



2-1-1 Nishishinjuku, Shinjuku-ku,
Tokyo 163-0410, JAPAN

PHONE: 81-3-6279-0800
FACSIMILE: 81-3-6279-0299

No.: EP SARS-CoV-2-001

Declaration of Conformity

MANUFACTURER: Fujirebio Inc.
2-1-1 Nishishinjuku, Shinjuku-ku, Tokyo 163-0410, JAPAN

EUROPEAN REPRESENTATIVE: Fujirebio Europe N.V.
Technologiepark 6, 9052 Gent, BELGIUM

PRODUCT: **ESPLINE SARS-CoV-2**
(ref 231906)

CLASSIFICATION: Neither LIST nor Self-Testing Products According to ANNEX II

CONFORMITY ASSESSMENT ROUTE:

The conformity assessment procedure followed is Annex III excluding section 6 of the Directive 98/79/EC.


STANDARDS: Listed in the latest version of Essential Requirements in the Technical Documentation

We herewith declare that:

- (1) the above mentioned product meets the provisions of the Council Directive 98/79/EC for In-Vitro Diagnostic Medical Devices,
- (2) the declaration of the conformity is issued under the sole responsibility of the Manufacturer, and
- (3) we retain all supporting documentations.

Start of CE-Marking: Tokyo, August 11, 2020

SIGNATURE: _____


Masahiro Hosono
Marketing Supervisor-General
Fujirebio Inc.

DATE: _____

