We are subject to the relevant laws and regulations of the countries in which we operate.

RELEVANT LAWS AND REGULATIONS IN SINGAPORE

The following is a summary of the material applicable laws and regulations in Singapore that were relevant to our business (other than those generally applicable to companies operating in Singapore) as of the Latest Practicable Date. As of the Latest Practicable Date, we were in compliance with all relevant laws and regulations that would materially affect our business operations.

Health Products Act 2007 (the "Health Products Act") and the regulations thereunder

Before a medical device may be supplied and used in Singapore, it must be registered under the Health Products Act with the Health Science Authority of Singapore ("**HSA**"). Under Schedule 1 of the Health Products Act, a "medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of –

(a) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(b) diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury;

(c) investigation, replacement, modification or support of the anatomy or of a physiological process, mainly for medical purposes;

(d) supporting or sustaining life;

(e) control of contraception;

(f) disinfection of medical devices; or

(g) providing information by means of *in vitro* examination of specimens derived from the human body, for medical or diagnostic purposes,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Under the Health Products Act, companies who intend to manufacture, import or wholesale health products, including medical devices, in Singapore are required to obtain and maintain a dealer's licence and carry out their respective activities in accordance with the conditions of such licence. Any contravention of the requirement to obtain and maintain a licence in order to manufacture, import or wholesale health products is an offence and upon

conviction, a person guilty of such an offence could be liable to a fine not exceeding S$50,000 or to imprisonment for a term not exceeding two years or to both. As at the Latest Practicable Date, the Company had obtained the following HSA dealer's licences:

1. Wholesaler (Class A, Class B, Class C, Class D, Class A IVD, Class D IVD, Class C IVD, Class B IVD).

2. Manufacturer (Class A IVD, Class D IVD, Class C IVD, Class B IVD).

3. Importer (Class A).

Medical devices may be classified into four (4) risk classes – A, B, C and D. The classification of general medical devices will depend upon a series of factors, including:

(a) the duration of medical device contact with the body;

(b) the degree of invasiveness;

(c) whether the medical device delivers medicinal products or energy to the patient; and

(d) whether they are intended to have a biological effect on the patient and local *versus* systematic effects.

The classification of *in vitro diagnostic* ("**IVD**") medical devices depends on a number of factors, including:

(a) determining if the product fulfils the definition of an IVD medical device in its intended purpose and the indications for use;

(b) taking into consideration the rules for proper classification. Where an IVD medical device has multiple intended purposes as specified by the product owner, which places the device into more than one class, it should be classified to the higher class;

(c) if two or more risk classification rules apply to the IVD medical device, it is assigned the highest risk class;

(d) the justification for placing a product in a particular risk class should be documented;

(e) calibrators intended to be used with an IVD reagent should be treated in the same class as the IVD reagent;

(f) control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes should be placed in the same class as the IVD reagents.

As at the Latest Practicable Date, we had completed the registration of two (2) medical devices with the HSA, including our GASTROClear™ test, and we currently have no medical devices pending registration with HSA.

Human Biomedical Research Act 2015 (the "Human Biomedical Research Act") and the regulations thereunder

The Human Biomedical Research Act sets out the regulatory frameworks for human biomedical research and human tissue for use in research, with the objectives to regulate the research, protect the safety and welfare of human research subjects, and prohibit commercial trading of human tissue.

Under the Human Biomedical Research Act, "human biomedical research" refers to:

(a) any research that is intended to study the prevention, prognostication, diagnosis or alleviation of any disease, disorder or injury affecting the human body; the restoration, maintenance or promotion of the aesthetic appearance of human individuals through clinical procedures or techniques; or the performance or endurance of human individuals, where the research involves:

  (i) subjecting an individual to any intervention (including any wilful act or omission) that has a physical, mental or physiological effect (whether temporary or permanent) on the body of the individual;

  (ii) the use of any individually-identifiable human biological material; or

  (iii) the use of any individually-identifiable health information; or

(b) any research that involves:

  (i) human gametes or human embryos;

  (ii) cytoplasmic hybrid embryos;

  (iii) the introduction of any human-animal combination embryo into an animal or a human;

(iv) the introduction of human stem cells (including induced pluripotent stem cells) or human neural cells into an animal at any stage of development (including a prenatal animal foetus or animal embryo); and

(v) any entity created as a result of any process referred to in paragraph (b)(iii) or (b)(iv).

Requirements under the Human Biomedical Research Act include obtaining appropriate informed consent in writing in the presence of a witness, and reporting serious adverse events, defined as any untoward medical occurrence as a result of any human biomedical research which:

(a) results in or contributes to death;

(b) is life threatening;

(c) requires inpatient hospitalisation or prolongation of existing hospitalisation;

(d) results in or contributes to persistent or significant disability or incapacity;

(e) results in or contributes to a congenital anomaly or birth defect; or

(f) results in such other event as may be prescribed.

In the event of any contravention of the Human Biomedical Research Act, the Director of Medical Services has the power to immediately require stoppage of research and issue directions to suspend the research. Liability on the part of our Company or our officers may also be incurred.

Workplace Safety and Health Act 2006 (the "Workplace Safety and Health Act") and the regulations thereunder

The Workplace Safety and Health Act and the regulations thereunder govern the safety, health and welfare of persons at work in workplaces. Among other things, the Workplace Safety and Health Act imposes a duty on employers to take, so far as is reasonably practicable, such measures as are necessary to ensure the safety and health of their employees at work. These measures include the following:

- providing and maintaining for those persons a work environment which is safe, without risk to health, and adequate as regards facilities and arrangements for their welfare at work;

- ensuring that adequate safety measures are taken in respect of any machinery, equipment, plant, article or process used by those persons;

- ensuring that those persons are not exposed to hazards arising out of the arrangement, disposal, manipulation, organisation, processing, storage, transport, working or use of things in their workplace, or near their workplace and under the control of the employer;

- developing and implementing procedures for dealing with emergencies that may arise while those persons are at work; and

- ensuring that those persons at work have adequate instruction, information, training and supervision as is necessary for them to perform their work.

Additional duties are imposed on employers under the Workplace Safety and Health (General Provisions) Regulations. Some of these duties include taking all reasonably practicable measures to protect workers from exposure to any infectious agents or biohazardous material which may constitute a risk to his health.

As at the Latest Practicable Date, our Group was in compliance with and had not breached any of the provisions set out above.

Environmental Public Health Act 1987 (the "Environmental Public Health Act") and the regulations thereunder

The Environmental Public Health Act and the regulations thereunder govern the matters relating to environmental public health. In particular, the Environmental Public Health (Toxic Industrial Waste) Regulations require any person whose act or process produces toxic industrial waste or whose act first causes toxic industrial waste to become subject to regulation, or the owner or the person having the charge, management or control of a source of toxic industrial waste, to not, on any premises which are used for the purposes of an undertaking carried on by him, keep or use, or cause or permit to be kept or used, toxic industrial waste unless there are on-site disposal facilities established with the permission of the Director-General of Public Health or a toxic industrial waste collector has been engaged to dispose of the waste.

As at the Latest Practicable Date, our Group was in compliance with and had not breached any of the provisions set out above.

Work Injury Compensation Act 2019 (the "Work Injury Compensation Act")

Work injury compensation is governed by the Work Injury Compensation Act and is regulated by the Singapore Ministry of Manpower ("**MOM**"). The Work Injury Compensation Act applies to any person (with the exception of the class of persons specified in the Fourth Schedule to the Work Injury Compensation Act) who has entered into or works under a contract of service or apprenticeship with an employer, whether: (a) by way of manual labour or otherwise; (b) the contract is express or implied or is oral or in writing; and (c) the remuneration is calculated by time or by work done.

The Work Injury Compensation Act provides that if in any employment personal injury by accident arising out of and in the course of the employment is caused to such person, his employer shall be liable to pay compensation in accordance with the provisions of the Work Injury Compensation Act. The amount of such compensation shall be computed in accordance with the provisions of the First Schedule to the Work Injury Compensation Act, subject to a maximum and minimum limit, taking into account factors such as the severity and permanence of the personal injury suffered.

Employment of Foreign Manpower Act 1990 (the "EFMA")

The EFMA governs the employment of foreign employees in Singapore. Under Section 5(1) of the EFMA, no person shall employ a foreign employee unless the foreign employee has a valid work pass issued by the MOM. Any person who contravenes Section 5(1) of the EFMA shall be guilty of an offence and shall (a) be liable on conviction to a fine of not less than S$5,000 and not more than S$30,000 or to imprisonment for a term not exceeding 12 months or to both; and (b) on a second or subsequent conviction, (i) in the case of an individual, be punished with a fine of not less than S$10,000 and not more than S$30,000 and with imprisonment for a term of not less than one month and not more than 12 months, or (ii) in any other case, be punished with a fine of not less than S$20,000 and not more than S$60,000.

An employer of foreign workers is also subject to, among others, the Employment Act and the Immigration Act 1959.

Employment Act 1968 (the "Employment Act")

The Employment Act is administered by the MOM and sets out the basic terms and conditions of employment and the rights and responsibilities of employers as well as employees. In particular, Part IV of the Employment Act sets out requirements for rest days, hours of work and other conditions of service for workmen who receive salaries not exceeding S$4,500 a month and employees (other than workmen or persons employed in managerial or executive positions) who receive salaries not exceeding S$2,600 a month. Section 38(8) of the Employment Act provides that an employee is not allowed to work for more than 12 hours in any one day except in specified circumstances, such as where the work is essential to the life of the community, defence or security, where urgent work is to be done to machinery or plant, or where an interruption of work which was impossible to foresee. In addition, Section 38(5) limits the extent of overtime work that an employee can perform to 72 hours a month.

Employers must seek the prior approval of the Commissioner for Labour (the "**CL**") for exemption if they require an employee or class of employees to work for more than 12 hours a day or more than 72 overtime hours a month. The CL may, after considering the operational needs of the employer and the health and safety of the employee or class of employees, by order in writing, exempt such employees from the overtime limits subject to such conditions as the CL thinks fit. Where such exemptions have been granted, the employer shall display the order or a copy thereof conspicuously in the place where such employees are employed.

An employer who breaches the above provisions shall be guilty of an offence and shall be liable on conviction to a fine not exceeding S$5,000, and for a second or subsequent offence to a fine not exceeding S$10,000 and/or to imprisonment for a term not exceeding 12 months.

Personal Data Protection Act 2012 (the "PDPA") and the regulations thereunder

The PDPA governs the collection, use and disclosure of personal data by organisations. For the purposes of the PDPA, "personal data" means data, whether true or not, about an individual who can be identified from that data, or from that data and other information to which the organisation has or is likely to have access.

Under the PDPA, the ten data protection obligations of an organisation in relation to the collection, use and disclosure of personal data are summarised as follows:

- Consent obligation – not to collect, use or disclose personal data about an individual unless the individual gives, or is deemed to have given, his consent under the PDPA to the collection, use or disclosure, or such collection, use or disclosure without the consent of the individual is required or authorised under the PDPA or any other written law;

- Purpose limitation obligation – to collect, use or disclose personal data about an individual only for purposes that a reasonable person would consider appropriate in the circumstances and that the individual has been informed of, if applicable;

- Notification obligation – to inform an individual of the purposes for the collection, use or disclosure of his personal data, on or before collecting such personal data, except if the individual is deemed to have consented to the collection, use or disclosure in accordance with the provisions of the PDPA or the organisation collects, uses or discloses the personal data without the consent of the individual in accordance with the provisions of the PDPA;

- Access and correction obligation – on request of an individual, to, as soon as reasonably possible, (i) provide the individual with personal data about the individual that is in the possession or under the control of the organisation, and information about the ways in which such personal data has been or may have been used or disclosed by the organisation within a year before the date of the request, unless certain specified exceptions apply and/or (ii) correct an error or omission in the personal data about the individual that is in the possession or under the control of the organisation, unless certain specified exceptions apply;

- Data breach notification obligation – to assess if a data breach will result in, or is likely to result in, significant harm to an affected individual, or is, or is likely to be, of a significant scale. If so, to notify the Personal Data Protection Commission (the

"**Commission**") as soon as is practicable, but in any case no later than three (3) calendar days after making such an assessment. Each affected individual must also be notified in any manner that is reasonable in the circumstances;

- Accuracy obligation – to make a reasonable effort to ensure that personal data collected by or on behalf of the organisation is accurate and complete, if the personal data is likely to be used by the organisation to make a decision that affects the individual to whom the personal data relates or is likely to be disclosed by the organisation to another organisation;

- Protection obligation – to protect personal data in the possession or under the control of the organisation by making reasonable security arrangements to prevent unauthorised access, collection, use, disclosure, copying, modification, disposal or similar risks;

- Retention limitation obligation – to cease to retain documents containing personal data, or remove the means by which the personal data can be associated with particular individuals, as soon as it is reasonable to assume that the purpose for which that personal data was collected is no longer being served by retention of the personal data and retention is no longer necessary for legal or business purposes;

- Transfer limitation obligation – not to transfer any personal data to a country or territory outside Singapore except in accordance with the requirements prescribed under the PDPA; and

- Accountability obligation – to implement the necessary policies and procedures in order to meet the obligations under the PDPA and shall make information about its policies and procedures publicly available.

