RELEVANT LAWS AND REGULATIONS IN THE PRC

Regulation of Medical Devices

Classification of Medical Devices

Pursuant to the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) (the **Medical Devices Regulation**"), promulgated by the State Council and effective from November 12, 2004, latest amended on December 6, 2024 and came into effect on January 20, 2025, and the Administrative Measures of Registration and Filing of In-vitro Diagnostic Reagents (《體外診斷試劑註冊與備案管理辦法》), promulgated by the SAMR and effective from October 1, 2021, medical devices, including in-vitro diagnostic reagents, are classified into three different categories, Class I, II and III on the basis of their respective degrees of risk. Medical devices of Class I refer to such devices with low level of risk, the safety and effectiveness of which can be ensured through routine administration. Medical devices of Class II refer to such devices with medium level of risk, the safety and effectiveness of which shall be strictly controlled. Medical devices of Class III refer to such devices with high level of risk, the safety and effectiveness of which shall be guaranteed and be subject to strict control through special administrative measures. The term "in-vitro diagnostic reagents" referred to in these measures denotes in-vitro diagnostic reagents regulated as medical devices. This includes reagents, test kits, calibrators, controls, and other products used for the in-vitro examination of human samples in processes such as disease prediction, prevention, diagnosis, treatment monitoring, prognosis observation, and health status assessment. These products may be used individually or in combination with instruments, appliances, equipment, or systems. The Notice of Strengthening the Administration of Products and Technologies Relating to Clinical Gene Sequencing (《關於加強臨床使用基因測序相關產品和技術管理的通知》), jointly promulgated by China Food and Drug Administration ("**CFDA**") and National Health and Family Planning Commission ("**NHFPC**"), and effective from February 9, 2014, further provides that gene sequencing diagnostic products, including gene sequencers and relevant diagnostic reagents and software, shall be regulated as medical devices.

In particular, *in-vitro* diagnostic reagents and test kits intended to be used in conjunction with instruments such as EL-100 and AXP-100 constitute a distinct category of medical devices and share the same overarching regulatory framework for registration and filing requirements under the PRC regulatory framework, but they are governed by more detailed and specific regulations in areas such as classification rules, documentation requirements for registration, and clinical evaluation. Based on their intended use and risk classification, such test kits will be classified as Class III medical devices. Each test kit must undergo clinical evaluation unless covered by the Exemption Catalogue or other applicable waiver conditions, and be registered independently from the instrument with the National Medical Products Administration (NMPA). In addition, the compatibility between the test kit and the instrument must be clearly demonstrated in the registration dossier, including validation data on analytical performance, software integration, and workflow consistency. Where a test kit is co-developed with a specific instrument, the regulatory authorities may require joint testing or bundled submission.

The Medical Device Classification Rules (《醫療器械分類規則》) (The "**2015 Rule**"), promulgated by CFDA on July 14, 2015 and took effect on January 1, 2016, establish explicit and detailed criteria for device categorization, providing enterprises with a standardized classification decision matrix that first segments medical devices into: (1) devices contacting the human body, and (2) devices not contacting the human body; these are then subclassified according to structural characteristics as either non-active medical devices or active medical devices, enabling manufacturers to definitively determine product classification through this matrix and subsequently initiate corresponding registration and filing procedures. However, the NMPA promulgated the Revised Draft for the Medical Device Classification Rules (The "**2025 Draft**") on April 7, 2025, which introduce four critical revisions compared to the 2015 Rule: (1) refined classification criteria incorporating technical characteristics and usage scenarios with a risk quantification scoring matrix; (2) dynamic adjustment mechanisms mandating annual updates to the classification catalogue and establishing a reclassification request pathway for enterprises to challenge disputed categorizations; (3) clarified regulatory responsibilities implementing a three-tiered governance structure where the NMPA oversees macro-level decision-making, the Classification Technical Committee provides expert support, and provincial authorities operate designated advisory portals to expedite enterprise consultations; and (4) enhanced manufacturer accountability requiring proactive classification self-assessment during R&D stages with mandatory justification in registration dossiers. Therefore, if the 2025 Draft takes effect thereafter, our existing and future products will be regulated by the provisions of the 2025 Draft and be classified based on its new classification matrix.

