OVERVIEW OF THE MAJOR LAWS, RULES AND REGULATIONS RELATING TO OUR BUSINESS IN THE PRC

This section sets forth a summary of the relevant significant PRC laws and regulations that affect our business and the industry in which we operate.

Regulations and Classification of Medical Devices

Pursuant to the Regulations on the Supervision and Administration of Medical Devices (Revised in 2024)(醫療器械監督管理條例(2024修訂)) (the "**2024 Medical Device Regulations**") recently amended on December 6, 2024 and came into effect on January 20, 2025, the medical products administrations of the State Council shall be responsible for the supervision of medical devices of the PRC. All relevant departments of the State Council shall be responsible for the supervision of medical devices within their respective scope of duties. In order to guarantee the safety of medical devices, local people's governments above the county level should reinforce their leading role in the supervision and administration of medical devices within their respective administration regions, organize and coordinate the supervision and administration of medical devices and contingency plans within their respective administration regions and strengthen the competency of supervision and administration of medical devices. The medical products administrations of local people's governments above the county level are responsible for the supervision and administration of medical devices in their respective administrative regions. Relevant departments of the local people's governments above the county level are responsible for the supervision and administration of medical devices within their respective scope of duties.

In the PRC, medical devices have been classified into three categories for administration based on the degree of risk. Category I medical devices shall refer to those devices with low risks, whose safety and effectiveness can be ensured through routine administration. Category II medical devices shall refer to those devices with moderate risks, which shall be strictly controlled and administered to ensure their safety and effectiveness. Category III medical devices shall refer to those devices with relatively high risks, which shall be strictly controlled and administered through special measures to ensure their safety and effectiveness.

On September 7, 2022, the General Department of the NMPA published the Guiding Opinions on Strengthening the Graded Supervision of Medical Device Production and Operation (關于加强醫療器械生產經營分級監管工作的指導意見) (the "**Guiding Opinions**") which came into effect on January 1, 2023. The Guiding Opinions require that the supervision of enterprises engaged in the production and operation of medical devices should be graded. The medical products administration divided the medical device enterprises into four regulatory levels according to the risk, and implemented the corresponding regulatory measures for enterprises at different regulatory levels. The enterprises kept good credit status for a long time can be adjusted downward regulatory level. For registers who commissioned the production of medical devices cross regional, or only for the entrusted production of the entrusted production enterprises, as well as remote warehouse management enterprises, should be appropriate to increase the level of supervision.

Registration and Filings of Medical Device Products

Pursuant to the Measures for the Administration of Registration and Record-filing of Medical Devices (醫療器械注冊與備案管理辦法) promulgated by the State Administration for Market Regulation ("**SAMR**") on August 26, 2021 and came into effect on October 1, 2021, Category II and Category III medical devices are subject to product registration management. Category I medical devices are subject to product filing management. Record-filing parties of domestic Category I medical devices shall submit record-filing materials to the drug regulatory authorities at the level of city divided into districts. Domestic Category II medical devices shall be examined by the drug regulatory authorities of provinces, autonomous region, and centrally-administered municipalities, which shall issue the Medical Device Registration Certificate upon

approval after examination. Domestic Category III medical devices shall be examined by the NMPA, which shall issue the Medical Device Registration Certificate upon approval after examination. The registration certificate for a medical device is valid for five years, and the registrant shall apply to the original registration departments for renewal at least six months prior to its expiration date.

According to the Measures for the Administration of Registration and Record-filing of Medical Devices, the clinical evaluation shall be conducted for the registration or record-filing of medical devices, but except for circumstances specified under any of the following: (I) the medical device has clear working mechanism, finalized design and mature production process, and the marketed medical devices of the same kind have been used in clinical application for years with no record of serious adverse event, and does not change the general purpose of the medical device; or (II) any other circumstance where the safety and effectiveness of the medical device can be proved through non-clinical evaluation. The NMPA issued Announcement on Issuing Catalog of Medical Devices Exempted from Clinical Evaluation (the "Catalog")(關於發布免於進行臨床評價醫療器械目錄的通告) on September 16, 2021, which came into effect on October 1, 2021. The Catalog was last amended on May 12, 2025, and effective on the same date.

Pursuant to the Technical Guidance Principles for Decision on Whether to Conduct Medical Device Clinical Trials (決策是否開展醫療器械臨床試驗技術指導原則), clinical trials are in principle required for Category III medical devices with high risks in clinical use, as well as medical devices that have significant differences in scope of application, technical characteristics, and/or biological properties compared with medical devices that have been approved for marketing in the PRC.

In order to strengthen the verification administration of the quality management system for medical device registration and to ensure the verification quality, the NMPA published the Guidelines for Inspection of Quality Management System for Medical Device Registration (醫療器械注冊質量管理體系核查指南) on September 29, 2022 to explicit the standards and requirements of Category II and Category III medical device quality management.

Good Clinical Practice for Clinical Trial

Clinical trials on medical devices shall be conducted by organizations that possess relevant qualifications as required by the Good Clinical Practice for Medical Devices Trials. According to the Good Clinical Practice for Medical Devices Trials (醫療器械臨床試驗質量管理規範), which became effective on June 1, 2016, the Good Clinical Practice includes full procedures of clinical trial of 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.

On March 24, 2022, the NMPA and the National Health Commission of the PRC jointly issued the new Good Clinical Practice for Medical Devices Trials (醫療器械臨床試驗質量管理規範) (the "**2022 Good Clinical Practice**") which became effective on May 1, 2022, as an amendment to the expired Good Clinical Practice for Medical Devices Trials (the "**2016 Good Clinical Practice**"). The 2022 Good Clinical Practice includes full procedures of clinical trial of 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.

Medical Device Registrant System

Pursuant to the Notice of the NMPA on Expanding the Pilot of the Medical Device Registrant System (國家藥監局關於擴大醫療器械注冊人制度試點工作的通知) promulgated by the NMPA and coming into force on August 1, 2019, in order to fully implement the medical device registrant system, the NMPA decided to further expand the pilot of the medical device registrant system on the basis of the pilot work of the medical device registrant system in the free trade zones of Shanghai, Guangdong and Tianjin. The contents and

objectives of the pilot program mainly include: exploring the establishment of the management system for entrusted production of medical devices, optimizing resource allocation and clarifying the liabilities of the parties concerned. An applicant for medical device registration who applies for and obtains a medical device registration certificate shall become a medical device registrant. The applicant may entrust an enterprise with corresponding production capacity to produce samples, and the registrant may entrust the production of the certified products to one or more enterprises with production capacity.

The Regulations on the Supervision and Administration of Medical Devices has further clarified the definition and obligations of the medical device registrant, and clarified the rights and obligations of the registrant and other market entities such as the entrusted production enterprises, operators of e-commerce platforms and users, indicating the full implementation of the medical device registrant system in China.

Innovative Medical Device Special Review and Approval Procedure

According to the Opinions of the State Council on Reforming the Evaluation, Review and Approval System for Drugs and Medical Devices (國務院關于改革藥品醫療器械審評審批制度的意見) issued by the State Council and coming into effect on August 9, 2015, the government encouraged the research, development and innovation of medical devices, and included the application for registration of innovative medical devices with the invention patent of core technology and significant clinical value into the scope of special review and approval, which shall enjoy the priority in handling.

In October 8, 2017, the General Office of the CPC Central Committee and the General Office of the State Council issued and implemented the Opinions on Deepening the Reforming of the Evaluation and Approval System and Encouraging the Innovation of Drugs and Medical Devices (關于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 of medical devices. According to the Opinions, priority in review and approval shall be given to innovative medical devices supported by major national science and technology projects and national key research and development programs, and clinical trials conducted by the National Clinical Research Center and approved by the administration authorities of the center.

