AGREEMENT EC REP
CMC MEDICAL DEVICES 200316

This Agreement made on March 16, 2020 between **Getein Biotech, Inc.** Located in No.9 Bofu Road, Lube District, Nanjing (211505) China. (hereinafter referred to as "COMPANY") and **M/s CMC Medical Devices & Drugs S.L.** located in C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain (hereinafter referred to as "Authorized Representative")

Have agreed as follows with regard to the handling of all products (hereinafter called "Products") manufactured by Company and sold to EU in order to comply to the requirements set out in the COUNCIL DIRECTIVE 93/42/EEC Concerning Medical Devices (MDD), Regulation (EU) 2017/745 or 98/79/EC, Regulation (EU) 2017/746 concerning in vitro diagnostic medical devices (as per applicability) and latest version of "Guidelines on a Medical Devices Vigilance System".

Appointment
Company hereby appoints Authorized Representative, who accepts such appointment, as a representative for the "Business Area" and "Product Categories" set out in Appendix A. The responsibility of both parties is as stated hereafter. Service of European Authorized Representative cover the MDD 93/42/EEC or 98/79/EEC. The service will cover the new Regulation (EU) 2017/745 and (EU)2017/746 on medical devices and in vitro diagnostic when this regulation take effect.

Claim Handling
Authorized Representative shall notify company about any received claims and any change of laws and regulations related to company's products set out in Appendix A. Company is the immediate responsible person for the claim handling and regulation compliance.

Accident Handling
On receiving information of an incident (accident), as defined in the MDD 93/42/EEC, Regulation (EU) 2017/745 or 98/79/EC, Regulation (EU) 2017/746 (as per applicability) and MEDDEV 2.12-1 "Guidelines on a Medical Devices Vigilance System", the following procedures shall be applied:

Authorized Representative shall notify occurrence of an incident in its business area to Company immediately upon receiving of incident.
Upon receiving information of any incident Company shall perform the necessary analysis of the situation immediately and send the incident report to Authorized Representative according to the requirements of latest version of "Guidelines on a Medical Devices Vigilance System". In that way Authorized Representative can submit the report to the relevant Competent Authority as defined in the timescale of latest version of "Guidelines on a Medical Devices Vigilance System".

If applicable, based on the report Company shall instruct Authorized Representative of the necessary countermeasures to be taken. Authorized Representative shall inform the relevant Competent Authority and customer as required in the countermeasure plan issued by Company.

Responsibilities on Technical Documentation:

i. Company shall establish necessary procedures to prepare and maintain Technical Documentation including the Declaration of Conformity for the "Product Categories" set out in Appendix A to be able to comply with the MDD and MDR requirements.
ii. Company shall transfer the agreed Technical Documentation and Declaration of Conformity to Authorized Representative upon request.
iii. Company shall have the responsibility to provide to Authorized Representative any additional documentation as required by the Competent Authority or Notified Body.
iv. The authorized representative shall provide a copy of this agreement to the competent authority, upon request.

Instruction Manual (If applicable)
Company shall be responsible for the content of instruction (user's) manuals, and shall ensure that English language instruction manuals are available to Authorized Representative. Company shall ensure that the required local language instruction manuals are provided to the customers.

Registration

The Authorized Representative shall register or notify the products set out in Appendix A to the Competent Authority of the member state in which he has his registered place of business.

Company shall have all data allowing for identification of concerned devices together with the label and the instruction for use available to authorized representative upon request by competent authority.

Tasks to be performed by Authorized Representative:

i. Verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the company;
ii. Keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, available for the competent authorities for a period of at least 10 years after the last device covered by the eu declaration of conformity has been

placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market;

iii. Comply with the registration obligations laid down in article 31 of MDR/2017/745 OR art 28 of MDR /2017/746 and verify that the company has complied with the registration obligations laid down in articles 27 and 29 MDR/2017/745 OR art 24 and 26 of MDR/2017/746;

iv. In response to a request from a competent authority, provide that the competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official union language determined by the member state concerned.

v. Forward to the company any request by a competent authority of the member state in which the authorized representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device;

vi. Cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

vii. Terminate this agreement if the company acts contrary to its obligations under this regulation;

viii. Authorized representatives will have permanently and continuously at their disposal at least one person responsible for regulatory compliance (PRRC) who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union.