Non-compliance may lead to financial penalties, or civil or criminal liability. The Commission also has broad powers to direct the organisations to comply with the provisions of the PDPA.

Central Provident Fund Act 1953 ("CPF Act")

The CPF Act governs the contributions made by employers and employees into the CPF. The CPF Act is administered by the Central Provident Fund Board ("**CPF Board**").

Section 7(1) of the CPF Act provides that subject to Section 69 of the CPF Act and any regulations made under Section 77(1) of the CPF Act, every employer of an employee shall pay to the CPF monthly in respect of each employee contributions at the appropriate rates set out in the First Schedule of the CPF Act. Pursuant to Section 7(2) of the CPF Act, notwithstanding the provisions of any written law or any contract to the contrary, an employer is entitled to recover from the monthly wages of an employee the amount shown in the First Schedule of the CPF Act as so recoverable from the employee.

Section 9(1) of the CPF Act provides that, where the amount of the contributions which an employer is liable to pay under Section 7 of the CPF Act in respect of any month is not paid within such period as may be prescribed, the employer shall be liable to pay interest on the amount for every day the amount remains unpaid commencing from the first day of the month succeeding the month in respect of which the amount is payable and such interest shall be calculated at the rate of 1.5% per month or the sum of S$5, whichever is greater.

Section 7(3) of the CPF Act provides that where any employer who has recovered any amount from the monthly wages of an employee in accordance with the CPF Act and fails to pay the contributions to the CPF within such time as may be prescribed, he shall be guilty of an offence and shall be liable on conviction to a fine not exceeding S$10,000 or to imprisonment for a term not exceeding seven (7) years or to both.

Section 61(1) of the CPF Act provides that except as otherwise provided in Section 61(2) of the CPF Act, any person convicted of an offence under the CPF Act for which no penalty is provided shall be liable on conviction:

(a) to a fine not exceeding S$5,000 or to imprisonment for a term not exceeding six (6) months or to both; and

(b) if that person is a repeat offender in relation to the same offence, to a fine not exceeding S$10,000 or to imprisonment for a term not exceeding 12 months or to both.

Section 61(2) of the CPF Act provides that where any person:

(a) is guilty of an offence under Section 7(5) or 58(1)(b) of the CPF Act; or

(b) being a director, manager or secretary or any other officer of a body corporate, is guilty of an offence under Section 60 by virtue of the fact that an offence under Section 7(3) or (5) or 58(1)(b) of the CPF Act has been committed by that body corporate and is found to have been committed with the consent or connivance of or to be attributable to any act or default on the part of that person, that person shall be liable on conviction:

    (i) to a fine of not less than S$1,000 and not more than S$5,000 or to imprisonment for a term not exceeding six (6) months or to both; and

    (ii) if that person is a repeat offender in relation to the same offence, to a fine of not less than S$2,000 and not more than S$10,000 or to imprisonment for a term not exceeding 12 months or to both.

Income Tax

(1) Individual Taxpayers

Individual taxpayers who are Singapore tax residents are subject to Singapore income tax on income accruing in or derived from Singapore. All foreign-sourced income received in Singapore on or after January 1, 2004 by a Singapore tax resident individual (except for income received through a partnership in Singapore) is exempt from Singapore income tax if the Comptroller of Income Tax in Singapore ("**Comptroller**") is satisfied that the tax exemption would be beneficial to the individual.

An individual taxpayer (both resident and non-resident) is subject to Singapore income tax on income accrued or derived from Singapore, subject to certain exceptions. Currently, a Singapore tax resident individual is subject to tax at the progressive rates ranging from 0.0% to 22.0% (increased to 24.0% from YA[1] 2024), after deductions of qualifying allowable expenses, donations and personal reliefs where applicable.

A non-Singapore tax resident individual is subject to Singapore income tax on their employment income accruing in or derived from Singapore at a flat rate of 15.0% or at progressive resident rates, whichever is higher. Other non-employment income accruing in or derived from Singapore by non-Singapore tax resident individual is taxed at 22.0% (increased to 24.0% from YA 2024), subject to certain exceptions and conditions.

An individual is regarded as a tax resident in Singapore if in the calendar year preceding the year of assessment, he was physically present in Singapore or exercised an employment in Singapore (other than as a director of a company) for 183 days or more, or if he ordinarily resides in Singapore, except for temporary absences.

(2) Corporate Taxpayers

A company is regarded as tax resident in Singapore if the control and management of its business is exercised in Singapore.

Corporate taxpayers who are Singapore tax residents are subject to Singapore income tax on income accrued in or derived from Singapore and, subject to certain exceptions, on foreign-source income received or deemed to be received in Singapore from outside Singapore. Foreign-source income in the form of dividends, branch profits and service income received or deemed to be received in Singapore by Singapore tax resident companies on or after June 1, 2003 are exempt from tax if the following conditions are met:

(a) the income is subject to tax of a similar character to income tax (by whatever name called) under the law of the territory from which the income is received;

1 Year of Assessment ("**YA**"), which refers to the year in which tax is calculated and charged for income earned in the preceding financial year.

(b) at the time the income is received in Singapore by the person resident in Singapore, the highest rate of tax of a similar character to income tax (by whatever name called) levied under the law of the territory from which the income is received on any gains or profits from any trade or business carried on by any company in that territory at that time is not less than 15.0%; and

(c) the Comptroller is satisfied that the tax exemption would be beneficial to the person resident in Singapore.

The prevailing corporate tax rate in Singapore for both resident and non-resident companies is currently 17.0%. In addition, under the Partial Tax Exemption scheme, 75.0% of up to the first S$10,000 of normal chargeable income, and 50.0% of up to the next S$190,000 is exempt from corporate tax. The remaining chargeable income (after the partial tax exemption) will be taxed at 17.0%.

Other taxes

Singapore does not currently impose withholding tax on dividends paid to resident or non-resident shareholders.

There is also no tax on capital gains in Singapore. Thus, any gains derived from the disposal of our shares acquired for long-term investment will not be taxable in Singapore.

Foreign shareholders are advised to consult their own tax advisers to take into account the tax laws of their respective home countries/countries of residence and the applicability of any double taxation agreement which their country of residence may have with Singapore.

RELEVANT LAWS AND REGULATIONS IN THE PRC

Regulation of Laboratories

Medical Test Laboratories

Pursuant to the Administrative Regulations on Medical Institutions (《醫療機構管理條例》), promulgated by the State Council, effective on September 1, 1994, and last amended on March 29, 2022, and the Implementation Measures of the Administrative Regulations on Medical Institutions (《醫療機構管理條例實施細則》), effective on September 1, 1994, latest amended by National Health and Family Planning Commission, or NHFPC, and effective from April 1, 2017, any entity or individual which intends to establish and operate a medical institution shall apply for an approval from National Health Commission, or NHC, or its local counterparts to obtain a medical institution practicing license. Pursuant to the Basic Standards and Practice of Medical Test Laboratory (《醫學檢驗實驗室基本標準和管理規範(試行)》), promulgated by NHFPC and effective from July 20, 2016, a medical test laboratory, which conducts clinical tests, including clinical hematology tests and body fluid tests, clinical chemistry tests, clinical immunology tests, clinical microbiology tests, clinical molecular

cytogenetic tests and clinical pathology tests, for diagnosis, management, prevention or treatment of diseases and health assessment, shall be regulated as a medical institution. The establishment and operation of a medical test laboratory shall apply for an approval from NHC or its local counterparts to obtain a medical institution practicing license. On March 29, 2022, the State Council promulgated the Decision of The State Council on Amending or Abolishing Certain Administrative Regulations (《國務院關於修改和廢止部分行政法規的決定》), which came into effect on May 1, 2022, and according to which, medical institutions must obtain a Medical Institution Practicing License before practicing, whilst a clinic may practice after filing with competent healthcare administrative authorities.

Clinical Gene Amplification Test Laboratories

Pursuant to the Administrative Measures for Clinical Gene Amplification Test Laboratories of Medical Institutions (《醫療機構臨床基因擴增檢驗實驗室管理辦法》), promulgated by the Ministry of Health, the former of NHFPC, and effective from December 6, 2010, and the Catalogue of Clinical Laboratory Items for Medical Institutions (2013) (《醫療機構臨床檢驗項目目錄(2013年版)》) promulgated by NHFPC on August 5, 2013, or the Testing Items Catalogue, the NHC at the provincial level is responsible for the supervision and administration of clinical gene amplification test laboratories of medical institutions. A clinical gene amplification test laboratory shall register its clinical testing items with the NHC at the provincial level after technical verification is passed by the center for clinical laboratories at the provincial level. In addition, pursuant to the Notice on Issues Related to the Management of Clinical Laboratory Items (《關於臨床檢驗項目管理有關問題的通知》), or Circular 167, promulgated by the NHFPC on February 25, 2016, the clinical testing items which are not included in the Testing Items Catalogue, but with clear clinical significance, relatively high specificity and sensitivity, and reasonable price, shall be validated in time to meet clinical needs. As of the Latest Practicable Date, we had registered one laboratory with regards to the clinical gene amplification testing activities.

Pathogenic Microorganism Laboratories

Pursuant to the Regulations on Administration of Bio-safety in Pathogenic Microorganism Laboratories (《病原微生物實驗室生物安全管理條例》), promulgated by the State Council, effective on November 12, 2004, and latest amended on March 19, 2018, pathogenic microorganism laboratories are classified into four levels, namely bio-safety levels 1, 2, 3 and 4 in terms of bio-safety protection levels in accordance with national standards on biosafety of laboratories. Laboratories at bio-safety levels 1 and 2 shall not engage in laboratory activities related to highly pathogenic microorganisms. The construction, alternation or expansion of a laboratory at bio-safety level 1 or 2 shall be filed for record with the local counterparts of NHC. The entity launched a pathogenic microorganism laboratory shall develop a scientific and strict management system, regularly inspect the implementation of the regulations on bio-safety, and regularly inspect, maintain and update the facilities, equipment and materials in the laboratory, to ensure its compliance with the national standards. As of the Latest Practicable Date, we had made filings of our laboratory with regards to the pathogenic microorganism testing activities.

Regulation of Medical Devices

Pursuant to the Regulations on Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), or the Medical Devices Regulations, promulgated by the State Council and effective from April 1, 2000, latest amended on February 9, 2021 and came into effect on June 1, 2021, the NMPA, shall be in charge of national supervision and administration of medical devices. The Medical Device Regulations regulates entities that engage in the research and development, production, operation, use, supervision and administration of medical devices in the PRC.

Classification of Medical Devices

According to the Medical Devices Regulation and the Administrative Measures for the Registration and Record-filing of In Vitro Diagnostic Reagents (《體外診斷試劑註冊與備案管理辦法》), or the IVD Registration Measures, promulgated by the SAMR on August 26, 2021 and came into effect on October 1, 2021, *in vitro* diagnostic reagents refer to *in vitro* diagnostic reagents regulated as medical devices or IVD. Medical devices, including IVDs, are classified into three categories based on the degree of risk. Class I medical devices shall refer to those devices with a low degree of risk, whose safety and effectiveness can be ensured through routine administration. Class II medical devices shall refer to those devices with a moderate degree of risk, which are strictly controlled and administered to ensure their safety and effectiveness. Class III medical devices shall refer to those devices with a high degree of risk, whose safety and effectiveness can be ensured by adopting special measures.