Pursuant to the Guiding Principles for the Classification of Next-Generation Sequencing-Related In Vitro Diagnostic Reagents (《二代基因測序相關體外診斷試劑分類界定指導原則》) (The "**Guiding Principle**"), promulgated by the National Medical Products Administration ("**NMPA**") and took effect on June 9, 2025, (1) nucleic acid extraction kits (e.g., column/bead-based isolators without target-specific components) are classified as Class I due to routine low-risk sample processing functions; (2) library preparation kits (incorporating target-specific oligos for adapter ligation and enrichment) universally qualify as Class III given their critical impact on diagnostic accuracy; and (3) sequencing reagents (platform-specific chemistry like reversible terminators or semiconductor sequencing cocktails, excluding library construction elements) retain Class I status provided they are strictly limited to signal detection and specify compatible NMPA-certified instruments. The Guiding Principle mandates integrated Class III registration for combined library prep and sequencing reagent systems, while permitting modular submissions only with documented technical demarcation and instrument linkage; crucially, it excludes non-NGS technologies and imposes a transition deadline of January 1, 2027 for reclassification or market withdrawal of non-compliant legacy products (particularly misclassified sequencing reagents), aligning with the Administrative Measures of Registration and Filing of In-vitro Diagnostic Reagents.

Registration and Filing of Medical Devices

Pursuant to the Administrative Measures for the Registration and Filing of Medical Devices (《醫療器械註冊與備案管理辦法》) promulgated by the SAMR and took effect on January 20, 2025, and the Administrative Measures of Registration and Filing of In-vitro

Diagnostic Reagents (《體外診斷試劑註冊與備案管理辦法》), promulgated by the SAMR and effective from October 1, 2021, for the filings of Class I medical devices (including in-vitro diagnostic reagents), the filing materials shall be submitted to the drug regulatory authority at the municipal level. In case of any amendments made to matters stated in the filings, such amendments shall be filed with the original filing department. Class II and Class III medical devices (including in-vitro diagnostic reagents) must obtain their respective product registrations before they can be marketed and sold in China. Class II medical devices (including in-vitro diagnostic reagents) shall be examined by the provincial branches of the NMPA and Class III medical devices (including in-vitro diagnostic reagents) shall be examined by the NMPA, and a Medical Device Registration Certificate (醫療器械註冊證) for such medical device (including in-vitro diagnostic reagents) shall be issued upon approval. In case of any substantial changes of the designs, raw materials, production technologies, scopes of application and application methods, among other things, of the registered Class II or Class III medical devices (including in-vitro diagnostic reagents), which may affect the safety and effectiveness of such medical devices (including in-vitro diagnostic reagents), the registrants shall submit the application for change of registration with the original registration departments within 30 days. The Medical Device Registration Certificate is valid for five years and the registrant shall file for renewal with the NMPA at least six months prior to its expiration date.

Special Procedures for Examination and Approval of Innovative Medical Devices

On October 8, 2017, the General Office of the CPC Central Committee (中共中央辦公廳) and the General Office of the State Council (國務院辦公廳) issued the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the "**Opinions**"), which aims to encourage the innovation for medical devices. Pursuant to the Opinions, the priority review and approval will be applicable to innovative medical devices supported by the National Science and Technology Major Projects (國家科技重大專項) and the National Key R&D Program of China (國家重點研發計劃支持項目), and the clinical trials of which having been conducted by the National Clinical Research Center (國家臨床醫學研究中心) and approved by the management department of the National Clinical Research Center

Pursuant to the Special Procedures for Examination and Approval of Innovative Medical Devices (《創新醫療器械特別審查程序》) promulgated by the NMPA on November 2, 2018, which came into effect on December 1, 2018, special procedures shall be applicable to the examination and approval for medical devices in the following circumstances: (1) the applicant legally owns the invention patent of the core technology of the product through its technological innovation activities in the PRC, or legally obtained the invention patent or the right of use thereof through transfer in the PRC, and the interval between the date of application for the special examination and approval of innovative medical devices to the date of authorized publication should not exceed five years; or the patent administration department of the State Council has disclosed the application for the invention patent of the core technology and the Patent Search and Consultation Center of the National Intellectual Property Administration of the PRC (國家知識產權局專利檢索諮詢中心) has issued the patent search report setting out the novelty and innovation of the core technology solution of the product; (2) the applicant has developed the prototype

product and completed the preliminary research under a true and controllable process that generated complete and traceable data; (3) the product has major working mechanism or mechanism of action which is the first of its kind in the PRC, has fundamental improvement in product performance or safety compared with similar products, is of an internationally leading standard in terms of techniques and has significant clinical value. The Center for Medical Device Evaluation of the NMPA (國家藥品監督管理局醫療器械技術審評中心) should give priority to the innovative medical devices in their technical review upon receiving the registration application, after which the NMPA will give priority to the product in their administrative approval.