Pursuant to the Innovative Medical Device Special Review and Approval Procedure (創新醫療器械特別審查程序) (the "**Green Path**") promulgated by the NMPA on November 2, 2018 and coming into force on December 1, 2018, the government opened the Green Path for innovative medical devices. The special review procedures shall apply to the examination of medical devices in the following circumstances: (i) the applicant legally owns the invention patent right of the core technology of the product in China through the technological innovation activities led by the applicant, or legally obtains the invention patent right or the right to use the same in China through an assignment in accordance with law, and the time between the application for the special review of innovative medical devices and the publication date of the patent authorization shall not exceed 5 years. Alternatively, the patent administrative 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 State Intellectual Property Office has issued a search report stating the novelty and creativity of the core technology solution of the product; (ii) the applicant has completed the preliminary research of the product and owns the product prototype, the research process is true and under control, and the research data is complete and traceable; (iii) the main working principle or mechanism of action of the product is the first of its kind in China. The product performance or safety has fundamental improvement compared with similar products, its technology is at the international leading level, and the clinical application value is significant. The Center for Medical Device Evaluation of the NMPA shall give priority to the technical review of innovative medical devices whose application for registration has been accepted. When the technical review is completed, the NMPA shall give priority to the administrative review and approval of the same. Prior to the acceptance of an application for the admission to the Green Path and during the following technical review process, the Center for Medical Device Evaluation of the NMPA shall assign designated personnel to provide timely guidance upon the applicant's request and

discuss relevant technical issues with the applicant. An applicant may also apply for discussions with the Center for Medical Device Evaluation of the NMPA for issues such as the design of clinical trials through filing discussion request forms. The Center for Medical Device Evaluation of the NMPA shall promptly review such discussion request forms and any supplemental materials submitted by the applicant. If the Center for Medical Device Evaluation of the NMPA agrees to have further discussions with the applicant, it shall clearly inform the applicant of the issues to be discussed, and liaise with the applicant to determine the form, time, place and participants of such discussions. The discussion record confirmed and signed by both parties will constitute a reference for further registrational review of such product candidate.

Medical Device Production Permit

According to the 2024 Medical Device Regulations, in addition to the required medical device registration certificates, a producer of medical devices shall file a record with or obtain a production license from medical products administrations of local people's governments at the corresponding level before commencing production. The medical device production license is valid for five years. Where the period of validity for the license needs to be extended upon expiry, the procedures for such extension shall be handled in accordance with the provisions of relevant laws on administrative licensing.

The Administrative Measures for the Supervision of the Production of Medical Devices (醫療器械生產監督管理辦法), was amended by the former CFDA and came into effect on November 17, 2017. In order to further strengthen the supervision and management of medical devices production, standardize medical device production activities and ensure the safety and effectiveness of medical devices, the Administrative Measures for the Supervision of the Production of Medical Devices (醫療器械生產監督管理辦法) (the "**2022 Supervisory and Administrative Measures for Production**") was last amended by the SAMR on March 10, 2022 and came into effect on May 1, 2022 in accordance with the 2024 Medical Regulations.

The enterprises engaging in the production of Category I medical devices shall make filings for such Category I medical devices with the local branches at the district city level of the NMPA and submit proofing materials of qualification to engage in the production of such medical devices.

The enterprises engaging in the production of Category II and Category III medical devices shall apply for a Manufacture License for Medical Devices (醫療器械生產許可證) to the provincial branches of the NMPA, and submit proofing materials of qualification to engage in the production of such medical devices and registration certificates for such medical devices produced.

Production and Quality Management of Medical Devices

Pursuant to the Good Manufacturing Practice for Medical Devices (醫療器械生產質量管理規範) promulgated by the former CFDA on December 29, 2014 and came into effect on March 1, 2015 (the "**GMP** "), an enterprise engaging in the production of medical devices shall establish and effectively maintain a quality control system in accordance with the requirements of the GMP. The enterprise engaging in the production of medical devices shall, in accordance with the requirements of the GMP and taking into account the characteristics of the products, establish a sound quality management system suitable for the medical devices produced and ensure its effective operation. The enterprise shall establish procurement control procedures to ensure that the purchased goods comply with the relevant requirements, which shall not be lower than the relevant requirements of laws and regulations and national mandatory standards. The enterprise shall establish a supplier review system and conduct reviews and evaluations on the suppliers. The enterprise shall record the procurement, production and inspection of raw materials. Such records shall be true, accurate, complete and traceable. The enterprise shall implement risk management throughout the whole process of design and development, production, sales and after-sales services. The measures taken shall be in line with the risks of the products.

Administration of Medical Device Operation

The Measures for the Supervision and Administration of Medical Devices Operation (醫療器械經營監督管理辦法) were promulgated on July 30, 2014, effective on October 1, 2014 and amended on November 17, 2017.

In order to strengthen the supervision and management of medical devices operation, regulate medical device operation activities, and ensure the safety and effectiveness of medical devices, the State Administration for Market Regulation has formulated the Measures for the Supervision and Administration of Medical Devices Operation (醫療器械經營監督管理辦法) (the "**2022 Supervisory and Administrative Measures for Operations**") in accordance with the 2024 Device Medical Regulations, which were promulgated on March 10, 2022 and came into effect on May 1, 2022. According to the 2022 Supervisory and Administrative Measures for Operations, 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 a quality control department or personnel suitable for the medical devices it operates. An enterprise engaged in the operation of Category II medical devices shall file with the competent municipal level medical products administration and provide proofing materials for satisfying the relevant conditions of engaging in the operation of Category II medical devices, while an enterprise engaged in the operation of Category III medical devices shall apply for a Business Operation License of Medical Devices (醫療器械經營許可證) to the competent municipal level medical products administration and provide proofing materials for satisfying the relevant conditions of engaging in the operation of such medical devices. The competent medical products administration which receives an 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 any medical device that has not been legally registered or filed for record, without a qualification certificate, outdated, invalid or disqualified.

Two-invoice System

According to the Notice on Opinions on the Implementation of the "Two-invoice System" in Drug Procurement by Public Medical Institutions (for Trial Implementation) (關於在公立醫療機構藥品採購中推行「兩票制」的實施意見(試行)的通知) (the "**Notice**"), jointly issued by the Medical Reform Office of the State Council, NHC, CFDA, NDRC, the Ministry of Industry and Information Technology, the Ministry of Commerce, the State Taxation Administration and the National Administration of Traditional Chinese Medicine on December 26, 2016, the "Two-invoice System" refers to the system that requires one invoice to be issued from pharmaceutical manufacturers to pharmaceutical distributors and the other invoice to be issued from pharmaceutical distributors to medical institutions. The Notice requires the gradual implementation of the "Two-invoice System" in drug procurement by public medical institutions, encourages other medical institutions to implement the "Two-invoice System," and strives to promote the "Two-invoice System" in full swing nationwide by 2018.

According to the Notice on Consolidating the Achievements of Canceling Drug Markups and Deepening Comprehensive Reforms in Public Hospitals (關于鞏固破除以藥補醫成果持續深化公立醫院綜合改革的通知) promulgated by the former National Health and Family Planning Commission, the Ministry of Finance, the NDRC and other departments on March 5, 2018, high value medical consumables shall be subject to classified and centralized purchase, and the "Two Invoice System" in relation to high-value medical consumables shall be gradually implemented.

On July 19, 2019, the General Office of the State Council issued the Notice on Printing and Distributing the Reform Plan for the Management of High-value Medical Consumables (國務院辦公廳關於印發治理高值醫用耗材改革方案的通知) (the "**Circular on High-Value Medical Consumables**"), which

encourages local governments to adopt the "Two-invoice System" on a case-by-case basis in order to reduce the circulation of high-value medical consumables and promote the transparency of purchase and sales. Pursuant to the Reply of the National Healthcare Security Administration (the "**NHSA**") to Recommendation No. 1209 of the Second Session of the 13th National People's Congress (國家醫療保障局對十三届全國人大二次會議第1209號建議的答覆) issued by NHSA on July 23, 2019, "Two Invoice System" for high-value consumables needs to be further discussed given the huge differences between high-value consumables and pharmaceuticals and the complexity of their clinical use and after-sales service.

Procurement Management of Medical Devices

Pursuant to the Notice on Further Strengthening the Administration of Centralized Procurement of Medical Devices (關于進一步加强醫療器械集中采購管理的通知) issued by the Ministry of Health on June 21, 2007, centralized procurement of medical devices shall be subject to geographic administration. It shall be led by the government and conducted at three levels, namely, the central level, the provincial level and the municipal level, and mainly at the provincial level. All non-profit medical institutions founded by the governments at various levels, industries and state-owned enterprises shall participate in centralized procurement of medical devices. No medical institution may evade centralized procurement in any way. The medical devices as mentioned above refers to medical equipment and medical consumables.

According to the Opinions of the State Council Leading Group for Deepening the Reform of Medical and Pharmaceutical Health System on Further Popularizing and Deepening the Reform of Medical and Pharmaceutical Health System (國務院關于印發「十三五」深化醫藥衛生體制改革規劃的通知)issued in November 2016, sunshine procurement of medical consumables, and centralized procurement of high value medical consumables, diagnostic reagents and large-scale medical equipment should be implemented.

According to the Notice of the State Council on Printing and Distributing the 13th Five-Year Plan for Deepening the Reform of Medical and Health System (國務院關于印發「十三五」深化醫藥衛生體制改革規劃的通知)issued in December 2016, centralized procurement of high-value medical consumables, diagnostic reagents and large-scale medical equipment should be carried out.