Registration and Filings of Medical Devices

Pursuant to the Medical Devices Regulations and the IVD Registration Measures, Class I IVDs are subject to filing and Class II and Class III IVDs are subject to registration administration. Class II IVDs shall be examined by the drug administration departments of the people's governments of the provinces, autonomous regions or municipalities directly under the central government where such applicants are located and a medical device registration certificate for such medical device shall be issued upon approval. Class III IVDs shall be examined by the NMPA and a medical device registration certificate for such medical device shall be issued upon approval. In case of any substantial change to the design, raw materials, production technologies, scopes of application and method of use, etc., of the registered Class II or Class III IVD, which may affect the safety and effectiveness of such IVDs, the registrants shall apply to the original registration authorities for modification of registration.

A medical device registration certificate is valid for five years and according to the Medical Devices Regulations and the IVD Registration Measures, where the period of validity of the medical device registration certificate needs to be extended upon the expiration, an application for such extension shall be made to the original registration department six months before the expiration.

Clinical Evaluation

Pursuant to the Medical Devices Registration and Record-filing Measures (《醫療器械註冊與備案管理辦法》), promulgated by the SAMR on August 26, 2021 and came into effect on October 1, 2021, clinical evaluation of medical devices refers to activities in which clinical data are analyzed and evaluated by adopting scientific and reasonable methods in order to confirm the safety and effectiveness of medical devices within the scope of application. The clinical evaluation shall be conducted for the registration or record-filing of medical devices but it may be exempted under any of the circumstances: (i) The medical device has clear working mechanisms, fixed design and mature manufacturing processes, and the medical devices of the same kind that are available on the market have been used in clinical practice for years without records of any serious adverse events and with their general purposes unchanged; or (ii) any other circumstance where the safety and effectiveness of such medical device can be proved through non-clinical evaluation. In accordance with the provisions of the NMPA, clinical trials shall be carried out for medical devices for which the existing clinical literature materials and clinical data are insufficient to confirm their safety and effectiveness in the clinical evaluation of medical devices. The catalog of the medical devices exempt from clinical evaluation shall be formulated, adjusted and published by the NMPA.

The NMPA promulgated the Notice on Publishing the Medical Device Catalog Exempted from Clinical Evaluation (《關於發佈免於臨床評價醫療器械目錄的通告》) on September 16, 2021 and it became effective from October 1, 2021, latest amended on July 20, 2023 and came into effect on the same day, which is the legal basis for the current catalog of medical devices exempted from clinical evaluation.

Production Permit and GMP for Medical Devices

The Measures on the Supervision and Administration of Medical Devices Production (《醫療器械生產監督管理辦法》), which was promulgated on March 10, 2022 and came into effect on May 1, 2022, stipulates that manufacturer of medical devices shall satisfy the following conditions:

- it has production sites, environmental conditions, production equipment and professional technicians that are suitable for such medical devices to be produced;
- it has organizations or professional examination staffs and examination equipment for carrying out quality examinations for such medical devices to be produced;
- it has formulated a management system that ensures the quality of the medical device;
- it has the capability of after-sale services that is suitable for such medical devices to be produced; and

- it satisfies the requirements as prescribed in R&D and production technique documents.

Medical device manufacturers shall be responsible for the quality of medical devices they manufacture. The enterprises engaging in the production of Class I medical devices shall make filings for such Class I medical devices with the local branches at the prefecture city level of the NMPA and submit materials to prove that it is qualified to engage in the production of such medical devices. The enterprises engaging in the production of Class II or Class III medical devices shall apply for a Manufacture License for Medical Devices (醫療器械生產許可證) with provincial branches of the NMPA, and submit materials proving it is qualified to engage in the production of such medical devices and a medical device registration certificate for the production of such medical devices. A Manufacture License for Medical Devices is valid for five years and the registrant shall file for renewal application with the original branch of the NMPA 90 business days to 30 business days prior to its expiration date.

Pursuant to the Good Manufacturing Practice of Medical Devices (《醫療器械生產質量管理規範》) promulgated by China Food and Drug Administration, or CFDA on December 29, 2014 and effective from March 1, 2015, the manufacturer of medical devices shall abide by the requirements of these measures in the process of design, development, production, sales and after-sales service of medical devices. The manufacturer of medical devices shall, in accordance with the requirements of these measures and, having taken into account product characteristics, establish and improve a quality management system that is compatible with the medical devices produced, and ensure their effective operation. The manufacturer of medical devices shall implement risk management throughout the entire process of design development, production, sales and after-sales service, for which the measures taken should be proportionate to the risks of the products.

Operation Permit and GSP for Medical Devices

According to the Measures for the Supervision and Administration of Medical Devices Operation (《醫療器械經營監督管理辦法》) promulgated by the SAMR on March 10, 2022 and came into effect on May 1, 2022, an enterprise engaging in the operation of medical devices shall have business premises and storage conditions suitable for the operation scale and scope, and shall have quality control department or personnel suitable for the medical devices it operates. An enterprise engaged in the operation of Class I medical devices, the license or record is not required for business activities, while an enterprise engaged in the operation of Class II medical devices shall file with the municipal level food and drug supervision and administration department and provide materials to prove it satisfies the relevant conditions of engaging in the operation of medical devices, and an enterprise engaged in the operation of Class III medical devices shall apply for a Business Operation License of Medical Devices (醫療器械經營許可證) to the municipal level drug supervision and administration department and provide material to prove that it satisfies the relevant conditions of engaging in the operation of such medical devices.

The relevant local department of NMPA which receives operation permit application shall grant the Business Operation License of Medical Devices if the enterprise meets the prescribed requirements. A Business Operation License of Medical Devices is valid for five years and may be renewed pursuant to the relevant regulations. An enterprise engaging in medical devices operation shall not operate or use any medical device that has not been legally registered or filed, without qualification certificate, outdated, invalid, or disqualified.

A medical device operator shall establish a quality control system and quality control measures covering the entire process including purchase, acceptance inspection, storage, sales, transport and after-sales service, in accordance with laws, regulations and GSP requirement and keep relevant records to ensure continuous compliance in its business conditions and acts.

Pursuant to the Good Sales Practice of Medical Devices (《醫療器械經營質量管理規範》) promulgated by CFDA and effective from December 12, 2014, an entity engaging in the procurement, acceptance, preservation, sales, transportation and after-sales of medical devices shall take effectively quality control measures.

Importation and Exportation of Medical Devices

According to the Administrative Provisions on the Filling of Customs Declaration Entities of the PRC (《中華人民共和國海關報關單位備案管理規定》), promulgated by the General Administration of Customs of the PRC on November 19, 2021 and came into effect on January 1, 2022, consignors or consignees of imported or exported goods or customs declaration enterprises that apply for filing shall obtain market entity qualifications.

Pursuant to the Regulations on the Administration of Export Sales Certificates of Medical Device Product (《醫療器械產品出口銷售證明管理規定》) promulgated by the NMPA on June 1, 2015 and came into effect on September 1, 2015, if the registration certificate for a medical device product and production permit for a medical device product has been obtained in China, or the medical device product registration and production recordation have been completed, the food and drug supervision and administration department may issue a Medical Device Product Export Sales Certificate (醫療器械產品出口銷售證明) to the relevant manufacturing enterprise. The validity term of the Medical Device Product Export Sales Certificate should not exceed the earliest deadline for the various documents submitted by the enterprise in the application materials, and the maximum validity term shall also not exceed two years.

Regulation of Human Genetic Resources

The Interim Administrative Measures on Human Genetic Resources (《人類遺傳資源管理暫行辦法》), promulgated by the Ministry of Science and Technology, or MOST, and the Ministry of Health in June 1998, aiming at protecting and utilizing human genetic resources in the PRC. The MOST promulgated the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources, or Taking Such Resources out of the PRC (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) in July 2015, according to which, the sampling, collection or research activities of human genetic resources by a foreign-invested sponsor fall within the scope of international cooperation, and the cooperating organization of China shall apply for approval of the China Human Genetic Resources Management Office through the online system. The MOST further promulgated the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》) in October 2017, which became effective in December 2017 and simplified the approval of sampling and collecting human genetic resources for the purpose of listing a drug in the PRC.

The Regulation for the Administration of Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》), promulgated by the State Council on May 28, 2019, and effective from July 1, 2019, regulates entities engaging in collection, preservation, utilization and outbound provision of human genetic resources. Human genetic recourses include (i) human genetic resources materials, such as organs, tissues and cells that contain hereditary substances such as human genomes genes, and (ii) human genetic resources information, such as data generated from human genetic resources.

Pursuant to the HGR Regulation, collection and preservation of human substances such as organs, tissues and cells and carrying out related activities for clinical diagnosis and treatment, blood collection and supply services, crime investigation, doping detection and funeral and interment shall be subject to other applicable laws and regulations.

Pursuant to the HGR Regulation, foreign entities, individuals and such entities established or actually controlled thereby (each, a "**Restricted Entity**") shall not, within the territory of China, collect or preserve human genetic resources of China, nor provide human genetic resources of China outward across the border; while a foreign entity is allowed to conduct scientific research activities by utilizing human genetic resources of China through cooperation with scientific research institutions, higher education institutions, medical institutions or enterprises of China (each, a "**Domestic Entity**"). The utilization of the human genetic resources of China in any international cooperative scientific research is subject to approval by the MOST. However, the aforesaid approval is not required, but instead, a filing for record with the MOST is required, if human genetic resources of China are utilized for international cooperative clinical trials without any outbound provision of human genetic resources, to obtain product registration of relevant medicine and medical device in China.

On May 26, 2023, the MOST released the Implementation Rules of the Administrative Regulations on Human Genetic Resources (《人類遺傳資源管理條例實施細則》), which came into effect on July 1, 2023. The Implementation Rules of the Administrative Regulations on Human Genetic Resources further clarified the regulatory requirements and details for the Regulation for the Administration of Human Genetic Resources of the PRC, including but not limited to,

(i) clarifying the scope of human genetic resource information, which shall include information resources generated from human genetic resource materials (such as human genes and genome data) and exclude clinical data, image data, protein data and metabolic data;

(ii) further clarifying the criteria to constitute a foreign entity, which shall include (a) any foreign organization or individual that holds directly or indirectly more than 50% of the shares, equity interests, voting rights, property shares or other interests in the institution, (b) any foreign organization or individual that is able to dominate or have material effect on the decision-making or management of the institution through its voting right or other interests, although the shares, equity interests, voting rights, property share or other interests it directly or indirectly holds in the institution is less than 50%, (c) any foreign organization or individual that is able to dominate or have material effect on the decision-making or management of the institution through investment relationship, contract or other arrangement, and (iv) other situations stipulated by laws, regulations and rules;

(iii) optimizing the scope of administrative licensing and filing, and clarifying that the collection activities involved in clinical trials for the purpose of obtaining permission for the market authorization of relevant medicines and medical devices in China need not apply for collection approval, etc.

Regulation of Environment Protection

Pursuant to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) which was promulgated by the Standing Committee of the National People's Congress, or SCNPC on December 26, 1989, and amended on April 24, 2014 and came into force on January 1, 2015, all enterprises and institutions which discharge pollutants shall adopt measures to prevent and control pollution and damage to the environment from waste gas, waste water, waste residues, medical waste, dust, malodorous gases, radioactive substances, noise, vibration, ray radiation and electromagnetic radiation generated in the course of production, construction or other activities. Pollution prevention and control facilities of a construction project shall be simultaneously designed, constructed and put into operation with the principal part of the construction project. Enterprises that manufacture, store, transport, sell, use or dispose of chemicals and materials containing radioactive substances shall comply with the relevant State regulations to prevent environmental pollution. The relevant authorities are authorized to impose various types of penalties on the persons or entities in violation of the environmental regulations, including fines, restriction or suspension of operation, shut-down, detention of office-in-charge, etc. Meanwhile, local environmental protection authorities may formulate local standards which are more rigorous than the national standards, in which case the concerned enterprises must comply with both the national standards and the local standards.