Clinical Evaluation and Clinical Trials of Medical Devices

According to the Medical Devices Regulation and the Administrative Measures for the Registration and Filing of Medical Devices, clinical evaluation is required for the registration and filing of medical devices. Clinical evaluation of medical devices refers to activities in which clinical data are analyzed and evaluated by adopting scientific and reasonable methods to confirm the safety and effectiveness of medical devices within the scope of application. However, clinical evaluation may be exempted under any of the following circumstances:

- the medical device has clear and definite working mechanisms, finalized designs and mature manufacturing techniques, the marketed medical devices of the same category have been put into clinical application for years with no record of severe adverse event, and their general purposes remain unchanged;

- the safety and effectiveness of such medical devices can be proved through non-clinical evaluation.

Clinical evaluation of medical devices may be carried out through clinical trials or analysis and evaluation of clinical literature materials and clinical data of medical devices of the same kind to prove the safety and effectiveness of medical devices in light of product characteristics, clinical risks, existing clinical data and other circumstances. Pursuant to the Notice on Release of Catalogue of Medical Devices Exempted from Clinical Evaluation (《關於發佈免於臨床評價醫療器械目錄的通告》) (the "**Exemption Catalogue**") issued by the NMPA on July 20, 2023 and came into effect on July 20, 2023, for medical devices that are not included in the Exemption Catalogue, clinical evaluations shall be conducted before the registration or filing.

Clinical trials shall be conducted in accordance with the Good Clinical Practice for Medical Device Trials (《醫療器械臨床試驗質量管理規範》) (the "**Good Clinical Practice**"), which was issued by the NMPA and the National Health Commission ("**NHC**") jointly on March 24, 2022 and came into effect on May 1, 2022. The Good Clinical Practice set forth the necessary procedures of clinical trials for medical devices, including, among others, the protocol design, conduct, monitoring, verification, inspection, and data collection, recording, analysis and conclusion and reporting procedure of a clinical trial. Prior to commencement of a clinical trial, the applicant must complete the pre-clinical research of the medical device, including product performance verification and confirmation, product inspection report based on the technical requirements, risk-benefit analysis, the

results of which should support the clinical trial. Prior to the commencement of a clinical trial, approval by the ethics committees of the relevant clinical trial organization should be obtained and the applicant, the clinical trial organization and the principal investigators must enter into agreements in writing to arrange their rights and obligations during the trial.

Operation Permit and GSP for Medical Devices

Pursuant to the Medical Devices Regulation and the Administrative Measures for Operation of Medical Devices (《醫療器械經營監督管理辦法》) (the "**Medical Devices Operation Measures**"), promulgated by CFDA, and latest amended on March 10, 2022 and effective from May 1, 2022, an entity engaging in the operation of medical devices of Class I is not required to obtain approval or filing for record with the NMPA, or its local counterparts; an entity engaging in the operation of medical devices of Class II shall file for record with the NMPA at municipal level where such entity is located; an entity engaging in the operation of medical devices of Class III shall apply for an operation permit from the NMPA at municipal level. The operation permit of medical devices is valid for five years and the holder of such permit shall apply for extension within 30 to 90 working days prior to its expiration. According to the Medical Devices Regulation, any entity shall not sell or use medical devices which are not properly registered or filed with the NMPA or its local counterparts. In addition, according to the Medical Devices Operation Measures, no additional operation permit or filing is required for any registered holder or record holder of medical devices or manufacturer of medical devices if it sells the medical devices at the place where it is domiciled or where the medical devices are manufactured.

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 July 1, 2024, an entity engaging in the procurement, acceptance, preservation, sales, transportation and after-sales of medical devices shall take effective quality control measures so as to ensure the quality and safety of products in the process of business operations.

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》) (the "**Measures on Medical Devices Production**"), 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 drug regulatory authority at the municipal level 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 at least six months 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.

