# CE CERTIFICATE NOTIFICATION

## CMC MEDICAL DEVICES & DRUGS SL

C/ Horacio Lengo Nº18, CP29006 Málaga-Spain

NO. CMC/CE/2020/17042020-1

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative for

**Annex I Medical Device Products with 1 page**

MANUFACTURER BY COMPANY:

**Zephyr Biomedicals – A Division of Tulip Diagnostics (P) Ltd.**
**Plot No: M-46/47, Phase IIIB, Verna Industrial Estate, Verna, Goa-India**

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

The manufacturer has provided CMC Medical Devices & Drugs S.L. with all the appropriate declarations as per the Council Directive 98/79/EEC, including EC Declaration of Conformity.

The products covered are in Annex I of 1 page. All IVD others products list was registered in Spanish Agency of Medical Devices (AEMPS) with registration number **RPS/531/2020**. This product list is in compliance with the Council Directive 98/79/EEC Annex III (IVD Others). This registration allows to place the CE in the products as well as its commercialization in the EU and EEA Territory.

Issued on: 17/04/2020

Authorized Signatory
CMC Medical Devices & Drugs SL

CE

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**LIST OF ITEMS COVERED BY THIS CERTIFICATE NO. CMC/CE/2020/17042020-1**

**COVISCREEN DEVICE (RAPID DOUBLE ANTIGEN SCREENING TEST FOR THE DETECTION OF IGM/IGG/IGA ANTIBODIES TO COVID-19 IN HUMAN SERUM/PLASMA/WHOLE BLOOD)**

**COVICHECK DEVICE (RAPID TEST FOR THE DETECTION OF IGM & IGG ANTIBODIES TO SARS-COV-2 VIRUS IN HUMAN SERUM/PLASMA/WHOLE BLOOD**