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:

COVID-19 IgG/IgM Rapid Test Cassette.

Description:

The rapid test from BIOLAN HEALTH, called COVID-19 IgG/IgM Rapid Test Cassette, is a lateral flow immunochromatographic assay for the qualitative detection and differentiation of IgG and IgM antibodies against SARS-CoV-2, the virus that causes COVID-19 disease, in human whole blood, serum or plasma.

Applicable reference standards:

Ref. / Number	*Title*	*Edition/Issue date*
UNE-EN ISO 13485	Productos Sanitarios. Sistemas de Gestión de la Calidad. Requisitos para fines reglamentarios.	2016
UNE-EN ISO 14971/2020	Productos Sanitarios. Aplicación de la gestión de riesgos a los productos sanitarios.	2020
UNE-EN ISO 18113-1:2012	Productos sanitarios para diagnóstico in vitro. Información proporcionada por el fabricante (etiquetado). Parte 1: Términos, definiciones y requisitos generales. (ISO 18113-1:2009)	2012
UNE-EN ISO 15223-1:2017	Productos sanitarios. Símbolos a utilizar en las etiquetas, el etiquetado y la información a suministrar. Parte 1: Requisitos generales. (ISO 15223-1:2016).	2017
ISO 15223-2:2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied -- Part 2: Symbol development, selection and validation.	2010

Additional information

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

This Declaration of Conformity is valid from: 18 December 2020.

Signed:

Asier Albizu Lluvia
Administrator

BIOLAN HEALTH
Parque Tecnológico de Bizkaia
Laida Bidea - Edificio 409
48170 Zamudio (Bizkaia)
CIF: B95788725