Importation and Exportation of Medical Devices

Pursuant to the Tariff Law of the PRC (《中華人民共和國關稅法》) promulgated by the Standing Committee of the National People's Congress (the "**SCNPC**") on April 26, 2024 and came into effect on December 1, 2024, tariffs on goods permitted for import and export and articles entering the country shall be levied by the Customs. The relevant authorities have the authority to adjust the imposed tariff rates in accordance with the provisions of the Tariff Law and relevant laws and regulations.

According to the Administrative Provisions on the Filing 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 ("**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 March 1, 2024, and effective from May 1, 2024, regulates entities engaging in collection, preservation, utilization and outbound provision of human genetic resources. Human genetic resources 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,

- 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;

- 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;

- 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.

Our Group's current overseas operations only involve the sharing of R&D progress, product specifications, and performance study reports with overseas entities, solely for the purpose of synchronizing R&D initiatives and providing technical support. For clarity, these activities do not involve any cross-border transfer of any personal information related to trial subjects. As advised by our PRC Legal Advisor, our Group is in compliance with relevant laws and regulations regarding human genetic resources in all material respects.

Regulation of 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 and effective from November 12, 2004, latest amended on December 6, 2024 and came into effect on January 20, 2025, 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 bio-safety 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.

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 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, wastewater, 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.

Pursuant to the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》) promulgated by SCNPC on October 28, 2002, effective on September 1, 2003 and latest amended on December 29, 2018, the PRC government implements administration by classification on the environmental impact of construction projects according to the level of impact on the environment. The construction unit shall prepare an environmental impact report or an environmental impact form or complete an environmental impact registration form (the "**Environmental Impact Assessment Documents**") for reporting and filing purposes. If the Environmental Impact Assessment Documents of a construction project have not been reviewed by the approving authority in accordance with the law or have not been granted approval after the review, the construction unit is prohibited from commencing construction works.

Pursuant to the Administrative Regulations on Environmental Protection in Construction Projects (《建設項目環境保護管理條例》) promulgated by the State Council on November 29, 1998, amended and effective on October 1, 2017 and the Interim Measures on Administration of Environmental Protection for Acceptance Examination Upon Completed Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) promulgated by the former Ministry of Environmental Protection on November 20, 2017, where a construction project needs complementary environmental protection facilities, those facilities must be designed, constructed and become operational at the same time as the main parts of the project. The project owner shall, after the completion of the construction project for which the environmental impact report or the environmental impact statement is prepared, according to standards and procedures prescribed by the environmental protection administrative department of the State Council, conduct acceptance check of the constructed complementary environmental protection facilities. The construction project may not be put into production or use until the constructed supporting environmental protection facilities have passed the acceptance check. The facilities that have not undergone or fail to pass the acceptance check shall not be put into production or use.

Pursuant to Law of the PRC on Prevention and Control of Environmental Pollution Caused by Solid Wastes (《中華人民共和國固體廢物污染環境防治法》) which was promulgated on October 30, 1995 and latest amended on April 29, 2020 and came into effect on September 1, 2020, the construction of projects which discharge solid waste and the construction of projects for storage, use and treatment of solid waste shall be carried out upon the appraisal regarding their effects on the environment and comply with the relevant state regulations concerning the management of environmental protection in respect of construction projects. The necessary supporting facilities for the prevention and control of environmental pollution caused by solid wastes as specified in the environmental impact assessment documents of the construction project shall be designed, constructed and put into operation simultaneously with the major construction works of the construction project.

According to the Regulations on the Management of Medical Waste (《醫療廢物管理條例》), which were promulgated by the State Council on June 16, 2003 and amended on January 8, 2011, and the Implementation Measures of the Management of Medical Waste (《醫療衛生機構醫療廢物管理辦法》), which were promulgated by the Ministry of Health ("**MOH**") on October 15, 2003 and came into effect on the same day, medical institution shall timely deliver medical wastes to an entity for centralized disposal of medical wastes and licensed by a relevant environment protection administrative department for dispose. Sewage generated by any medical institution and excretion of its patients or suspected patients of infectious diseases shall be sterilized in strict accordance with the relevant provisions, and shall not be discharged into sewage disposal systems until the relevant standards are met.