Procurement Management Policies for High-Value Medical Consumables

Pursuant to the Notice of Opinions on Reform of Pricing System of Pharmaceuticals and Medical Services(關于印發改革藥品和醫療服務價格形成機制的意見的通知) issued on November 9, 2009, the management on the pricing of medical devices will be strengthened. For high-value medical devices, especially for implantable and interventional medical devices, reasonable price formation can be guided by measures such as limiting the price difference rate in circulation links and publishing market price information.

According to the Administrative Norms on Centralized Procurement of High-Value Medical Consumables (Trial) (高值醫用耗材集中採購工作規範(試行)) issued on December 17, 2012, the online centralized procurement (the "**Centralized Procurement**") works of high-value medical consumables will be led by government and conducted by each province (regionally and municipally). Medical institutions and medical consumables production and operation enterprises shall procure through the Centralized Procurement platform established by each province (region and municipality). The administrative authorities in charge of the Centralized Procurement in each province (region and municipality) shall be responsible for formulating and preparing a Centralized Procurement list of high-value medical consumables within its administrative region. High-value medical consumables listed on the Centralized Procurement list may be procured by way of public tenders and invitational tenders or by other means stipulated by laws and regulations of the State.

On July 19, 2019, the General Office of the State Council issued the Circular on High-Value Medical Consumables and officially proposed to strengthen the standardized administration of high-value medical

consumables. It was required to explore the classification of high-value medical consumables in accordance with the principles of volume-based procurement, volume-price linkage, and promotion of market competition, and conduct centralized procurement.

The Guiding Opinions on National Organization of Centralized Volume-based Procurement and Use of High-Value Medical Consumables (關于開展國家組織高值醫用耗材集中帶量采購和使用的指導意見) which was issued by NHSA and other seven PRC authorities on April 30, 2021 stipulates that some high-value medical consumables with increased clinical usage, high purchase amount, mature clinical use, sufficient market competition, and high level of homogeneity will be included in the scope of volume-based procurement. All public medical institutions (including military medical institutions) are required to participate in the Centralized Procurement of high-value medical consumables in accordance with the regulations. The designated social medical institutions of medical insurance may voluntarily participate in the Centralized Procurement in accordance with the relevant regulations of their provinces, autonomous regions and municipalities, as applicable. On May 24, 2021, the General Office of the State Council released Notice of the General Office of the State Council on the Key Tasks of Deepening the Reform of the Medical and Health System in 2021 (國務院辦公廳關于印發深化醫藥衛生體制改革2021年重點工作任務的通知), expanding the scope of volume-based procurement of high-value medical consumables. On June 3, 2024, the General Office of the State Council released the Key Tasks of Deepening the Reform of the Medical and Health System in 2024 (深化醫藥衛生體制改革2024年重點工作任務),which stipulates further advancement in the centralized bulk procurement of medical consumables to improve quality and expand coverage.

The Key Control List of the First Batch of National High-value Medical Consumables (第一批國家高值醫用耗材重點治理清單) which was issued by the General Office of the NHC on January 8, 2020, clarifies 18 types of high-value medical consumables for key control. Pursuant to the Notice on the Rapid Collection of the Second Batch of High-value Medical Consumables Centralized Procurement Data and Price Monitoring (關於開展高值醫用耗材第二批集中採購數據快速採集與價格監測的通知) which was issued by the NHSA on November 20, 2020, the list of the second batch of medical consumables mainly included six kinds of high-value consumables, such as artificial hip joints, artificial knee joints, defibrillators, occluders, orthopedic materials and staplers.

According to the Circular on High-Value Medical Consumables, high-value medical consumables are defined as medical consumables directly used on humans, with strict requirements on safety, in great demand clinically, are relatively highly-priced, and that can pose heavy burdens on patients. The Circular on High-Value Medical Consumables releases several reform initiatives aiming at managing high-value medical consumables, including: (i) the classification and codes of high-value medical consumables in the national medical insurance system will be unified gradually, and rules on unique device identification in full life cycle of the high-value medical consumables, including but not limited to registration, procurement and usage, will be implemented by the NHSA, the NMPA, and the NHC by the end of 2020; (ii) the mechanism for including high-value medical consumables in basic medical insurance shall be built, and a list of high-value medical consumables shall be compiled, strengthening the dynamic adjustment mechanism. The access regulations shall be promulgated by the NHC and the MOF by the end of June 2020; (iii) the price markups placed on medical consumables at public hospitals will be abolished, and all medical consumables, including high-value medical consumables will be sold at procurement price at all public hospitals by the end of 2019; and (iv) the medical insurance payment policy shall be formulated and implemented by the NHSA, the MOF and the NHC. Meanwhile, the medical insurance payment standards on high-value medical consumables will be formulated and the dynamic adjustment mechanism will be established. The medical insurance funds and patients will share the cost of high-value medical consumables according to the medical insurance payment standards, and medical institutions shall further reduce procurement prices under the guidance of the Circular on High-Value Medical Consumables.

Export of Medical Devices

The 2024 Medical Device Regulations stipulates that the manufacturer of the medical devices for export shall ensure that the medical devices it produces meet the requirements of the importing country (region) and shall file the product information with the local municipal food and drug supervision and administration department.

Pursuant to the Administrative Provisions on the Export and Sales Certificate of Medical Device Products (醫療器械產品出口銷售證明管理規定) promulgated by the former CFDA on June 1, 2015 which took effect on September 1, 2015, where the registration certificate and the production permit certificate for medical device products have been obtained or the filing for medical device products and the production filing have been completed in the PRC, the food and drug administration authority may issue the Export and Sales Certificate for Medical Device Products to the relevant production enterprise. The validity period of the Export and Sales Certificate of Medical Device Products shall not exceed the deadlines of the certificates submitted by the enterprises in the application materials, whichever is the earliest, and shall not exceed two years.

Medical Device Recall, Adverse Event Monitoring and Re-evaluation

According to the Measures for the Administration of Medical Device Recalls (醫療器械召回管理辦法) promulgated by the former CFDA on January 25, 2017 which took effect on May 1, 2017, depending on the severity of defects of medical devices, the recall of medical devices can be divided into: (i) Level I recall: the use of the medical device may cause or has caused serious health hazards; (ii) Level II recall: the use of the medical device may cause or has caused temporary or reversible health hazards; or (iii) Level III recall: the medical device is less likely to cause harm but still needs to be recalled. Medical device manufacturers should determine the level of recall based on specific conditions and systematically design and organize the implementation of a recall plan based on the level of recall and the sales and use of medical devices.

According to the Administrative Measures for the Monitoring and Re-evaluation of Adverse Events of Medical Devices (醫療器械不良事件監測和再評價管理辦法) promulgated by the SAMR and the NHC on August 13, 2018 which took effect on January 1, 2019, holders of medical device marketing licenses shall have the quality management ability and corresponding capacity for liability to ensure the safety and effectiveness of medical devices, establish a medical device adverse event monitoring system, and directly report medical device adverse events to the technology institution for medical device adverse event monitoring. Any business enterprise authorized by the holder for sales or the medical device user shall report any medical device adverse event to the holder and the monitoring institution. The holder shall evaluate the identified adverse events, improve product quality according to the evaluation results, and report the evaluation results and measures for improving quality to the monitoring institution. Where approval from the original registration authority is required, an application shall be submitted as required.

The NMPA has established the national medical device adverse event monitoring information system, and strengthened the construction of medical device adverse event monitoring information network and database. The monitoring institutions designated by the NMPA are responsible for the unified management of the information on the medical device adverse events collected, and shall provide feedback to the relevant monitoring institutions, holders, business enterprises or users on the information related to the monitoring of medical device adverse events.

Regulations Relating to Advertisements of Medical Devices

In accordance with the Regulations on Medical Devices currently in force, the advertisements of a medical device shall be true and lawful, and its content shall not be false, exaggerated or misleading. Advertisements for medical devices shall be examined and approved by the food and medical products

administrations of the people's governments of the provinces, autonomous regions or municipalities where the manufacturing enterprises of medical devices or the agents of imported medical devices are located, and obtain the approval document for such advertisements for medical devices. A publisher of a medical device advertisement shall verify approval documents and their authenticity prior to the publication; if no approval document was obtained or the authenticity of any approval document has not been verified or the content of the advertisement is inconsistent with the approval documents, such medical device advertisement shall not be published.