Regulation of Product Quality and Production Safety

Product Quality

The Product Quality Law of the PRC (《中華人民共和國產品質量法》), as amended and effective as of December 29, 2018, applies to all production and sale activities in the PRC. Pursuant to the Product Quality Law of the PRC, products offered for sale must satisfy relevant quality and safety standards. Violations of state or industrial standards for health and safety and any other related violations may result in civil liabilities and administrative penalties, such as compensation for damages, fines, suspension or shutdown of business, as well as confiscation of products illegally produced and sold and the proceeds from such sales.

Pursuant to the PRC Civil Code (Part VII Liability for Tort) (《中華人民共和國民法典》(第七編侵權責任)) which was promulgated by the National People's Congress, or NPC on May 28, 2020 and came into effect on January 1, 2021, a patient may make a claim against a medical institution or producer for any damage arising from defects of a medical device. In respect of any claim made by a patient, the medical institution is entitled to make a claim against the producer after the settlement of the compensation paid to the patient.

Production Safety

Pursuant to the Production Safety Law of the PRC (《中華人民共和國安全生產法》), last amended by the SCNPC on June 10, 2021 and came into effect on September 1, 2021, the production and business operation entities shall (i) comply with this law and other laws and regulations on safety production, strengthen the management of safety production, establish a sound responsibility system for safety production for all employees and a system of rules and regulations on safety production; (ii) increase the investment and guarantee of safety production funds, materials, technologies, and personnel, improve safety production conditions, and boost safety production standardization and informatization; (iii) establish a dual prevention mechanism for safety risk classification and control, and for the investigation and treatment of hidden dangers, and improve the risk prevention and resolution mechanism to improve production safety standards and ensure production safety. Any entity that fails to provide required production safety conditions is prohibited from engaging in production activities.

Regulation of Foreign Investment

The establishment, operation and management of corporate entities in the PRC are governed by the Company Law of PRC (《中華人民共和國公司法》), or the Company Law, which was issued by the SCNPC on December 29, 1993 and latest revised and became effective on October 26, 2018. A foreign-invested company is also subject to the Company Law unless otherwise provided by the foreign investment laws.

On March 15, 2019, the NPC promulgated the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》), or the Foreign Investment Law, which became effective on January 1, 2020 and replaced the major former laws and regulations governing foreign investment in the PRC. Pursuant to the Foreign Investment Law, "foreign investments" refer to investment activities conducted by foreign investors directly or indirectly in the PRC.

According to the Foreign Investment Law and its implementing rules, the State adopts a system of pre-entry national treatment plus a negative list with respect to foreign investment administration. The pre-entry national treatment refers to granting to foreign investors and their investments, in the stage of investment access, the treatment no less favorable than that granted to domestic investors and their investments and the negative list refers to special administrative measures for access of foreign investment in specific fields as stipulated by the State. Foreign investors shall not invest in the prohibited industries, or must satisfy certain conditions stipulated in the negative list for investment in the restricted industries. The current industry entry clearance requirements governing investment activities in the PRC by foreign investors are set out mainly in the Special Administrative Measures (Negative List) (2021 version) for Foreign Investment Access (《外商投資准入特別管理措施(負面清單)(2021年版)》) and the Encouraged Industry Catalog for Foreign Investment (2022 version) (《鼓勵外商投資產業目錄(2022年版)》). Industries not listed in these two categories are generally deemed "permitted" for foreign investment unless otherwise restricted by other PRC laws.

On December 30, 2019, the MOFCOM and the SAMR jointly promulgated the Measures for Information Reporting on Foreign Investment (《外商投資信息報告辦法》), effective on January 1, 2020, pursuant to which, where a foreign investor directly or indirectly carries out investment activities in China, the foreign investor or the foreign-invested enterprise shall submit the investment related information to the competent commerce authority through the enterprise registration system and the national enterprise credit information publicity system for further handling.

Regulations relating to Merger and Acquisition of Domestic Enterprises by Foreign Investors and Overseas Listing

According to the Provisions on Merger and Acquisition of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》) (the "**M&A Rules**") which were jointly adopted by the MOFCOM, the SAFE and other four ministries on August 8, 2006, took effect on September 8, 2006 and amended on June 22, 2009, "mergers and acquisitions of domestic enterprises by foreign investors" refers to: (a) a foreign investor converts a non-foreign invested enterprise (domestic company) to a foreign invested enterprise by purchasing the equity interest from the shareholder of such domestic company or the increased capital of the domestic company (the "**Equity Merger and Acquisition**"); or (b) a foreign investor establishes a foreign invested enterprise to purchase the assets from a domestic enterprise by agreement and operates the assets therefrom; or (c) a foreign investor purchases the assets from a domestic enterprise by agreement and uses these assets to establish a foreign invested enterprise for the purpose of operation of such assets (the "**Assets Merger and Acquisition**").

M&A Rules provides that mergers and acquisitions of domestic enterprises by foreign investors shall be subject to the approval of the MOFCOM or its delegates at provincial level. In the event that any domestic company, enterprise or natural person merges or acquires a domestic company that has affiliated relationship with it through an overseas company legally established or controlled by such domestic company, enterprise or natural person, the merger and acquisition applications shall be submitted to the MOFCOM for approval. Any circumvention on the requirement including domestic re-investment of a foreign invested enterprise is not allowed.

The China Securities Regulatory Commission, or CSRC promulgated Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the "**Overseas Listing Trial Measures**") and five relevant guidelines on February 17, 2023, which became effective on March 31, 2023. The Overseas Listing Trial Measures regulate both direct and indirect overseas offering and listing by PRC domestic companies' by adopting a filing-based regulatory regime.

According to the Overseas Listing Trial Measures, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to complete the filing procedure with the CSRC and report relevant information.

The Overseas Listing Trial Measures also provide that if the issuer both meets the following criteria, the overseas securities offering and listing conducted by such issuer will be deemed as indirect overseas offering subject to the filing procedure set forth under the Overseas Listing Trial Measures: (i) 50% or more of the issuer's operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by domestic companies; and (ii) the issuer's business activities are substantially conducted in mainland China, or its principal place of business is located in mainland China, or the senior managers in charge of its business operations and management are mostly Chinese citizens or domiciled in Mainland China. Where an issuer submits an application for an initial public offering to competent overseas regulators, such issuer must file with the CSRC within three business days after such application is submitted. The Overseas Listing Trial Measures also require subsequent reports to be filed with the CSRC on material events, such as change of control or voluntary or forced delisting of the issuer who have completed overseas offerings and listings.

Based on the communication with the CSRC, the CSRC advised us to file with the CSRC in connection with the [**REDACTED**] under the Overseas Listing Trial Measures. Correspondingly, we will submit the filing application to the CSRC within the prescribed timeframe for the [**REDACTED**].

Regulations of Intellectual Property Rights

Patent

The Patent Law of the People's Republic of China (《中華人民共和國專利法》) (the "**Patent Law**") is revised by the SCNPC on October 17, 2020 and came into effect on June 1, 2021. According to the current Patent Law, when the invention or utility model patent is granted, unless otherwise stipulated in the Patent Law, without the approval of the patent owner, no entity or person shall implement the relevant patent, that is, manufacture, use, offer to sell, sell or import the patented products for business purpose, or use the patented method and use, offer to sell, sell or import the products directly obtained with the patented method. Implementing the patent without the approval of the patent owner constitutes the infringement of patent rights. Any dispute in connection with this shall be resolved by the relevant parties through negotiation. If the relevant parties refuse to negotiate or the negotiation fails, the patent owner or the relevant stakeholders may file a lawsuit in the people's court or turn to the patent administration authorities for handling.

Copyright

Copyright in the PRC, including copyrighted software, is principally protected under the Copyright Law of the PRC (《中華人民共和國著作權法》) and related rules and regulations. Under the Copyright Law of the PRC, the term of protection for copyrighted software is 50 years. On November 11, 2020, the SCNPC promulgated the newly amended Copyright Law, or the New Copyright Law, which took effect on June 1, 2021. The New Copyright Law increased the cost of infringement violations and expanded the protection coverage of Copyright Law. The Regulation on the Protection of the Right to Communicate Works to the Public over Information Networks (《信息網絡傳播權保護條例》), which was most recently amended on January 30, 2013, provides specific rules on fair use, statutory license, and a safe harbor for use of copyrights and copyright management technology and specifies the liabilities of various entities for violations, including copyright holders, libraries and Internet service providers. In order to further implement the Regulations for the Protection of Computer Software (《計算機軟件保護條例》) promulgated by the State Council on June 4, 1991 and lastly amended on January 30, 2013, the State Copyright Bureau issued the Registration of Computer Software Copyright Procedures (《計算機軟件著作權登記辦法》) on February 20, 2002, which applies to software copyright registration, license contract registration and transfer contract registration with respect to software copyright.

Trademark

Registered trademarks are protected under the Trademark Law of the PRC (《中華人民共和國商標法》) and related rules and regulations. Trademarks are registered with the State Intellectual Property Office, formerly the Trademark Office of the State Administration for Industry and Commerce, or SAIC. Where registration is sought for a trademark that is identical or similar to another trademark that has already been registered or given preliminary examination and approval for use in the same or similar category of commodities or services, the application for registration of this trademark may be rejected. Trademark registrations are effective for a renewable ten-year period unless otherwise revoked.

Domain Name

Domain names are protected under the Administrative Measures on Internet Domain Names (《互聯網域名管理辦法》) promulgated by the Ministry of Industry and Information Technology, or MIIT on August 24, 2017 and effective as of November 1, 2017. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and applicants become domain name holders upon successful registration. The domain name registration also follows the principle of "first file, first registration."

Regulations on Information Security and Privacy Protection

The Basic Standards and Practice of Medical Test Laboratory (《醫學檢驗實驗室基本標準和管理規範(試行)》) provides that medical laboratories must establish information management and patient privacy protection policies. The Measures for the Administration of General Population Health Information (for Trial Implementation) (《人口健康信息管理辦法(試行)》) as promulgated by the NHFPC on May 5, 2014 sets forth the operational measures for patient privacy protection in medical institutions. The measures regulate the collection, use, management, safety and privacy protection of general population health information by medical institutions. Medical institutions must establish information management departments responsible for general population health information and establish quality control procedures and relevant information systems to manage this information. Medical institutions must adopt stringent procedures to verify the general population health data collected, timely update and maintain the data, establish policies on the authorized use of this information, and establish safety protection systems, policies, practice and technical guidance to avoid divulging confidential or private information. In addition, medical institutions shall not store general population health information collected in the offshore servers or rent the offshore servers. On June 10, 2021, the SCNPC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》), which took effect on September 1, 2021. The Data Security Law sets forth the regulatory framework, the responsibilities of relevant governmental authorities in regulating data security and the responsibilities of data processors. On August 20, 2021, the SCNPC promulgated the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), which took effect on November 1, 2021 and aims to protect personal information rights and interests, regulate the processing of personal information, ensure the orderly and free flow of personal information and promote reasonable use of personal information.

We have implemented a set of policies and procedures to ensure the collection, use, management, safety and privacy protection of health information comply with applicable laws and regulations. We have established an information management system to enforce our data privacy and protection measures and there is standard operation procedure in place for data collection, test procedures, data storage as well as data access. We would also organize training from time to time to ensure privacy compliance and data security.

On November 7, 2016, the SCNPC promulgated the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》), which became effect on June 1, 2017, any network operator shall comply with laws and regulations and fulfill their obligations to ensure the security of the network when conducting business and providing services. Those who provide services through networks shall take technical measures and other necessary measures in accordance with laws, regulations and compulsory national requirements to safeguard the safe and stable operation of the networks, respond to network security incidents effectively, prevent illegal and criminal activities committed on the network, and maintain the integrity, confidentiality, and availability of network data. Network operators shall keep the user information that they have collected in strict confidence. In addition, the network operators shall neither collect the personal information irrelevant to the services provided by them nor collect or use the personal information in violation of the provisions of any law or administrative regulation or the agreement between both parties.

On December 28, 2021, the CAC and other twelve PRC regulatory authorities jointly revised and promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the "**Cyber Review Measures**"), which came into effect on February 15, 2022. The Cyber Review Measures stipulate that, among others, (i) when the purchase of network products and services by a critical information infrastructures operator (the "**CIIO**") or the data processing activities conducted by a network platform operator affect or may affect national security, a cybersecurity review shall be conducted pursuant to the Cyber Review Measures; (ii) an application for cybersecurity review shall be made by an issuer who is a network platform operator holding personal information of more than one million users before such issuer applies to list its securities abroad; and (iii) the relevant PRC governmental authorities may initiate cybersecurity review if such governmental authorities determine that the issuer's network products or services, or data processing activities affect or may affect national security.