Regulations of Fire Prevention

The Fire Prevention Law of the PRC (《中華人民共和國消防法》) (the "**Fire Prevention Law**"), which was promulgated by the SCNPC on April 29, 1998 and most recently amended on April 29, 2021, and the Interim Provisions on the Administration of Fire

Protection Design Review and Acceptance of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》), which was promulgated by the Ministry of Housing and Urban-Rural Development on August 21, 2023 and came into effect on October 30, 2023, stipulate that all construction projects must be designed to prevent fires under national fire protection technical standards, the construction unit must submit the fire prevention design documents for approval or filing purposes. Upon completion of such construction project, the construction unit must apply for fire protection approval or conduct fire protection filing for fire protection design and completion approval, as applicable.

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 ("**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 on December 29, 2023 and came into effect on July 1, 2024. 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)》). And the Special Administrative Measures (Negative List) (2024 version) for Foreign Investment Access (《外商投資准入特別管理措施(負面清單)(2024年版)》) has been promulgated on September 6, 2024, and came into effect on November 1, 2024. 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 CSRC promulgated 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.

Regulations of Intellectual Property Rights

Patent

The Patent Law of the PRC (《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》) which became effective in 1983 and was most recently amended on November 1, 2019 and related rules and regulations. Trademarks are registered with the Trademark Office of China National Intellectual Property Administration. Where registration is sought for a trademark that is identical or similar to another trademark which has already been registered or given preliminary examination 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."

Design of Integrated Circuit Layouts

On April 2, 2001 the State Council promulgated the Regulations on the Protection of Integrated Circuit Layout Designs (《集成電路布圖設計保護條例》 (the "**Regulations on the Protection**"). According to the Regulations on the Protection, the owner of an integrated circuit layout design has exclusive rights to the design, so long as they comply with the provisions of the Regulations on the Protection, which protects the proprietary rights of integrated circuit layout designs, encourage innovation in integrated circuit technology, and promotes the development of science and technology. The exclusive rights to the layout design arise upon registration with the intellectual property administration department of the State Council, and layout designs that have not been registered are not protected by the Regulations on the Protection. The protection period for the exclusive rights of a layout design is ten years, calculated from the date of the design registration application or the first date of commercial use anywhere in the world, whichever is earlier. However, a layout-design is no longer protected under these regulations 15 years after its creation, regardless of registration or commercial use.

Regulations of Tax

Enterprise Income Tax

The PRC enterprise income tax, or EIT, is calculated based on the taxable income determined under the applicable Enterprise Income Tax 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 MOF and the 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 ("**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.

Regulations of Labor Protection

Labor Protection

Pursuant to the Labor Law of the PRC (《中華人民共和國勞動法》), promulgated by SCNPC on July 5, 1994 and amended and effective on December 29, 2018 and the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》) amended by SCNPC and effective on July 1, 2013 and the Implementation Rules of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》) promulgated by the State Council and effective on September 18, 2008, employers shall establish and improve labor rules and regulations according to the laws and regulations and shall strictly comply with the national standards, provide trainings to their employees, protect their labor rights and perform its labor obligations. Employers shall execute written labor contracts with full-time employees. Labor contracts shall be categorized into labor contracts with fixed term, labor contracts without fixed term and labor contracts to be expired upon completion of certain tasks. All employers must comply with local minimum wage standards.

Social Insurance and Housing Provident Fund

According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) promulgated by SCNPC on October 28, 2010, amended and came into effect on December 29, 2018 and the Regulations on the Administration of Housing Provident Funds (《住房公積金管理條例》) amended by the State Council and came into effect on March 24, 2019 and the Provisional Regulations on Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) amended by the State Council and came into effect on March 24, 2019, employers in the PRC shall pay premium for basic pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, basic medical insurance and housing provident funds for its employees at the applicable rates based on the amounts stipulated by the laws.

According to the Interpretation II of the Supreme People's Court of Issues Concerning the Application of Law in the Trial of Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》) enacted by the Supreme People's Court on

July 31, 2025 and implemented on September 1, 2025. Where an employer and an employee enter into a written or verbal agreement that social insurance premiums need not be paid by both parties, the people's court shall not support this arrangement and shall determine that the agreement is invalid. Accordingly, when an employer fails to pay social insurance premiums even as previously agreed between the employer and an employee, upon the employee's termination of the employment contract, the employer shall make up the unpaid social insurance premiums and pay economic compensation to the employee in accordance with the provisions of the Labor Law.

