EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Hangzhou Clongene Biotech Co., Ltd.**
No.1 Yichuang Road, Yuhang Sub-district, Yuhang District,311121 Hangzhou,China

We declare under our sole responsibility that

the medical device: **COVID-19 Antigen Rapid Test Cassette (Saliva)**

of class: **Other**
according to aticle 9 of directive 98/79/EC

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device.

Conformity assessment procedure:**Directive 98/79/EC Annex III, excluding Section 6**

Standards Applied:

EN ISO 13485:2016	**EN ISO 15223-1:2016**
EN ISO 23640:2015	**EN 13612:2002/AC:2002**
EN 13975:2003	**EN ISO 14971:2012**
EN ISO 18113-1:2011	**EN ISO 18113-2:2011**
EN 62366-1:2015	

Name and address of the Authorised Representative: **Shanghai International Holding Corporation GmbH (Europe)**
Eiffestrasse 80
20537 Hamburg
Germany

Hangzhou, February 03, 2021
Place, date

Shujian Zheng, Legal representative
Name and function

杭州隆基生物技术有限公司
HANGZHOU CLONGENE BIOTECH CO., LTD.

Anlage 2
(zu § 4 Abs. 1 Nr. 1 DIMDIV)
Formularnummer 00160613

Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG
General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für In-vitro-Diagnostika / Form for In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code **DE/CA05**		
	Bezeichnung / Name **Behörde für Justiz und Verbraucherschutz, Referat V43**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20310**
	Straße, Haus-Nr. / Street, house no. **Postfach 30 28 22**		
	Telefon / Phone **+49-40-428280**		Telefax / Fax **+49-40-427310017**
	E-Mail / E-mail **medizinprodukte@justiz.hamburg.de**		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority **03.02.2021**		Registriernummer / Registration number **DE/CA05/lvD-238321-1721-00**
	Typ der Anzeige / Notification type Erstanzeige / Initial notification Änderungsanzeige / Notification of change Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG Hersteller / Manufacturer Bevollmächtigter / Authorised Representative Einführer / Importer Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)			
	Code **DE/0000040627**		
	Bezeichnung / Name **Shanghai International Holding Corporation GmbH (Europe)**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20537**
	Straße, Haus-Nr. / Street, house no. **Eiffestrasse 80**		
	Telefon / Phone **+49-40-2513175**		Telefax / Fax **+49-40-255726**
	E-Mail / E-mail **shholding@hotmail.com**		

Hersteller / Manufacturer			
	Bezeichnung / Name **Hangzhou Clongene Biotech Co., Ltd.**		
	Staat / State **CN**		
	Ort / City **Hangzhou**		Postleitzahl / Postal code **311121**
	Straße, Haus-Nr. / Street, house no. **No.1 Yichuang Road, Yuhang Sub-district, Yuhang District**		
	Telefon / Phone **+86-571-88262120**		Telefax / Fax **+86-571-88262112**
	E-Mail / E-mail **clongene@clongene.com**		

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) **Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG**			
	Bezeichnung / Name **Liang Jin**		
	Staat / State **Deutschland**		Land / Federal state **Hamburg**
	Ort / City **Hamburg**		Postleitzahl / Postal code **20537**
	Straße, Haus-Nr. / Street, house no. **Eiffestr.80**		
	Telefon / Phone **+49-40-2513175**		Telefax / Fax **+49-40-255726**
	E-Mail / E-mail **shholding@hotmail.com**		

Vertreter / Deputy (optional)			
	Bezeichnung / Name		
	Telefon / Phone		Telefax / Fax
	E-Mail / E-mail		
	Erstanzeige / Initial notification Änderungsanzeige / Notification of change		