Our PRC Legal Adviser and the PRC legal adviser to the Joint Sponsors conducted a telephone consultation with the name of our relevant PRC subsidiaries being disclosed with the China Network Security Review Technology and Certification Center (the "**Center**") on June 8, 2023 (the "**Consultation**"), during which the principal business of the PRC subsidiaries of the Group were introduced and discussed with the Center. Based on the Consultation, "listing abroad" does not include listing in Hong Kong and our application for [**REDACTED**] in Hong Kong currently does not need to proactively apply for cybersecurity review as required by the Cyber Review Measures. Therefore, it is understood that "listing abroad" does not include the listing in Hong Kong, and we consider, as advised by our PRC Legal Adviser, that we are not required to file an application for cybersecurity review to the CAC for its proposed [**REDACTED**] in Hong Kong.

Furthermore, we confirms that none of the subsidiaries of our Group established in the PRC (i) have been identified as CIIO by any government authorities; (ii) have participated in data processing activities that influence or may influence national security; (iii) have received any notice of cooperation with the CAC for cybersecurity review; or (iv) have been subject to any investigations or administrative penalties in respect of cybersecurity review.

In light of the above, we are of the view, and our PRC Legal Adviser and the Joint Sponsors concur, that the cybersecurity review as required under the Cyber Review Measures was not applicable to us as of the Latest Practicable Date and accordingly, the relevant rules and regulations was not applicable to the us. However, our PRC Legal Adviser cannot preclude the possibility that new rules or regulations promulgated in the future will not impose additional compliance requirements on us. As advised by our PRC Legal Adviser, we shall pay close attention to the law enforcement of the Cyber Review Measures and legislative development of other relevant laws and regulations as well as its specific provisions or implementation standards, maintain ongoing dialogue with competent PRC government authorities and consult competent PRC government authorities when necessary.

We and our PRC Legal Adviser are of the view, and the Joint Sponsors concur, that, we comply with the relevant cybersecurity rules and regulations in all material aspects during the Track Record Period and the relevant cybersecurity rules and regulations will not have a material adverse impact on our business operations and our proposed [**REDACTED**] in Hong Kong, on the basis that (i) as mentioned above, we are not required to file an application for cybersecurity review to CAC for the proposed [**REDACTED**] in Hong Kong under the Cyber Review Measures; (ii) as of the Latest Practicable Date, we had not been subject to any fines or administrative penalties, mandatory rectifications, or other sanctions by any competent regulatory authorities in relation to the infringement of cybersecurity and data protection rules and regulations; (iii) as of the Latest Practicable Date, there had been no material leakage of data or personal information or violation of cybersecurity and data protection and privacy laws and regulations by us which will have a material adverse impact on our business operations; (iv) as of the Latest Practicable Date, there had been no material cybersecurity and data protection incidents or infringement upon the rights of any third parties, or other legal proceedings, administrative or governmental proceedings, pending or, to the best of the knowledge of our Group, threatened against or relating to the us; (v) to mitigate the potential impact of any regulatory changes or further explanation or interpretation for "affect or may affect national security" be issued, we will pay close attention to the legislative and regulatory development in cybersecurity and data protection, maintain ongoing dialogue with relevant government authorities and consult the relevant government authorities as necessary and in due course and will adjust and optimize our data practices in a timely manner to keep pace with regulatory development; (vi) as of the Latest Practicable Date, we had not been involved in any investigations on cybersecurity review made by the CAC on such basis and nor have we received any inquiry, notice, warning, or sanctions in such respect. As of the Latest Practicable Date, we had not received any notification from the relevant competent or regulatory authorities that we had been determined to be a CIIO or network platform operators engaging in data processing activities that affect or may affect national security.

Regulation of Advertisement

Pursuant to the Advertisement Law of the PRC (《中華人民共和國廣告法》), which was promulgated by the SCNPC on October 27, 1994 and effective from February 1, 1995 and latest amended and effective from April 29, 2021, advertisements shall not contain false statements or be deceitful or misleading to consumers. Advertisements relating to pharmaceuticals and medical devices, shall be reviewed by relevant authorities in accordance with applicable rules before they are distributed.

Pursuant to the Medical Devices Regulations, the medical device advertisement shall be authentic and lawful and shall be based on the instructions of medical devices that have been registered or filed with the drug regulatory authority and shall not contain any false, exaggerated or misleading content. Before publishing medical devices advertisement, the content of the advertisement shall be examined by the advertisement examination organ appointed by the people's government of the province, autonomous region or municipality directly under the Central Government, and the approval number of medical device advertisement shall be obtained; no advertisement may be published without the examination.

Pursuant to the Medical Devices Regulations and the Interim Administrative Measures for Censorship of Advertisements for Drugs, Medical Devices, Dietary Supplements and Foods for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) which was promulgated by the SAMR on December 24, 2019 and came into effect on March 1, 2020, the contents of a medical device advertisement shall be based on the contents of the registration certificate or the recordation proof approved by the drug administrations, or the registered or filed product instructions. Medical device advertisement involving the name, scope of application, mechanism of action, or structure and composition of the medical device, must not exceed the scope of the registration certificate or the recordation proof.

Regulation of Anti-bribery

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by SCNPC, as amended and effective as of April 23, 2019, and the Interim Provisions on the Prohibition of Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》) promulgated by the SAIC on November 15, 1996, any business operator shall not provide or promise to provide economic benefits (including cash, other property or by other means) to a counter-party in a transaction or a third party that may be able to influence the transaction, in order to entice such party to secure a transactional opportunity or competitive advantages for the business operator. Any business operator breaching the relevant anti-bribery rules above-mentioned may be subject to administrative punishment or criminal liability depending on the seriousness of the cases.

Tax Regulations

Enterprise Income Tax

The PRC enterprise income tax, or EIT, is calculated based on the taxable income determined under the applicable EIT Law of the PRC (《中華人民共和國企業所得税法》) and its implementation rules, both of which became effective on January 1, 2008 and were most recently amended on December 29, 2018. The EIT Law generally imposes a uniform enterprise income tax rate of 25% on all resident enterprises in China, including foreign-invested enterprises. The EIT Law and its implementation rules permit certain High and New Technologies Enterprises, or the HNTEs, to enjoy a reduced 15% enterprise income tax rate if they meet certain criteria and are officially acknowledged.

Value Added Tax

On March 23, 2016, the Ministry of Finance, or MOF and the State Taxation Administration, or STA jointly issued the Circular on the Pilot Program for Overall Implementation of the Collection of Value Added Tax Instead of Business Tax (《關於全面推開營業税改徵增值税試點的通知》), or the Circular 36, which took effect on May 1, 2016. Pursuant to the Circular 36, all of the companies operating in construction, real estate, finance, modern service or other sectors which were required to pay business tax are required to pay value-added tax, or VAT, in lieu of business tax. A VAT rate of 6% applies to revenue derived from the provision of certain services. Unlike a business tax, a taxpayer is allowed to offset the qualified input VAT paid on taxable purchases against the output VAT chargeable on the revenue from services provided.

On March 20, 2019, the MOF, the STA and the General Administration of Customs issued the Announcement on Policies for Deepening the VAT Reform (《關於深化增值税改革有關政策的公告》), or the Announcement 39, which came into effect on April 1, 2019, to further slash VAT rates. According to the Announcement 39, (i) the 16% or 10% VAT previously imposed on sales and imports by general VAT taxpayers is reduced to 13% or 9% respectively; (ii) the 10% purchase VAT credit rate allowed for the procured agricultural products is reduced to 9%; (iii) the 13% purchase VAT credit rate allowed for the agricultural products procured for production or commissioned processing is reduced to 10%; and (iv) the 16% or 10% export VAT refund rate previously granted to the exportation of goods or labor services is reduced to 13% or 9%, respectively.

Regulation of Foreign Exchange and Dividend Distribution

The principal regulations governing foreign currency exchange in China are the Regulations on Foreign Exchange Administration of the PRC (《中華人民共和國外匯管理條例》), or the Foreign Exchange Regulations, promulgated by the State Council on January 29, 1996 and latest revised and effective on August 5, 2008. Under the Foreign Exchange Regulations and other PRC rules and regulations on a currency conversion, Renminbi is freely convertible for payments of current account items, such as trade and service-related foreign exchange transactions and dividend payments, but not freely convertible for capital account items, such as direct investment, loan or investment in securities outside China unless prior approval of the SAFE or its local counterpart is obtained.

The SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》) (the "**SAFE Circular 13**") on February 13, 2015, which was amended on December 30, 2019, and prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

The SAFE promulgated the Circular on Reforming the Management Approach regarding the Settlement of Foreign Capital of Foreign-invested Enterprise (《關於改革外商投資企業外匯資本金結匯管理方式的通知》) (the "**SAFE Circular 19**") on March 30, 2015, which was last amended on December 30, 2019, and further issued the Circular on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《關於改革和規範資本項目結匯管理政策的通知》) (the "**SAFE Circular 16**") on June 9, 2016. Pursuant to the SAFE Circular 19 and the SAFE Circular 16, the flow and use of the Renminbi capital converted from foreign currency denominated registered capital of a foreign-invested company shall not be used for business beyond its business scope, or to provide loans to persons other than affiliates unless otherwise permitted under its business scope.

On October 23, 2019, the SAFE released the Circular on Further Promoting Cross-border Trade and Investment Facilitation (《關於進一步促進跨境貿易投資便利化的通知》), which allows non-investment foreign-invested enterprises to use their capital funds to make equity investments in China, provided that such investments do not violate the negative list and the target investment projects are genuine and in compliance with laws.

According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通知》) issued by the SAFE on April 10, 2020, under the prerequisite of ensuring true and compliant use of funds and compliance and complying with the prevailing administrative provisions on use of income from capital projects, enterprises which satisfy the criteria are allowed to use income under the capital account, such as capital funds, foreign debt and overseas listing, etc., for domestic payment, without the need to provide proof materials for veracity to the bank beforehand for each transaction.

SAFE Circular 37

SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Administration of Overseas Investment and Financing and Return Investments Conducted by Domestic Residents through Special Purpose Vehicles (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》), or the SAFE Circular 37, on July 4, 2014, which replaced the former circular commonly known as the "SAFE Circular 75" (《關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》) promulgated by SAFE on October 21, 2005. SAFE Circular 37 requires PRC residents to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with their legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle". SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle, such as increase or decrease of capital contributed by PRC individuals, share transfer or exchange, merger, division or other material event. In the event that a PRC shareholder holding interests in a special purpose vehicle fails to fulfill the required SAFE registration, the PRC subsidiary of that special purpose vehicle may be prohibited from making profit distributions to the offshore parent and from carrying out subsequent cross-border foreign exchange activities, and the special purpose vehicle may be restricted in its ability to contribute additional capital into its PRC subsidiary. Furthermore, failure to comply with the various SAFE registration requirements described above could result in liability under PRC law for evasion of foreign exchange controls. On February 13, 2015, SAFE released SAFE Circular 13 which was amended on December 30, 2019, under which qualified local banks will examine and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration, from June 1, 2015. There exist substantial uncertainties with respect to its interpretation and implementation by government authorities and banks.

Labor Laws and Social Insurance

In accordance with the PRC Labour Law (《中華人民共和國勞動法》) and the PRC Labour Contract Law (《中華人民共和國勞動合同法》), employers must sign a written labour contract with each full-time employee. All employers must comply with the local minimum wage standards. Violation of the PRC Labour Contract Law and the PRC Labour Law may result in a fine or other administrative penalty, and serious circumstances may lead to criminal liability.

Furthermore, pursuant to the PRC Social Insurance Law (《中華人民共和國社會保險法》) and the Regulations on the Administration of Housing Funds (《住房公積金管理條例》), Chinese employers are required to offer their employees benefit schemes that cover pension, unemployment, maternity, work-related injury, medical and housing funds.