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 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.

Regulation of Information Security and Data Protection

According to the PRC Civil Code, the personal information of an individual shall be protected by the law. Any organization or individual that needs to obtain personal information of others shall obtain such information legally and ensure the safety of such information, and shall not illegally collect, use, process or transmit personal information

of others, or illegally purchase or sell, provide or publish personal information of others. In addition, the handling of personal information shall follow the principles of lawfulness, appropriateness and necessity.

On August 20, 2021, SCNPC promulgated the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), or the Personal Information Protection Law, which became effective on November 1, 2021. The Personal Information Protection Law requires, among others, that the handling of personal information should have a clear and reasonable purpose and should be directly related to the handling purpose, adopt a method that has the least impact on personal rights and interests. The collection of personal information shall be limited to the minimum scope necessary to achieve the handling purpose. The personal information handler shall not excessively collect personal information.

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》), or the Data Security Law, which came into effect on September 1, 2021. According to the Data Security Law, the central leading body of state security is responsible for the decision-making, deliberation and coordination of the national data security work, research and formulate and guide the implementation of the national data security strategy and relevant major guidelines and policies, coordinate major matters and important work in respect of national data security, and establish a coordination mechanism for national data security work. Competent authorities of industry, telecommunications, transport, finance, natural resources, health, education, science and technology, etc. assume the responsibilities of data security regulation for their respective industries or fields. Public security organs and national security organs, etc. assume the responsibilities of data security regulation within the scope of their respective functions and duties. The cyberspace administration of the State is responsible for the overall planning and coordination of cyber data security and relevant regulatory work.

On November 7, 2016, the SCNPC promulgated the Cyber Security Law of the PRC (《中華人民共和國網絡安全法》), which became effective on June 1, 2017, according to which, network operators shall fulfill their obligations to safeguard 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 according to 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, and maintain the integrity, confidentiality and usability of network data. The network operator shall not collect personal information irrelevant to the services it provides or collect or use the personal information in violation of the provisions of laws or agreements concluded with its users, and the operators of critical information infrastructure shall store within the PRC all the personal information and important data collected and produced within the PRC. The purchase of network products and services by critical information infrastructure operators that may affect national security shall be subject to national cyber security review organized by the cyberspace administration of the State in conjunction with relevant departments of The State Council.

On July 30, 2021, the State Council promulgated the Regulations on the Protection of the Security of Critical Information Infrastructure (《關鍵信息基礎設施安全保護條例》), which became effective on September 1, 2021. According to the Regulations on the Protection of the Security of Critical Information Infrastructure, a "critical information infrastructure" refers to an important network facility and information system in important industries such as public communications and information services, energy, transportation, water resources, finance, public services, e-government, national defense science and technology industries, as well as other important network facilities and information systems that may seriously endanger national security, the national economy, the people's livelihood, or the public interests in the event of damage, loss of function, or data leakage. The management authorities of the aforementioned important industries will be responsible for (i) organizing the identification of critical information infrastructures in their respective industries in accordance with certain identification rules, and (ii) promptly notifying the identified operators and the Ministry of Public Security of the identification results. These regulations require that the relevant operator shall submit a report to the competent PRC administrative authority in accordance with relevant provisions upon the occurrence of any major cybersecurity incident or the discovery of any major cybersecurity threat to the critical information infrastructures, and the operators of critical information infrastructures shall purchase the safe and trusted network products and services in the first place. If the purchase of network products and services may affect national security, such operators shall pass the cybersecurity review accordingly.

On December 28, 2021, the Cyberspace Administration of China (the "**CAC**"), jointly with 12 other administrative authorities, promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》, the "**MCR**"), which became effective on February 15, 2022. According to the MCR, critical information infrastructure operators that purchase network products and services, and network platform operators engaging in data handling activities that affect or may affect national security are subject to cybersecurity review under the MCR. In addition, network platform operators with personal information of over one million users shall be subject to cybersecurity review before listing abroad (國外上市). The competent administrative authorities may also initiate a cybersecurity review against the operators if the authorities believe that the network product or service or data handling activities of such operators affect or may affect national security.

