DECLARATION OF CE CONFORMITY

Manufacturer Name

CERTEST BIOTEC S.L.
POLIGONO IND. RIO GALLEGO II, CALLE J Nº1 – 50840, SAN MATEO DE GALLEGO, ZARAGOZA, (SPAIN)

Declares under its own responsibility that the product(s) subject to this declaration is/are in accordance with Directive 98/79/EC and R.D. 1662/2000 on *in vitro* diagnostic medical devices.

Product(s):	VIASURE *SARS-CoV-2, Flu & RSV* Real Time PCR Detection kit
GIVD Code:	15.30.04.42 *(Global InVitro Diagnostic (GIVD) Classification-Version 2018)* Infectious diseases
Catalogue reference(s)	VS-CFR106L, VS-CFR106H, VS-CFR112L, VS-CFR112H, VS-CFR113L, VS-CFR113H VS-CFR196T, VS-CFR136, VS-CFR172
Intended use:	VIASURE *SARS-CoV-2, Flu & RSV* Real Time PCR Detection Kit is a real-time RT-PCR test designed for the qualitative detection of RNA from the SARS-CoV-2, Influenza A/B (Flu A/B) and/or Human Respiratory Syncytial Virus A/B (RSV A/B) in respiratory specimens from individuals suspected of respiratory infections by their healthcare provider.
Device risk class:	*In vitro* diagnostic self-certification medical device not included in list A or B of the Annex II of the Directive 98/79/EC and the R.D. 1662/2000.

Reference to any Common Specifications and/or harmonized standards used which conformity is declared

EN ISO 13485:2016, EN ISO 14971, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN ISO 23640:2015, EN 13612:2002.

Notified Body

Name:	N/A
Identification number:	N/A
Conformity assessment procedure:	N/A
Identification of the certificate(s) issued:	N/A

Additional Information

N/A

San Mateo de Gállego, 4 September 2020

Nelson Gonçalves Fernandes
General Manager