BIOLAN HEALTH

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

In accordance with the following directive:

98/79/EC of 27 October on in vitro diagnostic medical devices. Annex III (self-marked).

Declares, under their sole responsibility, the conformity of the in vitro diagnostic Medical Device:

Commercial name: **COVID-19 Antigen Rapid Test**
Catalog numbers: **KACOV19-25, KACOV19-25C, KACOV19-5**
BASIC UDI-DI: **8437022705TSANTIG00TJ**

Description:

The rapid test from BIOLAN HEALTH, called COVID-19 Antigen Rapid Test is a lateral flow immunochromatographic assay intended for the qualitative detection of SARS-CoV-2 virus in nasal specimen swabs.

Applicable reference standards:

Ref. / Number	*Title*	*Edition/Issue date*
UNE-EN ISO 13485:2018	Medical devices. Quality Management Systems. Requirements for regulatory purposes. (ISO 13485: 2016)	2018
UNE-EN ISO 14971/2020	Medical devices. Application of risk management to medical devices. (ISO 14971:2020)	2020
UNE-EN ISO 18113-1:2012	In vitro diagnostic medical devices. Information provided by the manufacturer (labeling). Part 1: Terms, definitions and general requirements. (ISO 18113-1: 2009)	2012
UNE-EN ISO 15223-1:2017	Medical devices. Symbols to be used on labels, labeling and the information to be supplied. Part 1: General requirements. (ISO 15223-1: 2016).	2017
ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.	2021

Additional information

This Declaration of Conformity is supported by: Directive 98/79/EC.

This Declaration of Conformity is valid from: 2022-01-10

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Administrator

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