The Regulations on Promoting and Regulating the Cross-border Flow of Data (《促進和規範數據跨境流動規定》) promulgated by the CAC and effective on March 22, 2024 stipulates that if a data handler provides data overseas and meets one of the following conditions, it shall apply for cross-border data transfer security assessment to the cyberspace administration of the State through the local provincial cyberspace administration: (1) critical information infrastructure operators provide personal information or important data overseas; (2) data handlers other than critical information infrastructure operators provide important data overseas, or have provided overseas personal information of more than 1 million people (excluding sensitive personal information) or sensitive personal information of more than 10,000 people since January 1 of that year.

On September 24, 2024, the Regulations on Network Data Security Management (《網絡數據安全管理條例》) was issued by the State Council, which took effect on January 1, 2025. According to the Regulations on Network Data Security Management, network data handlers shall, in accordance with the provisions of laws and administrative regulations and the mandatory requirements of national standards, and on the basis of classified protection of cybersecurity, strengthen the protection of network data security, establish and optimize the system of network data security management, take technical measures to protect network data, and prevent illegal and criminal activities aiming at and using network data. The Regulations on Network Data Security Management also provide provisions for data handling activities carried out through networks, including but not limited to the formulating of rules for handling personal information, the general requirements on handling personal information and accepting individual requests regarding personal information. The network data handler shall specify the person in charge of network data security and the management body for network data security, which shall perform the responsibilities of network data security protection. If the security of data may be affected due to the merger, demerger, dissolution or bankruptcy of the network data handler, the handler shall take measures to ensure the security of network data, and report to the competent authority.

Our Group's current overseas operations only involve the sharing of R&D progress, product specifications, and performance study reports with overseas entities, solely for the purpose of synchronizing R&D initiatives and providing technical support. For clarity, these activities do not involve any cross-border transfer of any personal information related to trial subjects.

We are fully committed to complying with all applicable laws and regulations governing cross-border data transfers, cybersecurity, and data protection in our future operations. To this end, our Group has implemented a comprehensive suite of technical and administrative safeguards to ensure data security throughout its lifecycle. These measures include, but are not limited to, encrypted storage, access controls, backup and recovery protocols, and malware detection systems. These safeguards are further reinforced by our internal Data Security Management Policy, which establishes a robust governance framework designed to proactively detect, alert, and mitigate potential breaches across our value chain. As advised by our PRC Legal Advisor, our Group is in compliance with relevant laws and regulations regarding cybersecurity measures, including cross-border data transfer in all material respects.

Regulation of Artificial Intelligence

The Administrative Provisions on Deep Synthesis in Internet-based Information Services (《互聯網信息服務深度合成管理規定》) which was promulgated by the CAC on November 25, 2022 and took effective since January 10, 2023, impose certain compliance obligations upon service providers using deep synthesis technology to provide Internet-based information services, including but not limited to establishing a database to identify illegal or adverse information, adding tags on information generated from using deep synthesis technologies, authenticating users' real identities before allowing them to use deep synthesis information publishing services, etc.

On July 13, 2023, the CAC and six other ministries jointly published the Interim Administrative Measures on Generative AI Services (《生成式人工智能服務管理暫行辦法》)

("**Interim Measures on GAI**"), which came into effect on August 15, 2023. The Interim Measures on GAI apply to the provision of generating content such as text, images, audio and video to the public within the territory of China by utilizing generative AI technology ("**GAI Service**"). On the other hand, Interim Measures on GAI will not apply to industrial organizations, enterprises, educational and scientific research institutions, public cultural institutions, and relevant professional institutions that develop and apply generative AI technologies but do not provide GAI Services to the public within China.