Anti-Commercial Bribery and Anti-Corruption

China has established a comprehensive and robust legal framework to anti-commercial bribery and anti-corruption in the medical field. For instance, according to the Regulations on the Establishment of Adverse Records with Respect to Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》), which was promulgated by the National Health and Family Planning Commission, or NHFPC, and came into effect on March 1, 2014, where a manufacturer of drugs, medical devices and medical disposables, an enterprise, an agency or an individual offers staff of a medical institution any items of value or other benefits, the enterprise should be listed in the adverse records with respect to commercial bribery if relevant circumstances exist. If medical production and operation enterprises are listed into the Adverse Records of Commercial Briberies for the first time, their products shall not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies in local province for two years since publication of the record, and public medical institution, and medical and health institutions receiving financial subsidies in other province shall lower their rating in bidding or purchasing process. If medical production and operation enterprises are listed into the Adverse Records of Commercial Bribery more than once in five years, their products shall not be purchased by public medical institutions, and medical and health institutions receiving financial subsidies nationwide for two years since publication of the record.

According to the Anti-Unfair Competition Law of the PRC (《中華人民共和國反不正當競爭法》) promulgated by SCNPC, as amended and effective as of April 23, 2019, and the Interim Provisions on the Prohibition of Commercial Bribery (《關於禁止商業賄賂行為的暫行規定》) promulgated by the the State Administration for Industry and Commerce, or SAIC, on November 15, 1996, the business operator shall not provide or promise to provide economic benefits (including cash, other property or by other means) to a counter-party in a transaction or a third party that may be able to influence the transaction, in order to entice such party to secure a transactional opportunity or competitive advantages for the business operator. Any business operator breaching the relevant anti-bribery rules above-mentioned may be subject to administrative punishment or criminal liability depending on the seriousness of the cases.

Recent Regulatory Developments

On May 8, 2023, the National Health Commission ("**NHC**") and other relevant departments jointly issued the "Notice on the Key Points for the Work of Correcting Malpractice in the Medical Products Purchase and Sales and Medical Services in 2023" (《關於印發2023年糾正醫藥購銷領域和醫療服務中不正之風工作要點的通知》), which demands the establishment and enhancement of a comprehensive corrective governance system, with a primary emphasis on addressing significant corruption issues in the pharmaceutical sector.

On July 12, 2023, the NHC and 10 other departments convened a nationwide video conference on the focused rectification of corruption issues in the pharmaceutical sector. The conference centered on key areas such as production, supply, sales, utilization, and reimbursement within the pharmaceutical sector, and it emphasized the targeted deployment of rectification efforts.

On July 28, 2023, the Central Commission for Discipline Inspection and the National Supervisory Commission held a video conference to coordinate efforts in the concentrated rectification work. The meeting discussed strengthening supervision and law enforcement in the pharmaceutical sector and made internal arrangements within the disciplinary inspection and supervisory system.

According to the "Questions and Answers on the Nationwide Focused Rectification of Corruption Issues in the Pharmaceutical Sector" released by the Medical Emergency Department of the NHC on August 15, 2023, collaborative mechanisms for addressing corruption issues in the pharmaceutical sector have been established in all provinces. Localized work plans have been formulated, distributed and deployment arrangements have been made through convened meetings. Relevant departments in various provinces have swiftly initiated self-inspections and self-rectifications, resolved pertinent issues, and publicized multiple cases, cultivating a stringent tone and atmosphere. An extensive consensus against corruption has already taken shape within the pharmaceutical industry, and various tasks related to the focused rectification are progressing steadily. In the next phase, the focused rectification efforts will proceed in accordance with the overarching plan, maintaining continuous advancement. There will be an increased focus on providing guidance and coordination for the work, intensifying the handling and reporting of typical issues, all aimed at ensuring the effectiveness of the rectification efforts.

RELEVANT LAWS AND REGULATIONS IN THE UNITED STATES

U.S. Federal and State Regulation of Medical Devices

In the United States, the FDA regulates medical devices under the Food, Drug and Cosmetic Act and its implanting regulations ("**FDCA**"). The process of obtaining regulatory approvals to manufacture and market medical devices in the United States is subject to regulation under the FDCA and under applicable state law.

The Company currently has limited FDA-regulated operations in the United States because the Company is not manufacturing, selling or distributing any medical devices in the United States.

If the Company were to expand its operations and begin manufacturing, importing or distributing a medical device, or if FDA determines the Company's current research use only ("**RUO**") products are medical devices, the manufacturer would be subject to FDA pre- and post-market requirements, such as obtaining a 510(k) clearance for the medical devices prior to marketing, registering its manufacturing facility, listing the products it manufactures,

following FDA's good manufacturing practices, and having a required quality system, which includes adverse event reporting and recall policies. If the Company acts as an importer or distributor in the United States of an FDA regulated medical device, it would be required to register as an importer and have quality systems including recall policies and related post-marketing requirements in place.

Failure to comply with the applicable U.S. requirements at any time during the product development process, the approval process or following approval may subject the Company to administrative proceedings, administrative actions, government prosecution, judicial sanctions or any combination of them in the United States. These actions and sanctions could include, among others, refusal to approve pending applications, withdrawal of an approval or license, warning letters, product recalls, market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, restitution, disgorgement, civil or criminal fines or penalties, loss of government contracting privileges, enforcement actions, and import holds.

The Patient Protection and Affordable Care Act (the Affordable Care Act) includes provisions known as the Physician Payments Sunshine Act, which requires manufacturers of medical devices covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report this data to the Centers for Medicare & Medicaid Services for subsequent public disclosure. In October 2018, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act significantly expanded the types of healthcare providers for which reporting is required, beginning with reports filed in 2022. Similar reporting requirements have also been enacted on the state level, and an increasing number of governments worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals. Failure to report appropriate data may result in civil or criminal fines and penalties.

If the Company were to collect personally identifiable health information about labs or patients using directly or indirectly the Company's devices, the Company could become subject to regulations under a wide variety of U.S. laws and regulations designed to protect patient privacy. The regulation of data privacy and security, and the protection of the confidentiality of certain personal information (including patient health information, financial information and other sensitive personal information), is increasing. For example, various U.S. states (e.g., California, Virginia, and Colorado) have enacted data protection laws that contain significant compliance obligations and financial penalties for noncompliance. In addition, regulators with general consumer protection authority, such as the Federal Trade Commission and U.S. states Attorneys General, are focused on how consumer data is used by entities in the health care industry. Further, there are regulations of data privacy and security that are specific to health care companies. For example, the U.S. Department of Health and Human Services has issued rules governing the use, disclosure, and security of protected health information, and the FDA has issued further guidance concerning cybersecurity for medical devices. In addition, certain countries have issued or are considering "data localization" laws, which limit companies' ability to transfer protected data across country borders. Failure to comply with data privacy

and security laws and regulations can result in business disruption and enforcement actions, which could include civil or criminal penalties. Transferring and managing protected information will become more challenging as laws and regulations are enacted or amended, and the Company expects there will be increasing complexity in this area.

United States Federal and State Taxation

The Company currently has limited operations in the United States, and for federal and state income tax purposes is in a net operating loss position. Should the Company expand its U.S. operations, the Company's federal and state income tax liability may increase and could create a positive tax liability.

Expanding facilities, locations or operations may expose the Company to increased state income tax and property tax liability in multiple jurisdictions including jurisdictions not currently taxing the Company.

Additionally, the Company may owe additional payroll taxes for expanded U.S. headcount.

Significant provisions in the law known as the Tax Cuts and Jobs Act of 2017 will expire or become less generous after December 31, 2025. Expiration of these provisions could increase or change the Company's federal and state income tax liability. Moreover, Congressional and state legislative action in 2025 or beyond may increase the Company's federal and state income tax and other tax liability.

Any or all of these changes in U.S. and state tax law or the Company's operations could cause the Company to become subject to filing and reporting requirements and taxes and assessments to which it is not currently subject or increase its tax liability beyond current obligations. Failure to comply with tax obligations can result in the assessment of penalties and interest and can lead to tax administrative or civil proceedings and actions.

The forgoing is not intended to be exhaustive and [**REDACTED**] are advised to seek independent tax advice.

United States International Trade Laws and Regulations

To the extent that the Company were to begin to import products into the United States, its products will be subject to various federal laws and regulations enforced by U.S. Customs and Border Protection, including laws and regulations governing valuation, classification, country of origin marking requirements, and duty treatment requirements. Failure to comply with such laws can result in penalties and/or seizure actions.

Products can be imported into the United States from one of the Company's two manufacturing facilities in Singapore or the PRC. The Company's business is therefore subject to constantly changing international economic, social and political conditions, and local

conditions in these countries. The political relationships between these countries may affect the prospects of the Company's relationship with third parties, such as customers, suppliers, and global partners. Although the United States currently maintains a close and cooperative trade relationship with Singapore pursuant to The United States-Singapore Free Trade Agreement, which can include favorable tariff rates, trade relationships can be volatile and tariff rates could change in the future, impacting the price of the Company's products for sale in the United States and the cost of doing business in the United States.

Additionally, the U.S. International Trade Commission has jurisdiction over the importation of goods and products into the United States, and under the provisions of 19 U.S.C. § 1337 and Administrative Procedure Act can instruct U.S. Customs and Border Patrol to bar the importation of any goods or products that have been found to infringe U.S. intellectual property rights, including patents, trademarks, trade secrets, trade dress and copyrights. Further, the U.S. International Trade Commission can bar the importation of any goods manufactured outside of the U.S. for violation of other forms of U.S. unfair competition, including mask works, passing off, false advertising, and antitrust claims. If any such violation is found, the U.S. International Trade Commission can issue an exclusion order that directs U.S. Customs and Border Patrol to stop the importation of any goods found to be in violation. In addition, the Commission may issue cease and desist orders against named importers and other persons to prevent the further sale or distribution of goods already imported into the U.S..

Moreover, the United States enforces a number of trade restrictions on goods imported from the PRC, including tariffs under Section 301 of the Trade Act of 1974 which grants the Office of the United States Trade Representative (USTR) a range of responsibilities and authorities to investigate and take action to enforce U.S. rights under trade agreements and respond to certain foreign trade practices. The Section 301 tariffs against the PRC apply to a majority of the goods imported from the PRC. Complying with Section 301 tariffs means navigating a separate chapter of the Harmonized Tariff Schedule of the United States ("**HTSUS**") (Chapter 99) to determine whether additional tariffs or other modifications will be applicable to a product's HTSUS code. In the event the Company's products are imported from the PRC, the products could be subject to high tariffs, affecting the price of the Company's products for sale in the United States and the cost of doing business in the United States. Trade disputes may escalate going forward and may result in certain types of goods, such as advanced research and development equipment and materials, becoming significantly more expensive to procure from overseas suppliers or even becoming illegal to import. There can be no assurance that the Company's existing or potential service providers or collaboration partners will not alter their perception of the Company or their preferences as a result of adverse changes to the state of political relationships between the PRC and the United States. Any tensions, political concerns, and trade frictions between countries where the Company has operations may cause a decline in the demand for the Company's products and adversely affect its business prospects, financial condition, results of operations and cash flows.

In addition, for goods imported from the PRC, the Company would need to comply with the Uyghur Forced Labor Prevention Act, which requires proof that the Company's products and any components were not produced in factories using forced labor, primarily from the

Xinjiang region of the PRC. U.S. Customs and Border Protection assumes that products produced in Xinjiang are produced by forced labor, and thus, such products will be seized at the port of entry, unless the Company can prove otherwise. Trade restrictions and additional tariffs on PRC-origin goods are ever-evolving and subject to the political climate of the United States and the PRC; as such, compliance with such trade restrictions will create a regulatory burden for the Company to manage tariffs, duties, and import restrictions on an ongoing basis.

If the Company's products are physically in the United States or transiting through the United States, if the Company's products meet certain thresholds of U.S.-origin components or technology, or if the Company's products are the direct product of U.S.-origin components or technology, the Company's products will be subject to, and the company could be required to comply with, the export control laws of the United States, such as the Export Administration Regulations. The U.S. export control laws can affect who the Company may conduct business with and where the Company can send the Company's products. The export control jurisdiction of the United States is broad, and, in the event such jurisdiction applies to the Company's products, the Company would have compliance obligations when re-exporting the Company's products from the United States, selling the Company's products outside of the United States, and providing the Company's technology to non-U.S. persons within the United States where doing so involves the deemed export of a controlled product, service or information. The Company may have to obtain authorization from the U.S. Government to engage in certain transactions or to share information about the Company's products with certain non-U.S. persons. Failure to comply with such laws can result in civil and criminal penalties, a loss of export privileges, and other potential consequences for export controls violations.

