

REGULATORY OVERVIEW

Information disclosed in this section is relevant PRC laws and regulations (the “PRC Laws”) in effect which have a significant impact on the operation of our Group in the PRC as of the date of this document, which are subject to change in the future, but it does not include a detailed analysis of PRC Laws related to our business activities and operations in the PRC, or serve as all PRC Laws applicable to our operations in the PRC.

LAWS AND REGULATIONS RELATING TO COMPANY AND FOREIGN INVESTMENT

The establishment, operation and management of corporate entities in the PRC are governed by the Company Law of the PRC (《中華人民共和國公司法》)(the “**Company Law**”), which was promulgated by the Standing Committee of the National People’s Congress of the PRC (the “**SCNPC**”) on December 29, 1993, last amended on December 29, 2023 and implemented on July 1, 2024. Foreign invested entities are also subject to the Company Law unless otherwise provided by the Foreign Investment Law (as defined below). The Company Law generally governs two types of companies, namely limited liability companies and joint stock limited companies. Both types of companies have the status of legal persons, and the liability of shareholders of a limited liability company or a joint stock limited company is limited to the amount of registered capital they have contributed. The Company Law shall also apply to foreign invested companies in form of limited liability company or joint stock limited company.

Foreign invested entities in the PRC are also subject to the foreign investment laws and regulations including the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》)(the “**Foreign Investment Law**”), which was promulgated by the NPC and became effective on January 1, 2020, and the Regulations on Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》), which were promulgated by the State Council on December 26, 2019, and became effective on January 1, 2020. According to the Foreign Investment Law, the PRC adopts a system of national treatment which includes a negative list with respect to foreign investment administration. The negative list will be issued by, amended, or released upon approval by the State Council, from time to time.

On September 6, 2024, the NDRC and the MOFCOM jointly issued 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)》)(the “**Negative List**”), which came into effect on November 1, 2024. The Negative List uniformly sets forth the ownership requirements, requirements for senior executives, and other special administrative measures for the access of foreign investment. Fields not on the Negative List shall be administered under the principle of equal treatment for both domestic and foreign investment.

On October 26, 2022, the NDRC and the MOFCOM promulgated the Catalog of Industries for Encouraging Foreign Investment (2022 Version) (《鼓勵外商投資產業目錄(2022年版)》)(the “**Encouraging Catalog**”), which came into effect on January 1, 2023. The Encouraging Catalog lists the industries that encourage foreign investment.

Pursuant to the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which was jointly promulgated by the MOFCOM and the SAMR on December 30, 2019 and became effective on January 1, 2020, where a foreign investor carries out investment activities in PRC directly or indirectly, the foreign investor or the foreign-invested enterprise shall submit the investment information in a timely manner to the competent commerce department.

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LAWS AND REGULATIONS RELATING TO MEDICAL DEVICES

Pursuant to the Regulations on Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), or the Medical Devices Regulations, promulgated by the State Council and effective from April 1, 2000, latest amended on December 6, 2024 and came into effect on January 20, 2025, the NMPA, shall be in charge of national supervision and administration of medical devices. The Medical Device Regulations regulates entities that engage in the research and development, production, operation, use, supervision and administration of medical devices in the PRC.

Classification of Medical Devices

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

Registration and Filings of Medical Devices

Pursuant to the Medical Devices Regulations and the IVD Registration Measures, Class I IVDs are subject to filing and Class II and Class III IVDs are subject to registration administration. Class I IVD shall submit the registration materials to the municipal-level department responsible for drug supervision and administration. Class II IVDs shall be examined by the drug administration departments of the people’s governments of the provinces, autonomous regions or municipalities directly under the central government where such applicants are located and a medical device registration certificate for such medical device shall be issued upon approval. Class III IVDs shall be examined by the NMPA and a medical device registration certificate for such medical device shall be issued upon approval.

A medical device registration certificate is valid for five years and an application for an extension shall be made to the original registration department six months before the expiration.

