Declaration of Conformity

Manufacturer:
Hecin Scientific, Inc.
4F, Building A, #1 Ruifa Rd, Luogang District, Guangzhou, P. R. China 510530

European Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Product Name:
COVID-19 Real-time PCR Assay Kit

Model:
CRPA-1

Classification:
Other device, not in annex II, not for self-testing, not for performance evaluation.

Conformity Assessment Route: Annex III (IVDD 98/79/EC)
We herewith declare that the mentioned products meet the provisions of the following EC Council Directives. All supporting documentations are retained under the premises of the manufacturer. Hecin Scientific, Inc. takes exclusively responsible for this declaration of conformity.

Directives
In Vitro Diagnostic Medical Device Directive: DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices (IVDD 98/79/EC).

Standards Applied

EN ISO 13612: 2002	EN ISO 14971: 2012	EN ISO 18113-1: 2011
EN ISO 18113-3:2011	EN ISO 15223-1: 2016	

First Start of CE Marking: 2020-03-11

Signature: General Manager

Place, Date of Issue: Guangzhou, 2020-03-11