyeonggi-do, 17551, Korea

EC Representative : **MT Promedt Consulting GmbH**

Address : Altenhofstrasse 80, 66386 St. Ingbert, Germany

EDMA code : 15 70 90 90 00 Other Other Virology Rapid Tests

Date : 2020.11.30

Place of Issue : Anseong-si

Yoom, Joong Gyu

CEO of ASAN PHARMACEUTICAL CO., LTD.

Annex I. Applied standards

EN ISO 13485: 2016	Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971: 2019	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2016	Symbols for use in the labelling of medical devices
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 13612: 2002 / AC: 2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 18113-1: 2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labeling) – Part 1: Terms, definitions and general requirements
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
EN ISO 23640:2015	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
EN 62366:2008/A1:2015	Medical devices - Application of usability engineering to medical devices (IEC 62366:2007/A1:2014)