Clinical Evaluation

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

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The NMPA promulgated the Notice on Publishing the Medical Device Catalog Exempted from Clinical Evaluation (《關於發佈免於進行臨床評價醫療器械目錄的通告》) on September 16, 2021 and it became effective from October 1, 2021, latest amended on May 12, 2025 and came into effect on the same day, which is the legal basis for the current catalog of medical devices exempted from clinical evaluation.

Under the current regulatory framework of the PRC, according to the Biosecurity Law of the People’s Republic of China (《中華人民共和國生物安全法》), and the Administrative Regulations of the People’s Republic of China on Human Genetic Resources (《中華人民共和國人類遺傳資源管理條例》), any of the following activities shall be approved by the competent department of health under the State Council: (1) collecting human genetic resources of important genetic families and specific regions in China or such resources of types and quantities stipulated by the competent department of science and technology under the State Council; (2) preserving China’s human genetic resources; (3) conducting international scientific research and cooperation by use of China’s human genetic resources; or (4) transporting, posting or carrying China’s human genetic resource materials out of China. These activities are further clarified in the Implementation Rules of the Regulations on the Administration of Human Genetic Resources (《人類遺傳資源管理條例實施細則》).

Production Permit and GMP for Medical Devices

The Measures on the Supervision and Administration of Medical Devices Production (《醫療器械生產監督管理辦法》), which was promulgated on March 10, 2022 and came into effect on May 1, 2022, stipulates that manufacturer of medical devices shall satisfy the following conditions: (a) it has production sites, environmental conditions, production equipment and professional technicians that are suitable for such medical devices to be produced; (b) it has organizations or professional examination staffs and examination equipment for carrying out quality examinations for such medical devices to be produced; (c) it has formulated a management system that ensures the quality of the medical device; (d) it has the capability of after-sale services that is suitable for such medical devices to be produced; and (e) it satisfies the requirements as prescribed in R&D and production technique documents.

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

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

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Operation Permit and GSP for Medical Devices

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

Pursuant to the Good Sales Practice of Medical Devices (《醫療器械經營質量管理規範》) promulgated by CFDA and effective from July 1, 2024, an entity engaging in the procurement, acceptance, preservation, sales, transportation and after-sales of medical devices shall take effectively quality control measures.

Importation and Exportation of Medical Devices

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

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

Internet Drug Information Service Qualification

Pursuant to the Regulations on the Administration of Internet Pharmaceutical Information Services (《互聯網藥品信息服務管理辦法》) promulgated by the CFDA on July 8, 2004, latest amended and came into effect on November 17, 2017, Internet websites providing pharmaceutical information services shall be reviewed by the food and drug supervision and administration department of each province, autonomous region, and municipality directly under the central government. The food and drug supervision and administration department may issue a Internet Pharmaceutical Information Service Qualification Certificate (互聯網藥品信息服務資格證書) shall be to the eligible enterprises.

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LAWS AND REGULATIONS RELATING TO ENVIRONMENT PROTECTION

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

LAWS AND REGULATIONS RELATING TO PRODUCT QUALITY, PRODUCTION SAFETY AND CONSUMER PROTECTION

Product Quality

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

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

Production Safety

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

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LAWS AND REGULATIONS RELATING TO INTELLECTUAL PROPERTY RIGHTS

Trademarks

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) promulgated by the SCNPC on August 23, 1982, last amended on April 23, 2019 and implemented on November 1, 2019, and the Implementation Provisions of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) promulgated by the State Council on August 3, 2002, last amended on April 29, 2014 and implemented on May 1, 2014, registered trademarks in the PRC include commodity trademarks, service trademarks, collective trademarks and certification trademarks. The Trademark Office of China National Intellectual Property Administration handles trademark registrations and grants a term of ten years to registered trademarks, and another ten years if requested upon expiry of the first or any renewed ten-year term.

