

Manufacturer's EC Declaration of Conformity

Name of issuer/manufacturer: BIOLAN HEALTH, S.L.
Address: Parque Tecnológico de Bizkaia, Laida bidea 409. 48170 Zamudio (Bizkaia)
Telephone: 946 574 161
Website: www.biolanhealth.com

Biolan Health, S.L. declares, under their sole responsibility, that the named product:

Commercial name: *COVID-19 Antigen Rapid Test. Self Test*
Catalog numbers: *KASTCOV19-1, KASTCOV19-5, KASTCOV19-25*
BASIC UDI-DI: *8437022705TSANTIGST00P5*

complies with Directive 98/79/EC, of October 27, 1998, on in vitro diagnostic medical devices.

Description:

The rapid test from BIOLAN HEALTH for self testing, called *COVID-19 Antigen Rapid Test. Self Test*, is a lateral flow immunochromatographic assay intended for the qualitative detection of the nucleocapsid antigen of SARS-CoV-2 virus in nasal swab samples in only 15-20 minutes. The product is designed as a self-test for lay users.

This Declaration of Conformity is valid from: 2022-05-20



Larraitz Añorga Gómez
CEO