Conducting business in the United States also could require the Company to comply with a variety of U.S. economic sanctions laws, including laws administered by the U.S. Department of the Treasury's Office of Foreign Assets Control. The U.S. sanctions laws apply to all transactions involving U.S. persons (including U.S. citizens and permanent residents, regardless of where they are located, entities organized under the laws of the United States, and any individual physically present in the United States) and U.S. dollars. The U.S. economic sanctions laws can affect with whom the Company may do business including restricting the ultimate end-users of the Company's products, from whom the Company obtains products and services, and where the Company may engage in business. The Company may have to obtain authorization from the U.S. Government to engage in certain transactions or to conduct business in certain jurisdictions. Failure to comply with U.S. economic sanctions laws can result in civil and criminal penalties, and other potential consequences for U.S. economic sanctions violations.

The Company is also subject to the anti-bribery laws of various jurisdictions, particularly in the PRC and the United States. As the Company's business expands, the scope of the applicable anti-bribery laws will increase. The relevant laws generally prohibit companies and their intermediaries from making payments to government officials for the purpose of obtaining or retaining business or securing any other improper advantage. In addition, some of the Company's customers may require the Company to follow strict anti-bribery and anti-money laundering policies as part of doing business with the Company. The Company's

internal procedures and controls to monitor compliance with anti-bribery law may fail to protect the Company from reckless or criminal acts committed by the Company's employees or intermediaries. The Company could be liable for actions taken by the Company's employees or partners that violate anti-bribery, anti-corruption and other related laws and regulations in the PRC and other jurisdictions such as the United States. The government authorities may seize the products involved in any illegal or improper conduct engaged in by the Company's employees or intermediaries. Any misconduct by the Company's employees or intermediaries or changes in the regulatory environment regarding the sale of the Company's products could have a material adverse effect on the Company's business prospects, financial condition and results of operations.

Patent Term Restoration

The United States Patent and Trademark Office advises that patent term extension under 35 U.S.C. 156 is available to permit owners of patents related to medical device products to restore to the term of those patents some of the time lost while awaiting premarket government approval for the product from a regulatory agency such as the FDA. Owners of such a patent may apply for up to a five-year patent term extension. Extension time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for extension, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the patent holder must apply for extension within 60 days after approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term extension.

RELEVANT LAWS AND REGULATIONS IN PHILIPPINES

Licensing Covid-19 Testing Laboratories

Covid-19 testing can be conducted only in a Covid-19 testing laboratory duly licensed by the Department of Health ("**DOH**"). Under the DOH's Guidelines in Securing a License to Operate a Covid-19 Testing Laboratory in the Philippines, an individual, partnership, corporation or association seeking to perform SARS-CoV-2 detection in a Covid-19 testing laboratory must possess a License to Operate ("**LTO**") issued by the DOH through its Health Facilities and Services Regulatory Bureau. The LTO shall be issued upon proof of compliance with the standards and requirements of the bureau and Research Institute for Tropical Medicine and HFSRB, which include:

- notarized and accomplished application form;
- approved DOH-Permit to Construct and floor plan;
- notarized list of personnel;

- list of equipment;
- copy of Certificates of Product Registration ("**CPRs**") for all equipment, reagents, and supplies; and
- accomplished self-assessment tool.

An LTO shall be valid for one (1) year and must be renewed annually.

Covid-19 testing laboratories and/or the responsible personnel shall comply with relevant rules and regulations, issuances and other policy guidelines promulgated by the DOH. Violations may result in the cancellation or suspension of the LTO, as well as penalties on the Covid-19 testing laboratories and/or responsible personnel.

Regulation of Medical Devices under the Food and Drug Administration ("PFDA") Act of 2009 ("PFDA Act"; Republic Act No. 9711, as amended)

An establishment seeking to undertake the manufacturing, importation and distribution, exportation, sale, offering for sale, transfer, non-consumer use, promotion, advertising, or sponsorship activities of health products must obtain an LTO from the PFDA. An LTO covering a particular establishment shall be *prima facie* evidence of the licensee's authority to engage in the activity specified in the LTO. The LTO is required for the registration and distribution of a health product.

Health products include food, drugs, cosmetics, devices, biologicals, vaccines, *in vitro* diagnostic reagents and household/urban hazardous substances and/or a combination of and/or a derivative of such products.

The PFDA may issue an LTO upon compliance with standards and requirements such as:

- accomplished eApplication form filed online through the eServices Portal website, with a Declaration and Undertaking;
- locational Plan and Global Positioning System coordinates;
- name of Qualified Person, which refers to an employee of the establishment who possesses technical competence related to the establishment's activities;
- proof of business name registration (*i.e.*, Securities and Exchange Commission ("**PSEC**") Certificate of Registration); and
- business permit issued by the relevant local government unit.

An LTO shall be initially valid for two (2) years. Renewed LTOs are valid for three (3) years.

The LTO may be cancelled when:

- the application shows that the establishment does not meet the required technical requirements or appropriate standards;
- the applicant made misrepresentations, false entries or withheld relevant data; and
- the owner has violated any terms and condition of the license.

In addition to the LTO, a CPR from the PFDA is likewise required prior to the marketing, sale or distribution of health products to ensure their safety, efficacy, and quality. A separate CPR should be obtained for each particular health product.

For medical devices, the PFDA may issue a CPR upon compliance with standards and requirements which differ depending on the class of the medical device. The common requirements for a CPR for a medical device are:

- executive summary which shall include an overview of the medical device, intended uses, and indications for use of the medical device;
- relevant essential principles and method/s used to demonstrate conformity with the essential principles (*e.g.*, biocompatibility category for the finished medical device), if applicable;
- device description;
- summary of design verification and validation documents;
- pictures of label from all sides of the packaging;
- risk assessment; and
- physical manufacturer information.

A CPR shall be valid for five (5) years. A CPR may be cancelled when:

- the application shows that the establishment does not meet the required technical requirements or appropriate standards;
- the applicant made misrepresentations, false entries or withheld relevant data;
- the owner has violated any terms and condition of the registration;
- the label of the health product is false and misleading or does not conform to the labeling requirements; and

- the owner of the CPR fails to sell the health product or fails to cause it to be marketed during an uninterrupted period of at least three (3) years, without legitimate reasons.

The CPRs may be in the form of a *(a)* Certificate of Medical Device Registration ("**CMDR**") or Notification, *(b)* Certificate of Medical Device Listing ("**CMDL**"), or *(c)* Certificate of Product Registration for In-Vitro Diagnostic Device/Reagents, as may be applicable.

Medical devices intended for research use only ("**RUO**") are exempt from securing a CPR in the form of a CMDR or Notification. However, the researcher, institution, and/or user of such devices should obtain a CMDL from the PFDA. A CMDL authorizes the use of a medical device that is intended for research, clinical trial, exhibit, donation, etc. and that is not intended for sale.

PFDA Circular 2022-008 provides for the abridged processing of applications for CMDR of medical devices approved by the National Regulatory Authority ("**NRA**") of any ASEAN member country, except for *in vitro* diagnostic and refurbished medical devices, which are to be imported, distributed and sold in the Philippines. Under the abridged processing, the application for registration is limited to those classified as B (low-moderate risk), C (moderate risk), and D (high risk), pursuant to PFDA Circular 2022-008. However, the applicant must still submit legal requirements such as:

- attestation that the product details including the Common Submission Dossier Template ("**CSDT**") technical documentation submitted to PFDA are exactly the same as the product details and that the CSDT technical documentation are the latest filed or approved dossier by the reference NRA; and

- acknowledgement that if there is an unauthorized change in the product details and CSDT documentation, the PFDA shall automatically suspend the LTO and/or CMDR of the product, among others.

In case of failure to secure the required permits and approvals for the medical devices as provided under the PFDA Act and related issuances, the PFDA may, after due notice and hearing, *(a)* impose administrative fines ranging from the Peso equivalent of approximately USD880.00 to USD8,800.00, *(b)* seize and destroy the health products, *(c)* close the establishment, and *(d)* impose other penalties and sanctions provided by law.

The PFDA is authorized to develop and issue appropriate policies, standards, regulations, and guidelines that would cover establishments, facilities and health products.

The Foreign Investments Act ("FIA"; Republic Act No. 7042, as amended) and Revised Corporation Code ("RCC"; Republic Act No. 11232)

The FIA is the principal Philippine law specifically governing foreign investments.

An investment under the FIA is equity participation in any enterprise organized or existing under the laws of the Philippines and duly recorded in the enterprise's stock and transfer book. Foreign investments refer to equity investments made by a non-Philippine national in the form of foreign exchange or the monetary equivalent in Philippine peso of other assets actually transferred to the Philippines and duly registered with the *Bangko Sentral ng Pilipinas* ("**BSP**"; or the Philippine Central Bank). The FIA generally classifies Philippine-incorporated enterprises into domestic market enterprises and export enterprises.

The FIA requires the periodic issuance of the so-called the Foreign Investments Negative List ("**FINL**"), which is a list of areas of economic activity whose foreign ownership is limited to a maximum of 40% of the equity capital of the enterprises engaged in those activities. The latest FINL, the twelfth, was issued by the President of the Philippines on June 27, 2022.

The FINL is divided into two (2) lists, namely, List A and List B. List A enumerates the areas of economic activity which are reserved to Philippine nationals because foreign ownership in them has been limited by the Philippine Constitution or specific laws. These activities include mass media; advertising; the exploration, development, and utilization of natural resources; the operation of public utilities; and the ownership of private lands. List B enumerates the areas of economic activity where foreign ownership is limited for reasons of national security, defense, risk to health and morals, and protection of small- and medium-scale enterprises. An enterprise (whether an export enterprise or a domestic market enterprise) may be 100% foreign-owned if it is not included in the FINL and if the foreign equity for the enterprise is not otherwise restricted under other laws and regulations. In particular, a domestic market enterprise whose business is not covered by the FINL may be more than 40% foreign-owned if its paid-in equity capital is at least the Philippine Peso equivalent of USD200,000.00, unless a specific law or regulation provides otherwise.

The business activities of M Diagnostic Philippines Inc. and MiRXES Philippines Inc., as stated in their primary purposes, are not among the businesses covered by the FIA/FINL. The PFDA Act also does not also impose any special capitalization requirement for entities engaged in such business activities. To our knowledge, M Diagnostic Philippines Inc. and MiRXES Philippines Inc. are not otherwise engaged in any nationalized activity, *e.g.*, they do not own any land in the Philippines. They are domestic market enterprises and meet the USD200,000.00 capitalization requirement and so they may be more than 40% foreign-owned.

Under the FIA and the RCC, foreign investments are subject to the registration requirements of the PSEC (the primary Philippine agency regulating corporations in general) and other relevant government agencies. Among other things, the PSEC approves the incorporation of corporations under Philippine law, regardless of the extent of local or foreign ownership. The PSEC imposes continuing requirements for corporations in general, such as the submission of certain annual disclosures in their General Information Sheets and audited financial statements, which local or foreign-owned companies alike must comply with.

The PSEC has the power to suspend or revoke the certificate of registration of corporations and partnerships, after proper notice or hearing, on grounds such as the following: *(a)* fraud in procuring its certificate of registration; *(b)* serious misrepresentation as to what the corporation can do or is doing to the great prejudice of or damage to the general public; *(c)* refusal to comply or defiance of any lawful order of the PSEC restraining commission of acts which would amount to a grave violation of its franchise; *(d)* continuous in operation for a period of at least five (5) years; *(e)* failure to file required reports in appropriate forms as determined by the PSEC within the prescribed period; and *(f)* refusal or obstruction of the PSEC's exercise of its visitorial powers over corporations pursuant to the RCC.

Data Privacy Act of 2012 ("DPA"; Republic Act No. 10173)

The DPA is the Philippines' principal legislation relating to the protection of personal information.