Obligations of Manufacturer Company:

i. COMPANY must comply with all the requirements specified in Article 10 MDR - Regulation 2017/745 or art 10 MDR 746/2017 regarding general obligations of manufacturers.

ii. COMPANY shall procure and maintain at all times during the term of this Agreement a Product liability insurance covering the products placed on the European market. This liability insurance should include "EAR" as well. This insurance, however, will not protect "EAR" against liability which results from its unauthorized Activities, wrongful or negligent acts of omission, or breach of this Agreement.
This agreement will not be valid if the manufacturer does not meet this requirement.

Other Obligations of Authorized Representative & Company:

i. The authorized representative shall provide all documentation and information that a market surveillance authority may require for the purpose of market surveillance.

ii. The authorized representatives shall rescind his contract with the company if the latter does not provide him with the access to the necessary information.

iii. Company shall keep authorized representative informed in all matters that may be connected to the devices placed on the market in the EU. At the minimum, the exchange of information concerning paragraphs a) to c) hereunder shall be informed.

a) Safeguard Clause

i. "Where a Member State ascertains that any of the medical devices specified in Appendix A, when correctly used for their intended purpose may compromise the health and/or safety of patients, users or, where applicable, other persons, or the safety of property, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service." If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such measures to the company and advise the company as to the implications of this decision.

ii. When the Commission finds that national measures taken under the Safeguard Clause "are unjustified, it shall immediately so inform the Member State which took the measures and the company or authorized representative". If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such information to the company and advise the company as to the implications of this decision.

b) Vigilance

i. In case of an incident and If the relevant Competent Authority contacts the authorized representative, he should immediately communicate such information to the company and advise the company as to the implications of this decision.

ii. The company should ensure that the involved authorized representative is kept informed of incident reports and Field Safety Corrective Actions.

c) Serious adverse events during clinical investigation, i.e. in the premarket phase

i. According to Article 80 of MDR 745/2017 and art 76 of 746/2017, "all serious adverse events must be fully recorded and immediately notified to all Competent Authorities of the Member States in which the clinical investigation is being performed by the sponsor".

ii. Authorized representative should inform the company of decisions of a Member State in respect of refusal or restriction of the placing the devices specified in Appendix A in the market.

(Appendix A)

Product list:

Medical device

1. Single-Use Medical Face Mask (Non-Sterile)

In vitro diagnostic medical device

1. Novel Coronavirus (2019-nCoV) Real-time RT-PCR Kit
2. One Step Test for Novel Coronavirus(2019-nCoV) IgM antibody (Colloidal Gold)
3. One Step Test for Novel Coronavirus(2019-nCoV) IgG antibody (Colloidal Gold)
4. One Step Test for Novel Coronavirus(2019-nCoV) IgM/IgG antibody (Colloidal Gold)
5. Novel Coronavirus(2019-nCoV) IgM/IgG antibody Fast Test Kit
6. Novel Coronavirus(2019-nCoV) IgM antibody Fast Test Kit (Immunofluorescence Assay)
7. Novel Coronavirus(2019-nCoV) IgG antibody Fast Test Kit (Immunofluorescence Assay)
8. Real-time PCR Analyzer

The following countries represent Authorized Representative's Business Area:

EUROPEAN COMMUNITY TERRITORY

Annual Fee: 1000 €

Validity of Agreement: This agreement shall stand valid from **March 16, 2020** to **March 16, 2021**. The Company shall apply for renewal of the agreement at least 30 days prior to expiry of this agreement.

Getein Biotech, Inc.
(COMPANY)

Authorized Signatory

China on March 16, 2020

CMC MEDICAL DEVICES & DRUGS S.L.
(EC REP/AUTHORIZED REPRESENTATIVE)

Authorized Signatory

Spain on March 16, 2020.