On December 24, 2019, the State Administration for Market Regulation issued the Interim Measures for Examination and Administration of Advertisements for Drugs, Medical Devices, Health Foods and Formula Foods for Special Medical Purpose (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) (the "**Interim Measures for Review and Management**"), which came into effect on March 1, 2020. The Interim Measures for Review and Management provides that advertisements for medical devices shall not be published without examination, and the contents of advertisements for medical devices shall be subject to the content of the registration certificates or filing certificates, product specifications registered or filed and approved by the drug regulatory authorities. If the advertisement of medical devices involves the name, scope of application, mode of action or structure and composition of medical devices, it shall not exceed the scope of the registration certificate or filing certificate, or the product specifications registered or filed. The validity period of an advertisement approval for drugs, medical devices, health food and food for special medical use shall be consistent with the validity period of the registration certificate, record-filing certificate or the production license of the product, whichever is the shortest. Where no validity period is set forth in the registration certificate, record-filing certificate or the production license of the product, the advertisement approval shall be valid for two years.

Policies to Encourage the Development and Innovation of High-End Medical Devices Such as Surgical Robots

Certain laws, regulations and policies have been enacted in the PRC to encourage the development and innovation of high-end medical devices such as surgical robots.

On May 26, 2017, the General Office of the Ministry of Science and Technology issued the Notice of the General Office of the Ministry of Science and Technology on Printing and Distributing the "13th Five-Year Plan for Medical Device Technology Innovation"(科技部辦公廳關於印發<"十三五"醫療器械科技創新專項規劃>的通知) proposing to improve the independent innovation capability of medical devices in China and strengthen the application demonstration and promotion of domestic innovative medical devices, which is an important support for the establishment of an efficient, hierarchical, collaborative, homogeneous and accessible medical and health service system, improvement of medical and health service level and transformation of health service model.

In 2017, the NDRC issued the "Three-Year Action Plan for Enhancing the Core Competitiveness of Manufacturing Industry (2018-2020)"(增强製造業核心競爭力三年行動計劃(2018-2020年)), proposing to accelerate the development of advanced manufacturing industry, support and promote the industrialization of key technologies for high-end medical devices and drugs. In particular, in the field of medical devices, there are four categories and 27 sub-categories of medical devices industrialization projects with key support. Surgical robots are a kind of high-end treatment equipment with key support.

On December 26, 2017, the General Office of the NDRC issued the "Implementation Plan for the Industrialization of Key Technology of High-end Medical Devices and Drugs (2018-2020)"(高端醫療器械和藥品關鍵技術產業化實施方案(2018-2020年)), proposing to focus on high-end medical devices with large usage, wide application and high technical content. In the field of treatment equipment, the NDRC encouraged the industrialization of innovative equipment such as endoscopic surgical robots and neurosurgical robots, and promoted the upgrading and quality performance improvement of products such as orthopedic surgical robots.

On December 13, 2017, the Ministry of Industry and Information Technology issued the "Three-Year Action Plan to Promote the Development of the New Generation of AI Industry (2018-2020)" (促進新一代人工智能產業發展三年行動計劃(2018-2020)), proposing to accelerate the development of the AI industry and promote the deep integration of AI and the real economy. This document supports the cultivation of intelligent products including intelligent service robots, focuses on the development of key technologies such as 3D imaging positioning, intelligent precision and safety control, human-machine collaboration interface, supports the research and development of surgical robot operating system, and promotes the application of surgical robot in clinical medical treatment.

On November 10, 2019, 15 departments including the NDRC and the Ministry of Industry and Information Technology issued the Implementation Opinions on Deepening the Integrated Development of Advanced Manufacturing and Modern Service Industry (關于推動先進製造業和現代服務業深度融合發展的實施意見), proposing to promote the innovation and integration of key areas of consumer services and manufacturing industry, and focus on the development of high-end medical devices such as surgical robots, medical imaging, remote diagnosis and treatment, so as to gradually realize intelligent equipment and intelligent life.

On March 11, 2021, the NPC approved the Outline of the 14th Five-Year Plan for National Economic and Social Development of the People's Republic of China and the Vision for 2035 (中華人民共和國國民經濟和社會發展第十四個五年規劃和2035年遠景目標綱要), proposing to promote the reform of centralized and large-scale procurement and use of drugs and consumables organized by the State and develop high-end medical devices. The State Council will improve the fast-track review and approval mechanism for innovative drugs, vaccines, medical devices and other drugs, accelerate the review and approval of drugs and medical devices for urgent clinical needs and treatment of rare diseases, and promote the launch of new drugs and medical devices that have been launched overseas in urgent clinical needs as soon as possible.

On January 18, 2023, the Ministry of Industry and Information Technology and other 17 departments jointly issued the Notice on the Implementation Plan of the "Robot Plus" Application Action ((「機器人+」應用行動實施方案)), which clearly encourages qualified hospitals with needs to use robots to perform precise and minimally invasive surgery, build standardized operating rooms for robot applications, and study standards and norms for clinical applications of surgical robots.

EU REGULATORY OVERVIEW

Medical devices can be commercialized in the member states of the European Economic Area ("EEA") only if they meet the requirements of Regulation (EU) 2017/745 on medical devices ("MDR") and obtain the CE (Conformité Européenne) Mark.

Device Classifications and Conformity Assessment

In the EEA, devices are classified into Class I, Class IIa, Class IIb, and Class III based on the MDR classification rules (MEDDEV 2.4/1 rev.9). The classification is a risk-based mechanism according to the nature of human body contact and the contact duration of the medical devices. Medical devices in the EU must undergo a conformity assessment to demonstrate that they meet regulatory requirements to ensure they are safe and perform as intended. EU Member States can designate accredited notified bodies to conduct conformity assessments. The manufacturer of Class IIa, IIb, and Class III medical devices must lodge an application with a notified body to assess conformity to the MDR by submitting the compiled technical documentation.

Clinical Evaluation and Post-Market Surveillance

Under the MDR, manufacturers must conduct a clinical evaluation (guided by MEDDEV 2.7/1 rev.4) to verify the clinical safety and performance of their devices. The CE Mark may generally only be affixed to

a medical device if the product has passed the conformity assessment per the procedures outlined in the MDR. The CE certificates generally have a maximum validity period of five years.

Following market entry, medical device manufacturers are required to maintain comprehensive systems for risk management, quality management, and post-market surveillance. Manufacturers must actively gather and analyze post-market clinical follow-up studies (MEDDEV 2.12/2 rev.2) throughout the device's lifetime. Furthermore, they must comply with the medical devices vigilance system (MEDDEV 2.12/1 rev.8), which mandates the reporting of serious incidents and field safety corrective actions to the competent authorities.

U.S. FDA REGULATORY OVERVIEW

In the United States, medical devices are subject to extensive regulation by the Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations.

Device Classification and Premarket Pathways

The FDA classifies medical devices into three classes (Class I, II, and III) based on the level of risk associated with the device and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. Depending on the device classification, manufacturers must generally utilize one of two primary premarket pathways before commercial distribution:

- Premarket Notification [510(k)]: For most Class II devices, the manufacturer must submit a 510(k) premarket notification to the FDA demonstrating that the device is "substantially equivalent" to a legally marketed predicate device (21 CFR Part 807 Subpart E).

- Premarket Approval (PMA): For Class III devices (those that are life-sustaining, life-supporting, or present a potential unreasonable risk of illness or injury), the FDA requires the submission of a PMA application (21 CFR Part 814). The PMA process is more rigorous than the 510(k) pathway and requires the submission of valid scientific evidence, typically including extensive preclinical and clinical data, to independently demonstrate the device's safety and effectiveness.

Establishment Registration and Quality System Requirements

Prior to commercializing a medical device in the U.S., manufacturers and initial importers must register their establishments with the FDA and list the devices they manufacture or distribute (21 CFR Part 807).

Furthermore, manufacturers must strictly comply with the FDA's Quality System Regulation (QMSR) as set forth in 21 CFR Part 820. The QMSR establishes comprehensive requirements for the design, manufacture, packaging, labeling, storage, installation, and servicing of medical devices to ensure they consistently meet applicable requirements and specifications. The FDA enforces these requirements through routine and unannounced inspections of manufacturing facilities. Following market entry, manufacturers are also subject to stringent post-market surveillance and Medical Device Reporting (MDR) requirements, mandating the timely reporting of device-related adverse events and malfunctions.

OTHER INTERNATIONAL MARKETS REGULATORY OVERVIEW

In addition to the PRC, the EU, and the U.S., we may commercialize our products in other international markets. We have obtained or are evaluating regulatory pathways in various jurisdictions across Southeast Asia, Latin America, the Middle East, and other regions. While the specific laws

governing medical devices vary, these markets generally enforce risk-based classification systems and require product registration or marketing authorization from local competent authorities prior to commercialization.

Southeast Asia

In Southeast Asia, medical device regulations are increasingly harmonized under the ASEAN Medical Device Directive (AMDD), utilizing the Common Submission Dossier Template (CSDT) for product registration.

