FUJIFILM

FUJIFILM Corporation
26-30, NISHIAZABU 2-CHOME, MINATO-KU
TOKYO 106-8620, JAPAN

Declaration of Conformity

21 - CEI - 862 - A

Manufacturer:	FUJIFILM Corporation
Address:	26-30, Nishiazabu 2-chome, Minatoku, Tokyo 106-8620, JAPAN
European Representative:	FUJIFILM Europe GmbH
Address:	Heesenstrasse 31 40549 Duesseldorf, GERMANY
Product:	FUJIFILM COVID-19 Ag Test
GMDN Code	64787
EDMA Code	15.70.90.08
Start of CE Marking:	Lot No. xxx00001
Classification:	Other devices The device is not referred in Article 9 (2) and (3).
Conformity Assessment Route:	Annex III without Section 6

We herewith declare that the above mentioned product meets the provisions of the following EC Council Directive.

Directive:

COUNCIL DIRECTIVE 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices (IVDD 98/79/EC)

Standards:

EN ISO13485:2016 Medical devices - Quality management systems - Requirements for regulatory purpose

EN ISO 14971:2012 Medical devices - Application of risk management to medical devices

EN 13612: 2002 Performance evaluation of in vitro diagnostic medical devices

EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements

EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - 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

Place: Kanagawa, JAPAN

Date: 2021-2- 8

Naotake Mitsumori
General Manager,
Quality Assurance & Regulatory Affairs Division
Medical Systems Business Division
FUJIFILM Corporation