Under the DPA, personal information refers to any information whether recorded in a material form or not, from which the identity of an individual is apparent or can be reasonably and directly ascertained by the entity holding the information, or when put together with other information would directly and certainly identify an individual.

On the other hand, sensitive personal information is defined as personal information *(a)* about an individual's race, ethnic origin, marital status, age, color, and religious, philosophical or political affiliations; *(b)* about an individual's health, education, genetic or sexual life of a person, or to any proceeding for any offense committed or alleged to have been committed by such person, the disposal of such proceedings, or the sentence of any court in such proceedings; *(c)* issued by government agencies peculiar to an individual which includes, but not limited to, social security numbers, previous or current health records, licenses or its denials, suspension or revocation, and tax returns; and *(d)* specifically established by an executive order or an act of Congress to be kept classified.

The DPA generally applies to the processing of personal information done within the Philippines, and to the processing of personal information done outside the Philippines if certain conditions are met, such as if the data subject is a Philippine citizen or resident, or the processing is done or engaged in by an entity with links to the Philippines.

Under the DPA, when an entity such as a data controller or data processor collects personal data, the purpose and extent of processing of such information collected must be legitimate and declared specifically to the owner of the personal information. A data controller refers to a person who controls or supervises the person collecting, storing or processing the relevant personal information. A data processor is a person who processes the information, whether or not outsourced by the data controller. Moreover, the data subject must provide consent, evidenced by written, electronic or recorded means, unless the processing falls within the DPA's exceptions. Such exceptions include: *(a)* The personal data is needed pursuant to a subpoena; *(b)* The collection and processing are for obvious purposes, including, when it is necessary for the performance of or in relation to a contract or service to which the data subject

is a party, or when necessary or desirable in the context of an employer-employee relationship between the collector and the data subject; or *(c)* The information is being collected and processed as a result of a legal obligation.

Personal information collected must be retained only for a reasonable period or for as long as necessary for the fulfilment of the purposes for which the data was obtained or for the establishment, exercise or defense of legal claims, or for legitimate business purposes, or as provided by law. The retention period must be made known to the data subject.

The data collector must implement appropriate measures for the storage and protection of the collected personal information from accidental alteration, destruction, disclosure, and unlawful processing. Furthermore, the data controller must assign compliance officers to ensure compliance with the provisions of the data privacy law and its accompanying implementing rules and regulations.

National Privacy Commission ("**PNPC**", the main implementing agency of the DPA and its implementing rules) issued Memorandum Circular No. 2022-04 requiring the registration with the PNPC of the data protection officer ("**DPO**") and data processing systems ("**DPS**") of personal information controller ("**PIC**") or personal information processor ("**PIP**") which: *(a)* employ 250 or more persons; *(b)* process sensitive personal information of 1,000 or more individuals; or *(c)* process data that will likely pose a risk to the rights and freedoms of data subjects shall register all data processing systems. A DPS processing personal information or sensitive personal information involving automated decision-making or profiling shall be registered as well.

For newly implemented DPS or inaugural DPOs, the entity concerned must undertake the registration within 20 days from the commencement of such system or the effectivity date of such appointment.

Once registration with the PNPC has been completed, the PNPC shall issue a Certificate of Registration which shall be valid for one (1) year. This certificate must be renewed annually.

A PIC or PIP should comply with the DPA, its implementing rules, and other issuances of the PNPC.

Intellectual Property Code of the Philippines ("IP Code"; Republic Act No. 8293, as amended)

The IP Code governs the filing, examination, grant, and registration of intellectual property such as copyrights, trademarks, and patents. In general, intellectual property must be registered with the Intellectual Property Office ("**IP Office**") so that rights pertaining to such intellectual property may be enjoyed and enforced."

Under the IP Code, a trademark refers to any visible sign capable of distinguishing the goods (trademark) or services (service mark) of an enterprise and shall include a stamped or marked container of goods.

Once registered, a Certificate of Registration shall be issued by the Bureau of Trademarks of the IP Office, which shall be *prima facie* evidence of the validity of the registration, the registrant's ownership of the mark, and of the registrant's exclusive right to use the trademark in connection with the goods or services and those that are related to them as specified in the certificate. The Certificate of Registration shall be valid for ten (10) years, and may be renewed for periods of ten (10) years at its expiration. The owner of a registered mark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade or similar signs or containers for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion.

An application for registration of a mark or the registration itself, may be assigned or transferred with or without the transfer of the business using the mark through execution of a document in writing, duly signed by the contracting parties, and recorded with the IP Office to bind third parties.

On the other hand, a patent or a patentable invention is any technical solution of a problem in any field of human activity which is new, involves an inventive step and is industrially applicable. The grant of a patent by the IP Office's Bureau of Patents confers upon the owner of the patent the exclusive rights to restrain, prohibit, and prevent any unauthorized person or entity from making, using, offering for sale, selling or importing the product subject of a patent; using the process and manufacturing or dealing in using, selling, or offering for sale, or importing any product obtained directly or indirectly from the process subject of a patent. The term of a patent shall be 20 years from the filing date of application.

A patent may be subject of technology transfer arrangement through a voluntary licensing contract to transfer to a third person the right to exploit the subject matter of the contract for a specified term or through a compulsory licensing granting a third person who has shown capability to exploit the invention even without the agreement of the patent owner.

The Labor Code of the Philippines (Republic Act No. 442, as amended)

The Labor Code is the main Philippine law regulating employment practices and labor relations. The Philippines' Department of Labor and Employment ("**DOLE**") is the principal implementing agency of the Labor Code. The DOLE Secretary may issue rules to implement the law.

The Labor Code regulates, among others, classes of employees, standards and conditions of employment such as the normal hours of work, payment of wages, overtime work, employee benefits such as holiday pay and retirement pay, and labor relations including unionization of employees and collective bargaining. The Labor Code also governs the employment of foreign nationals in the Philippines insofar as it allows applications for alien employment permit of foreign nationals who intend to engage in gainful employment in the Philippines, after the conduct of labor market test, or after determining the non-availability of a Filipino citizen who is competent, able, and willing at the time of application to perform the services for which the foreign national is desired.

The Labor Code likewise prescribes rules for the hiring and termination of employees. It implements the Philippine Constitution's policy on security of tenure for employees by providing for the just causes (such as serious misconduct, willful disobedience or insubordination, gross and habitual neglect of duties, fraud or willful breach of trust, commission of a crime or offense, and analogous causes) and authorized causes (such as installation of labor-saving devices, redundancy, retrenchment or downsizing, closure or cessation of operation, and disease) for, and requiring due process in, the termination of employees.

Repatriation of capital and profits

There are no restrictions on the remittance of dividends or other payments (including repatriation of capital) from M Diagnostic Philippines Inc. and MiRXES Philippines Inc. to MiRXES PTE Ltd. generally, as long as such remittance is made in a currency other than Philippine Pesos. However:

- where such payment is made in Philippine Pesos, prior approval from the BSP is required in relation to a payment exceeding P$50,000.00 (approximately USD900.00);

- the declaration and payment of dividends may be undertaken only when a corporation has unrestricted retained earnings and upon obtaining corporate approvals, namely, Board of Directors approval and *(a)* in case of stock dividends, also stockholder approval; and *(b)* in case of property dividends, also PSEC approval;

- a corporation may return capital to its stockholders only in limited instances, namely: *(a)* amendment of the articles of incorporation to reduce the corporation's authorized capital stock; *(b)* purchase of redeemable shares by the corporation regardless of the existence of unrestricted retained earnings; and *(c)* dissolution and eventual liquidation of the corporation; and

- BSP registration of the foreign investment will be necessary if the foreign currency required to service any dividend or capital payment/repatriation will be sourced from the local banking system.

The registration of foreign investments with the BSP is not mandatory. However, such registration enables the purchase of foreign currency from authorized agent banks in the Philippines and/or their subsidiary or affiliate foreign exchange corporations in the Philippines to fund capital repatriation or dividends distribution to foreign investors.

No withholding tax shall be imposed on repatriation of capital. However, profit derived from M Diagnostic Philippines Inc. and MiRXES Philippines Inc. may generally be subjected to tax at the rate of 25% unless the preferential tax rate applies under the Philippines-Singapore tax treaty. Except for property dividends (whose distribution requires approval of the PSEC in the Philippines), the declaration and payment of dividends does not require Philippine government authorization.

Dividends declared and remitted by M Diagnostic Philippines Inc. and MiRXES Philippines Inc. to a non-resident foreign corporation shareholder are subject to a final withholding tax at a rate of 25% of the amount of cash and/or property dividends. The rate may be reduced to 15% if the country in which the foreign corporation is domiciled does not impose income tax on such dividends, or allows a tax deemed paid credit of 10% which is the difference between the 25% corporate income tax and 15% tax on dividends.

RELEVANT LAWS AND REGULATIONS IN JAPAN

The Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices

Sellers or lessors of controlled medical devices in Japan (including our subsidiary, MiRXES Japan Co., Ltd., the "**Sellers**") are, among others, subject to a notification obligation under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices of Japan (Act No. 145 of 1960, as amended, the "**Pharmaceutical and Medical Devices Act**").

Under the Pharmaceutical and Medical Devices Act, the Sellers are required to notify the prefectural governor of the region where the business offices of the Sellers are located of certain matters specified by the relevant ordinance. The Sellers are required to comply with the methods for quality control of the controlled medical devices as specified by the Minister of Health, Labor and Welfare (the "**MHLW**") under the ministerial ordinance of the Ministry of Health, Labor and Welfare of Japan (the "**Ministerial Ordinance**") and the standards for the structure and equipment of the business offices for the Sellers as specified by the MHLW under the Ministerial Ordinance. Also, the Pharmaceutical and Medical Devices Act requires the Sellers to take measures to ensure their legal compliance related to pharmaceutical affairs as required under the relevant ordinance.

In addition, a person intending to manufacture medical devices or *in vitro* diagnostics in a foreign country that are to be exported to Japan (a "**Foreign Manufacturer of Medical Devices**") is required under the Pharmaceutical and Medical Devices Act to obtain registration from the MHLW for each manufacturing facility. Accordingly, MiRXES Singapore has obtained the registration from the MHLW as a foreign *in vitro* diagnostic manufacturer. A Foreign Manufacturer of Medical Devices is required to comply with the methods of tests and inspections of medical devices or *in vitro* diagnostics at manufacturing facilities and other matters specified by the MHLW under the Ministerial Ordinance.

Further, a person intending to manufacture and distribute IVDs in Japan or manufacture IVDs in a foreign country and distribute them through a designated marketing authorization holder in Japan must, depending on the classification of the IVDs, obtain an approval of, or file a notification with, the Minister of Health, Labor and Welfare of Japan, or obtain a certification of the registered certification institution, and a person intending to obtain such approval or certification is required to submit clinical trial results and other relevant materials together with the application documents as evidence to support the quality, efficacy and safety of such IVDs. Accordingly, MiRXES Singapore has been in consultation with the PMDA to explore an IVD approval of GASTROClear™ in Japan. For more details, see "Business – Our Early Detection and Precision Multi-omics Business Segment – GASTROClear™ – Our Core Product – Further Development Plan".

The Act on the Protection of Personal Information

The Act on the Protection of Personal Information is a legislation generally governing protection of personal information in Japan. This Act provides a comprehensive set of personal information protection, which contains provisions imposing obligations on certain business operators which utilize or maintain databases containing personal information. Pursuant to this Act, such business operators are required to (i) specify and notify the purpose for which personal information will be used prior to handling the information, (ii) save for cases expressly permitted under the act, refrain from using such personal information beyond the purpose specified, (iii) save for cases expressly permitted under the act, refrain from disclosing such personal information to a third party without obtaining the prior consent of the person to whom such information relates, and (iv) take necessary and appropriate measures to securely manage and prevent leakage, damage and loss of the personal information.

Under the Act on the Protection of Personal Information, the Personal Information Protection Commission has the authority, upon violation of certain requirements under this Act, to issue a recommendation to the business operator to suspend such violation or take other necessary action to rectify the violation. The Personal Information Protection Commission also has the authority to order the business operator who does not follow such recommendation to take action pursuant to the said recommendation or suspend such violation or take other necessary action to rectify the violation, subject to certain conditions. Non-compliance with such order will subject the ordered business operator to criminal sanctions.