- Indonesia: The Ministry of Health (MOH) regulates devices under Regulation No. 1190/Menkes/VIII/2010 on the Circulation Permit of Medical Devices and Household Health Supplies, supported by classification and evaluation guidelines.

- Singapore: The Health Sciences Authority (HSA) oversees devices under the Health Products Act 2007, the Health Products (Medical Devices) Regulations 2010, and the Health Products (Clinical Trials) Regulations 2016.

- Malaysia: The Medical Device Authority (MDA) enforces compliance through guidelines on classification (MDA/GD/0009), CSDT submissions (MDA/GD/0008), labeling (MDA/GD/0026), and essential principles of safety and performance (MDA/GD/0007).

- Thailand: The Thai FDA regulates devices under the Medical Device Act B.E. 2551 (2008) and its amendment B.E. 2562 (2019), along with rules on risk classification and labeling.

- Vietnam: The MOH manages devices under Decree No. 98/2021/ND-CP (as amended by Decree No. 07/2023/ND-CP) and its guiding circulars (Circular 05/2022/TT-BYT and Circular 39/2016/TT-BYT).

- Philippines: The FDA regulates devices under the Food and Drug Administration Act of 2009 (RA 9711) and Administrative Order No. 2018-0002 regarding the issuance of authorizations based on ASEAN harmonized requirements.

Latin America

In Latin America, regulatory authorities mandate strict adherence to Good Manufacturing Practices (GMP) and local registration requirements:

- Colombia: INVIMA regulates devices primarily under Decree 4725 of 2005 regarding sanitary registration and surveillance.

- Ecuador: ARCSA enforces the Substitute Technical Sanitary Regulation for the Registration and Control of Medical Devices for Human Use, along with GMP and storage regulations.

- Brazil: The Brazilian Health Regulatory Agency (ANVISA) regulates medical devices under Law No. 6,360/1976 and Decree No. 8,077/2013.

Middle East and Other Regions

- Saudi Arabia: The SFDA regulates market access through the Medical Devices Marketing Authorization (MDS-G002) and clinical research requirements (MDS-REQ 2).

- United Arab Emirates: The EDE governs medical products under Federal Law No. 8 of 2019 and health information technology under Federal Law No. 2 of 2019.

- Hong Kong SAR: The Medical Device Division (MDD) operates a voluntary listing system guided by documents such as GN-01 (overview), GN-02 (listing of Class II/III/IV devices), and TR-003 (classification).

Many of these international jurisdictions recognize marketing approvals granted by reference regulatory authorities (such as the U.S. FDA or the EU Notified Bodies for CE marking) to streamline their local registration processes. Foreign manufacturers are typically required to appoint a local authorized representative to hold the product registration and handle post-market vigilance reporting under the applicable local laws.

OTHER LAWS AND REGULATIONS

This section sets forth a summary of the relevant significant PRC laws and regulations that affect our daily operations.

Regulations on the Establishment and Operation of Foreign-invested Enterprises

Foreign Investment

The Foreign Investment Law of the People's Republic of China (中華人民共和國外商投資法) (the "**Foreign Investment Law**") which was passed by the National People's Congress on March 15, 2019 and came into force on January 1, 2020, and the Implementation Regulations for the Foreign Investment Law of the People's Republic of China (中華人民共和國外商投資法實施條例) which was promulgated by the State Council on December 26, 2019 and came into force on January 1, 2020, were the legal foundation for foreign investment in the PRC.

The Foreign Investment Information Reporting Measures (外商投資信息報告辦法) promulgated by MOFCOM and the SAMR on December 30, 2019, and effective on January 1, 2020, explicitly established the foreign investment information reporting system which requires foreign investors or foreign-invested enterprises to submit investment information to the commercial authorities through the enterprise registration system and the enterprise credit information publicity system.

The Negative List

The Negative List refers to the special administrative measures for foreign investment access implemented according to the requirements of the state with respect to foreign investment in specific industries, and the national treatment will be given to foreign investments outside the negative list. The negative list currently implemented is the Special Administrative Measures for Access of Foreign Investment (Negative List) (2024 Edition) (外商投資准入特別管理措施(負面清單)(2024年版)) promulgated by the NDRC and the MOFCOM on September 6, 2024, and effective on November 1, 2024.

According to the Special Administrative Measures for Access of Foreign Investment (Negative List) (2024 Edition) and the Catalog of Industries for Encouraging Foreign Investment (2025)(鼓勵外商投資產業目錄(2025年版)), which was promulgated by the NDRC and the MOFCOM on December 15, 2025 and became effective on February 1, 2026, foreign investment projects can be classified into four categories, namely encouraged, permitted, restricted and prohibited. Foreign investment projects that are not included in the Negative List are permitted foreign investment projects.

Regulations on Labor Protection and Social Security

Labor

According to the Labor Law of the PRC (中華人民共和國勞動法) issued by the SCNPC on July 5, 1994, implemented on January 1, 1995 and finally amended on December 29, 2018, employers shall develop and improve their rules and regulations in accordance with the law to ensure that workers enjoy their labor rights and perform their labor obligations. Employers shall develop and improve the system of labor safety and sanitation, strictly implement the national protocols and procedures on labor safety, guard against labor safety accidents and reduce occupational hazards. Labor safety and sanitation facilities shall meet the relevant national standards. Employers must provide workers with the necessary labor protection equipment that meets the safety and hygiene conditions stipulated under national regulations by the State, and conduct regular health checks for workers who engage in operations with occupational hazards.

According to the Labor Contract Law of the PRC (中華人民共和國勞動合同法) issued by the Standing Committee of the National People's Congress (the "**SCNPC**") on June 29, 2007, came into effect on January 1, 2008 and finally revised on December 28, 2012, and the Implementation Regulation on 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 on September 18, 2008 and became effect on the same day, the relationship between the employers and the employees shall be regulated by a labor contract, which shall be drawn up in writing.

The Social Insurance

According to the Social Insurance Law of PRC (中華人民共和國社會保險法) promulgated by the SCNPC on October 28, 2010 and implemented on July 1, 2011 and further amended on December 29, 2018, employees shall participate in basic pension insurance, basic medical insurance and unemployment insurance. Basic pension, medical and unemployment insurance contributions shall be paid by both employers and employees. Employees shall also participate in work-related injury insurance and maternity insurance. Work-related injury insurance and maternity insurance contributions shall be paid by employers rather than employees. An employer shall make registration with the local social insurance agency in accordance with the provisions of the law. For employers failing to conduct social insurance registration, the administrative department of social insurance shall order them to make corrections within a prescribed time limit; if they still fail to do so within the time limit, employers shall have to pay a penalty over one time but no more than three times of the amount of the social insurance premium payable by them, and their directly responsible executive staff and other directly responsible persons shall be fined RMB500 to RMB3,000. Also, those employer who fail to promptly contribute social insurance contributions in full amount shall be ordered by the social insurance collection agency to make or supplement contributions within a designated period, and shall be subject to a late payment fine computed from the due date at the rate of 0.05% per day of the outstanding contribution amount; where payment is not made within the designated period, the relevant administrative authorities shall impose a fine ranging from one to three times of the outstanding contribution amount.

According to the Reform Plan of the State Tax and Local Tax Collection Administration System (國税地税徵管體制改革方案), which was promulgated by the General Office of the Communist Party of China and the General Office of the State Council of the PRC on July 20, 2018, from January 1, 2019, all the social insurance premiums including the premiums of the basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and basic medical insurance will be collected by the tax authorities.

The Housing Provident Fund

According to the Regulations on the Administration of Housing Provident Fund (住房公積金管理條例) promulgated by the State Council and became effective on April 3, 1999, and was finally amended on

March 24, 2019, housing provident fund paid and deposited both by employees themselves and their employer shall be owned by the employees. The newly established enterprise shall register with the Housing Provident Fund Management Center for housing provident fund payment and deposit within 30 days from the date of establishment, and within 20 days from the date of registration, go through the procedures for the establishment or transfer of housing provident fund accounts for the employees of this enterprise. When an employer employs an employee, it shall register with the housing provident fund management center within 30 days from the date of employment, and go through the procedures for the establishment or transfer of an employee's housing provident fund account. Employers shall timely pay and deposit housing provident fund contributions in full amount and late or insufficient payments shall be prohibited. With respect to employers who violate the regulations here in above and fail to complete housing provident fund payment and deposit registrations or open housing provident fund accounts for their employees, such employers shall be ordered by the housing provident fund administration center to complete such procedures within a designated period. Those who fail to complete their registrations within the designated period shall be subject to a fine from RMB10,000 to RMB50,000. When employers are in breach of these regulations and fail to pay the deposit housing provident fund contributions in full amount as they fall due, the housing provident fund administration center shall order such employers to pay within a prescribed time limit period, failing which an application may be made to a people's court for compulsory enforcement.