Patents

According to the Patent Law of the PRC (《中華人民共和國專利法》) promulgated by the SCNPC on March 12, 1984, and latest amended on October 17, 2020 and came into effect on June 1, 2021 and the Implementation Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), promulgated by the State Council and latest amended on December 11, 2023 and came into effect on January 20, 2024, there are three types of patents in the PRC, which are invention patents, utility model patents and design patents. The protection period of a patent right for invention patents shall be 20 years, the protection period of a patent right for utility model patents shall be 10 years, and the protection period of design patent right is 15 years, both commencing from the filing date.

Software Registration

Pursuant to the Regulation on Computer Software Protection (《計算機軟件保護條例》) promulgated on June 4, 1991 by the State Council and last amended on January 30, 2013 and the Measures for the Registration of Computer Software Copyright (《計算機軟件著作權登記辦法》) promulgated on April 6, 1992 and last amended by the National Copyright Administration on July 1, 2004, the National Copyright Administration is mainly responsible for the registration and management of software copyright in China and recognizes the China Copyright Protection Center as the software registration organization. The China Copyright Protection Center shall grant certificates of registration to computer software copyright applicants in compliance with the regulations of the Measures for the Registration of Computer Software Copyright and the Regulation on Computers Software Protection.

Domain Names

Pursuant to the Administrative Measures of Internet Domain Names (《互聯網域名管理辦法》) promulgated on August 24, 2017 and implemented on November 1, 2017 by the Ministry of Industry and Information Technology, the Ministry of Industry and Information Technology is the major regulatory body for national domain name services. The principle of “first-to-file” is adopted for domain name services. The applicant of domain name registration shall provide the agency of domain name registration with the true, accurate and complete information about the domain name holder’s identity for the registration purpose. Upon completion of the domain name registration, the applicant will become the holder of such registered domain names.

LAWS AND REGULATIONS RELATING TO ADVERTISEMENT

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

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

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

LAWS AND REGULATIONS RELATING TO ANTI-BRIBERY AND ANTI-CORRUPTION

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

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

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LAWS AND REGULATIONS RELATING TO EMPLOYMENT AND SOCIAL SECURITY

Labour Contract

Pursuant to the Labour Law of the PRC (《中華人民共和國勞動法》) promulgated by the SCNPC on July 5, 1994 and last amended and implemented on December 29, 2018, the Labour Contract Law of the PRC (《中華人民共和國勞動合同法》) promulgated by the SCNPC on June 29, 2007, last amended on December 28, 2012 and implemented on July 1, 2013 and the Implementation Regulations of the Labour Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》) promulgated and implemented by the State Council on September 18, 2008, an employer shall establish and improve labour rules and regulations according to the laws, and shall strictly comply with the national standards, provide relevant training to its employees, protect their labour rights and perform its labour obligations. If an employer establishes labour relationship with an employee, they should enter into a written labour contract. Labour contracts shall be categorised into fixed-term labour contract, unfixed-term labour contract and labour contract for the completion of certain work assignments. The wages payable by an employer to its employees shall not be less than local minimum wage. In addition, an employer must establish and improve the labour safety and health system, stringently implement national protocols and standards on labour safety and health, conduct labour safety and health education for employees, so as to prevent accidents in the labour process and reduce occupational hazards.

Social Insurance

According to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》), promulgated by the SCNPC on October 28, 2010 and last amended and implemented on December 29, 2018, and the Provisional Regulations on Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》), promulgated by the State Council on January 22, 1999 and last amended and implemented on March 24, 2019, an employer is required to make contributions to social insurance schemes for its employees, including basic pension insurance, basic medical insurance, unemployment insurance, maternity insurance and work-related injury insurance. If the employer fails to make social insurance contributions in full and on time, the social insurance authorities may demand the employer make payments or supplementary payments for the unpaid social insurance premium within a prescribed time limit together with a 0.05% surcharge of the unpaid social insurance premium from the due date. If the payment is not made within such time limit, the relevant administrative authorities will impose a fine ranging from one to three times the total outstanding amount. According to the Interpretation (II) of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Labor Dispute Cases (最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)), promulgated by the Supreme People's Court on July 31, 2025 and effective from September 1, 2025, any agreement between an employer and an employee, or any undertaking by an employee, that exempts the employer from paying social insurance contributions shall be deemed invalid by the People's Court.

