EC DECLARATION OF CONFORMITY

In compliance with Regulation Directive 98/79/EC of the European Parliament and of the Council on 27 October 1998 of in vitro diagnostic medical devices ANNEX III, this declaration of conformity applies to the product:

INgezim® COVID 19 DR

PRODUCT CODE	PRESENTATION
R.50.CoV.K.0	1 plate
R.50.CoV.K.0/5	5 plates

The product is a dual recognition immunoenzymatic assay for detecting antibodies specific to SARS-CoV-2 in serum or plasma samples

Classified as: Other Device (all devices except Annex II and self-testing devices).

Produced by: Inmunología y Genética Aplicada, SA (INGENASA)
Avenida de la Institución Libre de Enseñanza, 39 28037 MADRID
In vitro diagnostic devices manufacturer license 7709-PS

This Declaration attests that all provisions concerning the manufacturing of In Vitro Diagnostic Devices on the EC DIRECTIVE 98/79/CEE and in its transposition to Spanish legislation in Royal Decree 1662/2000 are applied and the product conforms to the Essential Requirements of this Directive

The Standards used for the showing compliance with the essential requirements in the specified directive(s) is EN-ISO 9001:2015.

Madrid, 3th May 2020

Signed by: Belen Barreiro
INGENASA General Manager

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