Regulations on Production Safety

According to the Safety Production Law of the People's Republic of China (中華人民共和國安全生產法) revised by the SCNPC on June 10, 2021 and effective on September 1, 2021, a production and business operation entity must (i) abide by this law and other laws and regulations related to production safety, strengthen production safety management, and establish a sound production safety responsibility system and formulate a set of production safety rules and regulations for all employees; (ii) increase the efforts to guarantee the input of funds, supplies, technology and personnel to production safety, improve production safety conditions, and strengthen standardization and informatization of production safety; (iii) construct a dual prevention mechanism consisting of graded management and control of safety risks and examination and control of potential risks, improve the risk prevention and resolution mechanism, enhance production safety levels and ensure production safety. Entities that do not have the conditions for safe production shall not engage in production and business activities.

Regulations on Environmental Protection

Environmental Protection

The Environmental Protection Law of the People's Republic of China (中華人民共和國環境保護法), promulgated by the SCNPC on December 26, 1989 and amended on April 24, 2014, summarizes the rights and responsibilities of environmental protection regulatory authorities. The Ministry of Environmental Protection (now the Ministry of Ecology and Environment) is authorized to promulgate national standards for environmental quality and discharge and to supervise China's environmental protection policies. At the same time, local environmental protection authorities may formulate local standards that are stricter than the national standards, in which case, the companies concerned shall comply with the national and local standards.

Environmental Impact Assessment

According to the Regulations on the Administration of Construction Project Environmental Protection (建設項目環境保護管理條例) promulgated by the State Council on November 29, 1998 and amended on July 16, 2017 and taking effect on October 1, 2017, the construction entity shall submit an environmental impact report or an environmental impact statement, or fill in a registration form depending on the degree of impact the construction project has on environment. For a construction project for which an environmental

impact report or environmental impact statement shall be prepared, the construction entity shall submit the environmental impact report and environmental impact statement to the competent administrative department of the environmental protection for approval before starting construction. 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 shall be prohibited from commencing construction works.

According to the Law of the People's Republic of China on Environmental Impact Assessment (中華人民共和國環境影響評價法) promulgated by the SCNPC on October 28, 2002 and amended on July 2, 2016 and December 29, 2018, for construction projects that have an impact on the environment, entities shall prepare an environmental impact report, report form or registration form in accordance with the severity of the impact that the project may have on the environment.

Completion and Acceptance

The Interim Measures for Acceptance of Environmental Protection upon Completion of Construction Projects (建設項目竣工環境保護驗收暫行辦法) as promulgated and implemented by the former Ministry of Environmental Protection (now the Ministry of Ecology and Environment) on November 20, 2017. The Measures regulates the procedures and standards for environmental protection acceptance by construction units upon the completion of construction projects.

Pollutant Discharge

Pursuant to the Law of the PRC on Prevention and Control of Environmental Pollution Caused by Solid Wastes (Revised in 2020)((中華人民共和國固體廢物污染環境防治法(2020修訂)), promulgated on April 29, 2020 and took effect on September 1, 2020, the construction of projects which discharge solid waste and the construction of project for storage, use and treatment of solid waste shall be carried out upon the appraisal regarding their effects on environment and in compliance with the relevant state regulations concerning the management of environmental protection in respect of construction projects.

According to the Catalog of Classified Management of Pollutant Discharge Permits for Stationary Pollution Sources (2019 Edition)(固定污染源排污許可分類管理名錄(2019年版)) promulgated by the Ministry of Ecology and Environment came into effect on December 20, 2019, key management, simplified management and registration management of pollutant discharge permits are implemented based on factors such as the amount of pollutants generated, the amount of pollutants discharged and the degree of impact on the environment. The pollutant discharging entity subject to registration management does not need to apply for the pollutant discharge permit, but shall fill in the pollutant discharge registration form on the national pollutant discharge permit management information platform.

Product Liability and Protection of Consumers' Rights

According to the Product Quality Law of The People's Republic of China (中華人民共和國產品質量法) amended by the SCNPC which took effect on December 29, 2018, producers and sellers shall establish and improve their internal system for product quality control, and strictly apply the quality standards for jobs, the quality responsibility system and the related check measures. Producers and sellers are responsible for the product quality according to the provisions of the law.

According to the Civil Code of the People's Republic of China (中華人民共和國民法典), which was promulgated by the National People's Congress on May 28, 2020 and came into effect on January 1, 2021, patients who suffer from damage due to defects in drugs, disinfectant products and medical devices, or the infusion of unqualified blood may claim compensation from the drug marketing license holder, the manufacturer, the blood provider, or the medical institution. Where a patient claims compensation from a medical institution, the medical institution shall, after paying the compensation, have the right to recover such compensation from the responsible drug marketing license holder, producer and blood provider.

Lease of Property

According to the Administrative Measures for Commodity House Leasing (商品房屋租賃管理辦法) which was promulgated by the Ministry of Housing and Urban-Rural Development on December 1, 2010 and came into effect on February 1, 2011, the parties to a commodity house lease shall complete the lease registration with the competent construction (real estate) departments of the municipalities directly under the Central Government, cities and counties where the leased property is located within 30 days after the lease is executed. The competent construction (real estate) departments of the municipalities directly under the Central Government, cities and counties shall urge those who do not register on time hereof to make rectification within a specified time limit, and shall impose a fine below RMB1,000 on individuals who fail to rectify within the specified time limit, and a fine between RMB1,000 and RMB10,000 on institutions which fail to rectify within the specified time limit.

According to the Civil Code of the People's Republic of China, promulgated by the SCNPC on May 28, 2020, and effective on January 1, 2021, if the parties to a lease contract fail to go through the formalities of registration of such contract in accordance with the provisions of laws and administrative regulations, the validity of the contract shall not be affected.

Fire Prevention

The Fire Prevention Law of the PRC (中華人民共和國消防法) (the "**Fire Prevention Law**"), was adopted in April 1998 and last amended in April 2021. The Fire Prevention Law provides that fire control design and construction of a construction project shall comply with the State's fire control technical standards. Developers, designers, builders and project supervisors shall be responsible for the quality of the fire control design and construction of the construction project pursuant to the law. Construction project fire control design examinations and acceptance systems shall be implemented for construction projects which are required to have fire control design in accordance with the national fire protection technical standards.

According to the Fire Prevention Law and the Interim Provisions on Design Inspection and Acceptance of Fire Protection of Construction Projects (建設工程消防設計審查驗收管理暫行規定) (the "**Interim Provisions on Fire Protection**") which was promulgated by the Ministry of Housing and Urban-Rural Development of the PRC on April 1, 2020 and recently amended on August 21, 2023 and effective on October 30, 2023, a special construction project as stipulated in the Interim Provisions on Fire Protection shall be subject to fire protection design review before such project commences construction and shall be subject to fire protection inspection before such project was put into use. Other construction projects other than a special construction project shall be subject to fire protection inspection recordation, and the competent department of housing and urban-rural development shall conduct a random fire protection inspection thereof. If the project fails to pass the random fire protection inspection, such project shall be ceased to be put into use.

Anti-Unfair Competition

Pursuant to the Anti-Unfair Competition Law of the People's Republic of China (中華人民共和國反不正當競爭法) (the "**Anti-Unfair Competition Law**"), which was amended by the SCNPC and came into effect on April 23, 2019, unfair competition is defined as an act in which an operator violates the provisions of the Anti-Unfair Competition Law in its production and operation activities, disturbs the market competition order and damages the legitimate rights and interests of other operators or consumers. According to the Anti-Unfair Competition Law, business operators shall abide by the principles of voluntariness, equality, fairness and integrity and abide by laws and business ethics in their market transactions. Operators who violate the provisions of the Anti-Unfair Competition Law shall be subject to corresponding civil, administrative or criminal liabilities according to the specific circumstances.

Pursuant to the Provisional Regulations of the State Administration of Industry and Commerce on Banning Commercial Bribery (國家工商行政管理局關於禁止商業賄賂行為的暫行規定) (the "**Provisions on**

Banning Commercial Bribery") promulgated by the former State Administration for Industry and Commerce and taking effect on November 15, 1996, commercial bribery refers to the act of a business operator to bribe another entity or individual by using property or other means for the purpose of selling or purchasing goods, and "other means" refers to the means of providing benefits other than property, such as travel or visits, in various names at home and abroad. According to the Anti-Unfair Competition Law and the Provisions on Banning Commercial Bribery, the supervision and inspection authorities may impose fines according to the circumstances, and confiscate any illegal gains.

