



EC DECLARATION OF CONFORMITY

We, Ansh Labs, 445 Medical Center Blvd, Webster, TX 77598-4217, USA declare under our sole responsibility that the product

Product Code: AL-1002-i
Product Name: SARS-CoV2 IgM ELISA (μ -Capture)
Manufacturer: Ansh Labs, Webster, 77598, Texas, USA

meets the provisions of Annex I of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices.

The following harmonized standard has been applied:

ISO 13485:2016

A Conformity assessment procedure according to Annex III (European Directive 98/79/EC) for self-declared in vitro Diagnostic Medical Devices was accomplished by the European Representative.

European Representative:
RD-RatioDiagnostics GmbH
Westerbachstr.47
60489 Frankfurt
Germany

Technical documentation demonstrating compliance is kept by the European Representative (RD-RatioDiagnostics GmbH, Westerbachstr.47, 60489 Frankfurt, Germany).

Respectfully Submitted,


Gopal Savjani
President

Date: April 13, 2020