RELEVANT LAWS AND REGULATIONS IN THE UNITED STATES

United States Regulation of Medical Devices

Medical devices are subject to extensive and ongoing regulation by the FDA, the Centers for Medicare and Medicaid Services ("**CMS**"), the Department of Health and Human Services Office of Inspector General ("**OIG**") and regulatory bodies in the United States. Regulations govern virtually every critical aspect of a medical device company's business operations, including research activities, product development and testing, manufacturing and production, contracting, reimbursement, product messaging, medical communications, sales, marketing and advertising. In the United States, the Federal Food, Drug and Cosmetic Act ("**FDCA**") and the implementing regulations of the FDA govern product design and development, preclinical and clinical testing, premarket clearance or approval, product manufacturing, product labeling, product storage, advertising and promotion, product sales and distribution, import, export and post market clinical surveillance.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, grant of a *de novo* classification request, or approval of a premarket approval ("**PMA**") application. The FDA classifies medical devices into one of three classes. Devices deemed to pose low to moderate risk are designated as either Class I or II. Class I devices are subject to general controls such as establishment registration and device listing, labeling, adherence to current good manufacturing practices outlined in FDA's Quality System Regulation ("**QSR**"), maintenance and investigation of product complaint records, and adverse event reporting, but are usually exempt from premarket notification requirements. Class II devices are subject to the same general controls and may be subject to special controls such as performance standards, post-market surveillance, particularized labeling requirements and/or clinical testing prior to clearance. Manufacturers of Class II devices, absent an exemption, are required to submit to the FDA a premarket notification prior to commercial distribution. Devices are designated as Class III, which requires approval of a PMA application, if they are deemed by the FDA to pose the greatest risk. These high-risk devices include life sustaining or life supporting devices, certain implantable devices, and other devices that are intended for a use that is of substantial importance in preventing impairment of human health or that present a potential unreasonable risk of illness or injury. The PMA approval process is more comprehensive than the 510(k) clearance process and typically takes several years to complete.

510(k) Clearance Marketing Pathway

A 510(k) notification requires the sponsor to demonstrate that a medical device is substantially equivalent to another marketed device, termed a "predicate device," that is legally marketed in the United States and for which a PMA was not required. A device is substantially equivalent to a predicate device if it has the same intended use and technological characteristics as the predicate, or has the same intended use but different technological characteristics that do not raise new questions of safety and effectiveness, and information submitted to the FDA demonstrates that the device is at least as safe and effective as the predicate device.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If there is no viable predicate device for a new device because, for example, of a new intended use, the device is automatically designated as a Class III device. Unless the *de novo* pathway is available for the new device, the device sponsor must fulfill more rigorous PMA requirements. The PMA process requires that the manufacturer demonstrate that the device is safe and effective for its intended uses, which generally requires the submission of extensive data, including results from pre-clinical studies and human clinical trials. A PMA must also contain a full description of the device and its components, the methods, facilities, and controls used for manufacturing, and proposed labeling. The PMA process is burdensome, and in practice, the FDA's review of a PMA application may take up to several years following initial submission.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, requires a new 510(k) clearance, or depending on the modification, could require the filing of a *de novo* classification request or a PMA application, which would require the submission to the FDA of clinical trial data, among other information. Medical device companies are required to determine, for each modification to their cleared products, whether to submit a new 510(k) notification for the modification, based on the nature of the modification. If the company determines a new 510(k) submission is not required, the decision and justification are documented in a "letter to file." If the FDA disagrees with the company's determination, the FDA can require the company to cease marketing or recall the modified device until 510(k) clearance, grant of a *de novo* classification request or approval of a PMA is obtained.

***De Novo* Classification Process**

A manufacturer can request a risk-based classification determination for a novel device in accordance with the "*de novo*" process. Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. Low-to-moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device may utilize the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring

the submission and approval of a PMA application. Manufacturers may request *de novo* classification directly without first submitting a 510(k) pre-market notification to the FDA and receiving a not-substantially-equivalent determination. *De novo* classification requests, like PMA applications and 510(k) notifications, are subject to the payment of user fees.

FDA is required to reach a decision within 120 days following receipt of the *de novo* request, although the process may take significantly longer. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. If the FDA grants the *de novo* request, the device may be legally marketed in the United States. However, the FDA may reject the request if the FDA identifies a legally marketed predicate device that would be appropriate for a 510(k) notification, determines that the device is not low-to-moderate risk, or determines that general controls would be inadequate to control the risks and/or special controls cannot be developed. After a device receives *de novo* classification, any modification that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, another *de novo* request or even PMA approval.

Medical Device Clinical Trials

Clinical trials are required for PMA applications and sometimes required to support 510(k) or *de novo* submissions. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption ("**IDE**") regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical trials, but must still comply with abbreviated IDE requirements when conducting such trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or presents a potential for serious risk to a patient in some other way. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

Regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board ("**IRB**") for each clinical site. The IRB is responsible for the initial and continuing review of the clinical study, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, the sponsor, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, such as strategic business decisions or a belief that the risks to study subjects may outweigh the anticipated benefits.