According to the Compliance Guidelines for Pharmaceutical Enterprises on Prevention of Commercial Bribery Risks (醫藥企業防範商業賄賂風險合規指引) issued by the SAMR on January 10, 2025, pharmaceutical enterprises are the principal entities responsible for preventing their own commercial bribery risks. Pharmaceutical enterprises should implement the main responsibility, strengthen internal control and compliance management to prevent commercial bribery risks, and consciously resist commercial bribery behaviors. This Guidelines advocated that pharmaceutical enterprises introduce professional institutions to evaluate the construction and implementation of their compliance management systems for preventing commercial bribery risks.

Regulations on Intellectual Property

Trademark

Trademarks are protected by the Trademark Law of the PRC (中華人民共和國商標法) issued by the SCNPC on August 23, 1982, came into effect on March 1, 1983 and finally amended on April 23, 2019 and the Implementation Regulation of the PRC Trademark Law (中華人民共和國商標法實施條例) issued by the State Council on August 3, 2002 and came into effect on September 15, 2002, amended on April 29, 2014 and came into effect on May 1, 2014. The Trademark Office of National Intellectual Property Administration of the PRC handles trademark registration and grants registered trademarks for a validity period of ten years. Trademarks may be renewed every ten years where a registered trademark needs to be used after the expiration of its validity period. Trademark registrants may license, authorize others to use their registered trademark by signing up a trademark license contract. The trademark license agreements shall be submitted to the trademark office for recording.

Patent

According to the Patent Law of the People's Republic of China (中華人民共和國專利法) which was revised by the SCNPC on October 17, 2020 and came to effect on June 1, 2021, and the Implementing Regulations of the Patent Law of the People's Republic of China (中華人民共和國專利法實施細則) which was revised by the State Council on December 11, 2023 and came to effect on January 20, 2024, the patent administration department under the State Council is responsible for the patent work throughout the country. It receives and examines patent applications and grants patent rights for inventions-creations in accordance with law.

Copyright and Software Registration

According to the Copyright Law of the PRC (中華人民共和國著作權法) which was promulgated by the SCNPC on September 7, 1990 and implemented on June 1, 1991, and finally revised on November 11, 2020 and came into effect on June 1, 2021, and the Implementation Regulations of the Copyright Law of the PRC (中華人民共和國著作權法實施條例) promulgated by the State Council on August 2, 2002 and implemented on September 15, 2002, and finally revised on January 30, 2013, copyright holders enjoy a variety of personal and property rights, including the right of publication, the right of authorship, the right of reproduction, and the right of communication of information on networks.

The Regulation on Computers Software Protection ((計算機軟件保護條例), which was promulgated by the State Council on June 4, 1991 and amended in 2001 and 2013, respectively, was formulated for the purposes of protecting the rights and interests of copyright owners of computer software, regulating the relationship of interests generated in the development, dissemination and use of computer software, encouraging the development and application of computer software, and promoting the development of software industry and the informatization of national economy. According to the Regulation on Computer Software Protection, Chinese citizens, legal entities or other organizations are entitled to the copyright in the software which they have developed, whether published or not. A software copyright owner may register with the software registration institution recognized by the copyright administration department of the State Council. A registration certificate issued by the software registration institution is a preliminary proof of the registered items.

Domain Name

In accordance with the provisions of the Administrative Measures for Internet Domain Names (互聯網域名管理辦法) promulgated by the Ministry of Industry and Information Technology on August 24, 2017 and taking effect on November 1, 2017, to establish domain name root servers and domain name root server operating organizations, domain name registration management organizations and domain registration service organizations within the territory of China, licenses from the Ministry of Industry and Information Technology or the telecommunications administration authority of the province, autonomous region or municipality directly under the central government shall be obtained in accordance with the relevant regulations. The domain name registration service shall be conducted following the principle of "apply first, register first." The Notice of the Ministry of Industry and Information Technology on Regulating the Use of Domain Names in Internet Information Services (工業和信息化部關於規範互聯網信息服務使用域名的通知) promulgated by the Ministry of Industry and Information Technology on November 27, 2017 and effective on January 1, 2018 provides for the obligations of internet information service providers and other entities to fight terrorism and maintain network security.

Information Security and Data Privacy

Pursuant to the PRC Civil Code (中華人民共和國民法典), the personal information of a natural person shall be protected by the law. An information processor shall not disclose or tamper with any personal information collected or stored thereby; and without the consent of the natural person, no personal information shall be illegally provided to any other person, excluding the information through which the specific individual cannot be identified after processing and which cannot be restored. An information processor shall take technical measures and other necessary measures to ensure the security of the personal information collected and stored thereby and prevent information leakage, tampering, and loss.

On May 8, 2017, the Supreme People's Court and the Supreme People's Procuratorate jointly released the Interpretations of the Supreme People's Court and the Supreme People's Procuratorate on Several Issues Concerning the Application of Law in the Handling of Criminal Cases Involving Infringement of Citizens' Personal Information (最高人民法院、最高人民檢察院關於辦理侵犯公民個人信息刑事案件適用法律若干問題的解釋) (the "**Interpretations**"), which came into effect on June 1, 2017, clarifies several concepts regarding the crime of "infringement of citizens' personal information" stipulated by Article 253A of the Criminal Law of the PRC (中華人民共和國刑法), including the "provision of citizens' personal information" and "illegally obtaining any citizen's personal information by other methods." In addition, the Interpretations specify the standards for determining "serious circumstances" and "particularly serious circumstances" of this crime.

The Data Security Law of the PRC (中華人民共和國數據安全法), which was promulgated by the SCNPC on June 10, 2021 and took effect on September 1, 2021, provides that China shall establish a data classification and grading protection system, formulate the important data catalogs to enhance the protection of important data. Processors of important data shall specify the person responsible for data security and management

agencies to implement data security protection responsibilities. Relevant authorities will establish the measures for the cross-border transfer of important data. If any company violates the Data Security Law of the PRC to provide important data outside China, such a company may be punished by administrative sanctions, including penalties, fines, and/or suspension of relevant business or revocation of the business license.

The Personal Information Protection Law of the PRC (中華人民共和國個人信息保護法) (the "Personal Information Protection Law") was promulgated by the SCNPC on August 20, 2021 and came into effect on November 1, 2021. The Personal Information Protection Law reiterates the circumstances under which a personal information processor could process personal information and the requirements for such circumstances, such as when (1) the individual's consent has been obtained; (2) the processing is necessary for the conclusion or performance of a contract to which the individual is a party; (3) the processing is necessary to fulfill statutory duties and statutory obligations; (4) the processing is necessary to respond to public health emergencies or protect natural persons' life, health and property safety under emergency circumstances; (5) the personal information that has been made public is processed within a reasonable scope in accordance with this Law; (6) personal information is processed within a reasonable scope to conduct news reporting, public opinion-based supervision, and other activities in the public interest; or (7) under any other circumstance as provided by any law or regulation. It also stipulates the obligations of a personal information processor. Any violation of the provisions and requirements under the Personal Information Protection Law may subject a personal information processor to rectifications, warnings, fines, suspension of the related business, revocation of licenses, being entered into the relevant credit record or even criminal liabilities.

The Opinions on Strictly Cracking Down on Illegal Securities Activities in Accordance with the Law (關於依法從嚴打擊證券違法活動的意見), which were issued by the General Office of the State Council and another authority on July 6, 2021, require to speed up the revision of legislation on strengthening the confidentiality and archives coordination between regulators related to overseas issuance and listing of securities, and improvement to the legislation on data security, cross-border data flow, and management of confidential information.

The Measures for Cybersecurity Review (網絡安全審查辦法) which was published by Cyberspace Administration of China in December 28, 2021 and took effect on February 15, 2022, provides that, which provided that: (1) network platform operators holding personal information of more than one million users shall be subject to cybersecurity review by the Cybersecurity Review Office prior to listing abroad; (2) critical information infrastructure operators (the "**CIIO**") procuring network products and services that affect or may affect national security shall be subject to cybersecurity review; and (3) network platform operators carrying out data processing activities that affect or may affect national security shall be subject to cybersecurity review.

On September 24, 2024, the Regulations on Network Data Security Management (《網絡數據安全管理條例》) (the "**Network Data Security Management Regulations**") was promulgated by the State Council and took effect on January 1, 2025. The Network Data Security Management Regulations apply to the network data handling activities conducted within the territory of the PRC and stipulates that if the network data handling activities affect or may affect national security, a national security review must be conducted in accordance with relevant regulations. The Network Data Security Management Regulations restate and further specify the legal requirements for personal information, cross-border transfer of important data and personal information, data handling activities in network platform services and also provides intensified requirements for important data handlers and large-scale Internet platform service providers. Any failure to comply with such requirements may subject the data processor to, among others, suspension of services, fines, revoking relevant business permits or business licenses and penalties.