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 on April 3, 1994 and last amended and implemented on March 24, 2019, employers are required to make contributions to housing provident funds for their employees. Any entity fails to make payment of housing provident fund within the time limit or has shortfall in payment of housing provident fund will be ordered to make the payment or makeup the shortfall within the prescribed time limit, otherwise, the housing provident management center is entitled to apply for compulsory enforcement with the People's Court.

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LAWS AND REGULATIONS RELATING TO OVERSEAS LISTING

On February 17, 2023, with the approval of the State Council, 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》) (the “**Trial Measures**”) and five relevant guidelines, which came into force on March 31, 2023. According to the Trial Measures, (i) PRC domestic companies that seek to offer or list securities overseas, both directly and indirectly, should fulfill the filing procedure and submit relevant information to the CSRC; if a domestic company fails to complete the filing procedure or conceals any material fact or falsifies any major content in its filing documents, it may be subject to administrative penalties, such as order to rectify, warnings and fines, and its controlling shareholders, de facto controllers, the person directly in charge and other directly liable persons may also be subject to administrative penalties, such as warnings and fines; (ii) direct overseas offering and listing by domestic companies refers to the overseas offering and listing of the companies limited by shares registered and established in the PRC; and (iii) any companies limited by shares registered and established in the PRC are required to file with the CSRC within three business days after their application document of overseas listing is submitted. Failure to complete the filing under the Trial Measures may subject a PRC domestic company to a rectification order issued by the CSRC, warnings, and a fine of RMB1 million to RMB10 million.

Besides, domestic companies seeking to overseas offering and listing shall strictly comply with the laws, administrative regulations and relevant provisions of the PRC government on foreign investment, State-owned asset management, industry regulation, overseas investment, cybersecurity, data security, etc., shall not disrupt domestic market order, and shall not harm national interests, public interests and the legitimate rights and interests of domestic investors.

The CSRC and other three relevant government authorities jointly promulgated the Provisions on Strengthening the Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (《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》) (the “**Provision on Confidentiality**”) on February 24, 2023, and came into effect on March 31, 2023. Pursuant to the Provision on Confidentiality, when a domestic company provides or publicly discloses the documents and materials involving state secrets and working secrets of state organs to the relevant securities companies, securities service institutions, overseas regulatory authorities and other entities and individuals, or provides or publicly discloses such the documents and materials through its overseas listing subjects, it shall report to the competent department with the examination and approval authority for approval, and file with the same level secrecy administration department. Domestic companies providing accounting archives or copies thereof to entities and individuals such as securities companies, securities service institutions and overseas regulatory authorities shall perform the relevant procedures according to relevant regulations. The working papers formed within the territory of the PRC by the securities companies and securities service institutions that provide related services for the overseas offering and listing of domestic enterprises shall be kept within the territory of the PRC. Cross-border transferring of such working papers shall go through the examination and approval formalities in accordance with the relevant regulations.

LAWS AND REGULATIONS RELATING TO FULL CIRCULATION OF H SHARES

On November 14, 2019, CSRC promulgated the Guidance for the Application for the “Full Circulation” of the Domestic Unlisted Shares of H-share Companies (《H股公司境內未上市股份申請“全流通”業務指引》) (the “**Guidance**”), which came into effect on the same day and further amended on August 10, 2023. According to the Guidance, 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, 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, and the corresponding H-share listed company may be entrusted to file with the CSRC. An unlisted domestic joint stock company may file with the CSRC for “full circulation” at the time of its initial public offering and listing overseas. After domestic unlisted shares are listed and circulated on the Stock Exchange, they may not be transferred back to China.