In-vitro-Diagnostikum / In vitro diagnostic medical device	
	Klassifizierung / Classification Produkt der Liste A, Anhang II / Device of List A, Annex II Produkt der Liste B, Anhang II / Device of List B, Annex II Produkt zur Eigenanwendung / Device for self-testing Sonstiges Produkt / Other device (all devices except Annex II and self-testing devices)
	App (Software auf mobilen Endgeräten) ja / yes nein / no
	Anzeige nach § 25 Abs. 3 Nummer 3 MPG Notification pursuant to § 25 (3) number 3 Medical Devices Act, MPG "Neues In-vitro-Diagnostikum / New in vitro diagnostic medical device"
	Handelsname des Produktes / Trade name of the device **Clongene**
	Produktbezeichnung / Name of device **COVID-19 Antigen Rapid Test Cassette (Saliva)**
	Angabe der benutzten Nomenklatur / Nomenclature used EDMS-Klassifikation / EDMS Classification GMDN
	Nomenklaturcode / Nomenclature code **15-70-90-90-00**
	Nomenklaturbezeichnung / Nomenclature term **OTHER OTHER VIROLOGY RAPID TESTS**
	Kurzbeschreibung / Short description In Deutsch / In German
	In Englisch / In English **The COVID-19Antigen Rapid Test Cassette (Saliva) is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in saliva from individuals who are suspected of COVID-19 by their healthcare provider. **

Zusätzliche Angaben im Falle der In-vitro-Diagnostika gemäß Anhang II und der In-vitro-Diagnostika zur Eigenanwendung / Addtional information for Annex II and self-testing in vitro diagnostic medical devices	
	Nummer(n) der Bescheinigung(en) / Certificate number(s)
	In Übereinstimmung mit den Gemeinsamen Technischen Spezifikationen (für Produkte gem. Anhang II, Liste A) In conformity with Common Technical Specifications (for Annex II List A devices)
	Ergebnisse der Leistungsbewertung Outcome of performance evaluation

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort
City **Hamburg**

Datum
Date **2021-01-15**

Name **Liang Jin**

Unterschrift
Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority			
	Bearbeiter / Person responsible **Frau Bianca Tiemann**		Telefon / Phone **040-42837 2008**

COVID-19 Antigen Rapid Test Cassette (Saliva)
Clinical Sensitivity and Specificity Study Report

1. Objective

The CLUNGENE® COVID-19 Antigen Rapid Test Cassette (Saliva) (hereinafter referred to as the CLUNGENE Device) manufactured by Hangzhou Clongene Biotech Co., Ltd. is a lateral flow immunoassay intended for the qualitative detection SARS-CoV-2 nucleocapsid antigens in saliva from individuals who are suspected of COVID-19 by their healthcare provider.

This study is intended to evaluate the clinical performance, between the CLUNGENE Device and the comparator RT-PCR assay.

2. Method

A study of 645 direct nasopharyngeal swabs and saliva specimens was performed. The specimens were prospectively collected from patients in community meeting Department of Public Health definition of a suspected COVID-19 case and being tested for SARS-CoV-2 part of routine medical care at 5 locations and tested at a single central laboratory.

One nasopharyngeal swab and one saliva specimen were collected from individual symptomatic (within 7 days of onset) or asymptomatic patients who were suspected of COVID-19. At all locations, saliva specimen was tested directly with the COVID-19 Antigen Rapid Test Cassette (Saliva) according to product instructions for use, and the nasopharyngeal swab was eluted in 3 mL viral transport media and tested with RT-PCR assay for detection of SARS-CoV-2. Nasopharyngeal swabs and saliva specimens were tested by operators who were blinded to the RT-PCR test result.

The positive percent agreement (PPA) was calculated as 100% x (True Positive/[True Positive + False Negative]). The negative percent agreement (NPA) was calculated as 100% x (True Negative / [True Negative + False Positive]). The 95% (two-sided) confidence interval (CI) was calculated using the Wilson Score Method.

3. Comparator method

Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2, manufactured by BGI Genomics Co. Ltd., is a real-time reverse transcription polymerase chain reaction (RT-PCR) test. This product has got CE, NMPA certifications and FDA Emergency Use Authorized. A specimen is positive for SARS-CoV-2 if the Ct value of ORF1ab gene is not higher than 37 and the Ct value of human housekeeping gene β-Actin is not higher than 35.

4. Enrollment criteria (inclusion/exclusion criteria)

4.1 Inclusion criteria

- Patients in community meeting Department of Public Health definition of a suspected COVID-19 case and being tested for SARS-CoV-2 part of routine medical care.
- Symptomatic (within 7 days of onset) or asymptomatic patients who were suspected of COVID-19.

4.2 Exclusion criteria

- Unable to obtain samples of information needed for the experiment
- Samples that have been contaminated or contaminated during sample storage
- Samples with inappropriate storage conditions

5. Result

The results are summarized in the following table.

The RT-PCR cycle threshold (Ct) is the relevant signal value. Lower Ct value indicate higher viral load. The