According to the Measures on Security Assessment of Cross-border Data Transfer (《數據出境安全評估辦法》) issued by the Cyberspace Administration of China on July 7, 2022 and became effective on September 1, 2022, a data processor that provides data overseas under any of the following circumstances shall apply to the national cyberspace administration for the security assessment of the outbound data

transfer through local provincial cyberspace administration: (I) a data processor provides important data abroad; (II) the critical information infrastructure operator or the data processor that has processed the personal information of more than 1 million people provides personal information abroad; (III) the data processor that has provided the personal information of over 100,000 people or the sensitive personal information of over 10,000 people cumulatively since January 1 of the previous year provides personal information abroad; and (IV) any other circumstance where an application for the security assessment of outbound data transfer is required by the national cyberspace administration. The Cyberspace Administration of China promulgated the Provisions on Promoting and Regulating Crossborder Data Flows (《促進和規範數據跨境流動規定》) on March 22, 2024, which further clarifies the implementation and convergence of the existing data exit security assessment, personal information exit standard contract, personal information protection certification and other data exit systems, relaxes the conditions for cross-border data flow, and narrows the scope of data exit security assessment.

Regulations Relating to Overseas Direct Investment

Pursuant to the Regulations on the Foreign Exchange Administration of the Overseas Direct Investment of Domestic Institutions (《境內機構境外直接投資外匯管理規定》) issued by the SAFE on July 13, 2009 and came into effect on August 1, 2009, upon obtaining approval for overseas investment, an enterprise in Chinese Mainland shall apply for foreign exchange registration for its overseas direct investments. According to the Notice of the State Administration of Foreign Exchange on Further Simplifying and Improving the Foreign Exchange Management Policies for Direct Investment, the administrative approval for foreign exchange registration approval under overseas direct investment has been canceled, and the banks are entitled to review and carry out foreign exchange registration under overseas direct investment directly.

Pursuant to the Measures for the Administration of Overseas Investment (《境外投資管理辦法》), which was issued by the MOFCOM on September 6, 2014 and came into effect on October 6, 2014, the MOFCOM and the commerce departments at provincial levels shall subject the overseas investment of enterprises to recordation or confirmation management, depending on the actual circumstances of investment. Overseas investment involving any sensitive country or region, or any sensitive industry shall be subject to confirmation management. Overseas investment under other circumstances shall be subject to recordation management.

Pursuant to the Administrative Measures for Outbound Investment by Enterprises (《企業境外投資管理辦法》) promulgated by the NDRC on December 26, 2017 and came into effect on March 1, 2018, the investing activities of enterprises in Chinese Mainland such as acquiring overseas ownerships, controlling rights, operating and management rights and other relevant interests by way of investing assets and interests or providing financing and guarantees to control its overseas enterprises, either directly or indirectly, are required to obtain approval or filing with the NDRC in accordance with the relevant conditions of the overseas investment projects. Outbound investment projects that involve sensitive countries and regions or sensitive industries shall be subject to administration of verification and approval by the NDRC and non-sensitive outbound investment projects shall be subject to administration by record-filing. For non-sensitive projects of US$300 million or above invested by local enterprises in Chinese Mainland or carried out by overseas enterprises controlled by them, the investors shall file with the NDRC and non-sensitive outbound investment projects, of which the investment amount of investors in Chinese Mainland is less than US$300 million (exclusive) shall file with the provincial counterpart of the NDRC.

Regulations Relating to Overseas Securities Offering and Listing

The CSRC promulgated the Trial Administrative Measures of 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》), or the Overseas Listing Trial Measures, and five relevant guidelines on February 17, 2023, which took effect on March 31, 2023. The Overseas Listing Trial Measures comprehensively reformed the regulatory regime for overseas offering and listing of PRC domestic companies' securities, either directly or indirectly, into a filing-based system.

According to the Overseas Listing Trial Measures, the PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfill the filing procedure with the CSRC and report relevant information. The Overseas Listing Trial Measures provides that an overseas listing or offering is explicitly prohibited, if any of the following applies: (i) such securities offering or listing is explicitly prohibited by provisions in PRC laws, administrative regulations or relevant state rules; (ii) the proposed securities offering or listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with laws; (iii) the domestic company intending to be listed or offer securities in overseas markets, or its controlling shareholder(s) and the actual controller, have committed crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the latest three years; (iv) the domestic company intending to be listed or offer securities in overseas markets is currently under investigations for suspicion of criminal offenses or major violations of laws and regulations, and no conclusion has yet been made thereof; or (v) there are material ownership disputes over equity held by the domestic company's controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or actual controller.

Where an issuer submits an application for initial **[REDACTED]** to competent overseas regulators, filing application with the CSRC shall be submitted within three business days thereafter. Subsequent securities offering of an issuer in the same overseas market where it has previously offered and listed securities shall be filed with the CSRC within three business days after the offering is completed. Subsequent securities offering and listing of an issuer in other overseas markets shall be filed as initial public offerings.

On February 24, 2023, the CSRC and other relevant government authorities promulgated the Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Issuance and Listing by Domestic Enterprises (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》), or the Provision on Confidentiality, which took effect on March 31, 2023. Pursuant to the Provision on Confidentiality, where a domestic enterprise provides or publicly discloses to the relevant securities companies, securities service institutions, overseas regulatory authorities and other entities and individuals, or provides or publicly discloses through its overseas listing subjects, documents and materials involving state secrets and working secrets of state organs, it shall report the same to the competent department with the examination and approval authority for approval in accordance with the law, and submit the same to the secrecy administration department of the same level for filing. Domestic enterprises providing accounting archives or copies thereof to entities and individuals concerned such as securities companies, securities service institutions and overseas regulatory authorities shall perform the corresponding procedures pursuant to the relevant national provisions.

Regulations on the H Share Full Circulation

According to the Guidelines on Application for "Full Circulation" of Domestic Unlisted Shares of H-share Companies (2023 Amendment) (H股公司境內未上市股份申請「全流通」業務指引(2023修正)), which was issued and implemented by the CSRC on November 14, 2019 and amended on August 10, 2023, shareholders of domestic unlisted shares may determine by themselves through consultation the amount and proportion of shares, for which an application will be filed for circulation, and authorize the domestic enterprises to file the "Full Circulation" application, provided that the requirements laid down in the relevant laws and regulations and set out in the policies for state-owned asset administration, foreign investment and industry regulation are met. The shareholders of domestic unlisted shares shall authorize the domestic enterprises to file the "Full Circulation" application with CSRC by filing materials on key compliance issues, including whether the "Full Circulation" has fulfilled adequate internal decision-making procedures, necessary internal approvals and authorizations, and whether the "Full circulation" involves approval or filing procedures set out in the laws, regulations and policies for state-owned asset administration, industry supervision and foreign investment, and if so, whether such approval or filing procedures have been performed. Domestic enterprises that are not yet listed may file the "Full Circulation" application when applying for listing in an

overseas IPO. After an application for "Full Circulation" has been approved by the CSRC, the domestic enterprise shall submit relevant status reports to the CSRC within 15 days after the shares involved in the application completing the transfer registration in CSDC. The domestic unlisted shares may not be transferred back to China after they have been listed and circulated in Hong Kong.

According to the Measures for Implementation of H-share "Full Circulation" Business (H股「全流通」業務實施細則) promulgated by the China Securities Depository and Clearing Corporation Limited (the "**CSDC**") and Shenzhen Stock Exchange (the "**SZSE**") on December 31, 2019, the businesses of cross-border transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of participants, services of nominal holders, etc. in relation to the "Full Circulation" business, are subject to the Measures for Implementation. Where there is no provision in the Measures for Implementation, it shall be handled with reference to other business rules of the CSDC, China Securities Depository and Clearing (Hong Kong) Company Limited and the SZSE.

The Shenzhen Branch of CSDC promulgated the Guide to the Program for H-share "Full Circulation" Business of the Shenzhen Branch of China Securities Depository and Clearing Corporation Limited (中國證券登記結算有限責任公司深圳分公司H股「全流通」業務指南) on September 20, 2024. These guidelines aim at standardizing the business operations of H-share "Full Circulation" and have made provisions for relevant businesses related to H-share "Full Circulation," including business preparation, cross-border transfer registration, overseas share custody, initial maintenance of detailed domestic holdings, change and maintenance of detailed domestic holdings, handling of corporate actions, settlement and delivery, and risk management.