RELEVANT LAWS AND REGULATIONS IN THE PRC

We are required to comply with various laws, rules and regulations in the PRC in many aspects. This section summarizes the major PRC laws, rules and regulations applicable to our business.

REGULATIONS ON MEDICAL DEVICES

Classification of Medical Devices

Pursuant to the Regulations on the Supervision and Administration of Medical Devices (2024 Revision) (《醫療器械監督管理條例(2024修訂)》) promulgated by the State Council and most recently amended on December 6, 2024 (effective as of January 20, 2025), the National Medical Products Administration (the "**NMPA**") is in charge of the supervision and administration of medical devices in the PRC.

Medical devices in the PRC are subject to a risk-based classification system comprising three categories — Class I, Class II, and Class III. Under the Regulations on the Supervision and Administration of Medical Devices, Class I medical devices refer to those with a low level of risk, the safety and effectiveness of which can be ensured through routine administration. Class II medical devices are subject to more stringent supervision and control due to their moderate level of risk to ensure safety and effectiveness. Class III medical devices, carrying a relatively high level of risk, require special administrative measures to guarantee their safety, effectiveness, and quality throughout the entire life cycle. The production, distribution, and use of medical devices are subject to registration, filing, and supervision requirements depending on their classification.

Registration and Filing of Medical Devices

Pursuant to the Administrative Measures for the Registration and Filing of Medical Devices (《醫療器械註冊與備案管理辦法》) promulgated by the State Administration for Market Regulation (the "**SAMR**") on August 26, 2021 and took effect on October 1, 2021, medical devices of Class I are subject to record-filing, while medical devices of Class II and III are subject to registration. Medical device registration and filing shall comply with relevant laws, regulations, rules, and mandatory standards, demonstrate that the devices are safe, effective, and quality-controlled, and ensure the authenticity, accuracy, completeness, and traceability of all information throughout the process.

Medical Devices Production Licensing

Pursuant to the Measures for the Supervision and Administration of Medical Device Production (《醫療器械生產監督管理辦法》) most recently amended by the SAMR on March 10, 2022 with effect from May 1, 2022, the supervision for the production of medical devices follows a risk-based classification. Entities producing Class I medical devices are only required to submit a production filing to the municipal-level drug regulatory authority. Entities producing Class II or III medical devices must obtain approval from the provincial-level drug regulatory authority where they are located and secure a medical device production license in accordance with the law. Each medical device production license is valid for five years and may be renewed upon expiry, provided that an application for renewal is submitted between 90 and 30 working days prior to the expiration.

The Measures for the Supervision and Administration of Medical Device Production further specifies that medical device registrants, filers, and manufacturers shall fulfill the following obligations to ensure the quality of ex-factory medical devices: (i) establish, improve, and maintain a quality management system commensurate with the medical devices produced in accordance with the requirements of the Good Manufacturing Practice for Medical Devices (《醫療器械生產質量管理規範》) (the "**GMP**"); (ii) organize production under strict product technical requirements that have been registered or filed for record. Additionally, registrants, filers and manufacturers of medical devices shall conduct an annual self-inspection of the operation of their quality management system, and submit a self-inspection report to the local drug regulatory authority by March 31 of the following year.

The GMP promulgated by the China Food and Drug Administration (the "**CFDA**") on December 29, 2014, revised by the NMPA on November 4, 2025 and to take effect on November 1, 2026 requires manufacturers of medical devices to fulfill their responsibility for quality and safety by implementing all requirements for product safety, efficacy, and quality control throughout the entire lifecycle of medical devices.

Medical Devices Operation Licensing

Pursuant to the Measures for the Supervision and Administration of Medical Device Operation (《醫療器械經營監督管理辦法》), most recently amended by the SAMR on March 10, 2022 and effective from May 1, 2022, the operation of medical devices in the PRC is subject to a risk-based classified supervision system. Under this framework, the operation of Class III medical devices requires a permit, while the operation of Class II medical devices requires record-filing with the competent authority. The operation of Class I medical devices requires neither a permit or filing. An operation license for medical devices is valid for five years, and the license holder must apply for renewal between 90 and 30 working days prior to its expiration. If an operator establishes a new business premises, it must submit a separate operation license application or complete the corresponding filing procedures in accordance with the law. No operation permit or record filing is required for the registrant or filer of medical devices to sell its medical devices at its registration address or production sites as long as it meets the prescribed operating conditions, while it is required for it to store and sell medical devices in other places.

Pursuant to the Good Supply Practice for Medical Devices (《醫療器械經營質量管理規範》) (the "**GSP**"), which was promulgated by the NMPA on December 4, 2023 and became effective from July 1, 2024, medical devices operators shall implement risk management commensurate with the risk level of the products they supply, adopt effective quality control measures, and ensure product quality, safety, and traceability throughout all stages — including procurement, inspection, storage, sales, transportation, and after-sales service. Additionally, enterprises engaged in the operation of Class II and III medical devices shall conduct self-inspections in accordance with GSP and the quality management self-inspection system, and submit a self-inspection report for the previous year to the municipal- and county-level drug regulatory authorities where they are located by March 31 of the following year.

Online Sales of Medical Devices

On December 20, 2017, the CFDA promulgated the Administrative Measures on Supervision of Online Sales of Medical Devices (《醫療器械網絡銷售監督管理辦法》) (the "**Online Medical Devices Sales Measures**"), which became effective on March 1, 2018. According to the Online Medical Devices Sales Measures, only duly licensed or filed manufacturers or distributors may sell medical devices online, unless otherwise exempt. Enterprises selling medical devices online must adopt technical measures to ensure that data and records of online medical device sales are authentic, complete, and traceable. Record retention periods vary by product type: two years after the device's expiration date, at least five years for devices without an expiration date, and permanently for implanted devices. In addition, online sellers must also prominently display their medical device manufacturing or operation licenses or filing certificates on their websites, ensure all published information matches registered or filed details, and restrict online sales to the scope authorized in their licenses or filings.

The Good Practice for Online Sales of Medical Devices (《醫療器械網絡銷售質量管理規範》), promulgated by the NMPA on April 28, 2025 and effective from October 1, 2025, further specifies that online sellers must establish a quality management department appropriate to their business scope, mode and scale of their online sales. Online sellers engaged in wholesale business of Class II or III medical devices shall also verify purchaser qualifications and maintain a system for its ongoing management.

According to the Notice of Effectively Carrying out the Promotion and Implementation of Best Practices from Relevant Pilot Reforms (《關於做好有關改革試點經驗推廣落實工作的通知》) released by the NMPA in January 2025, the regulatory framework for online information services involving medical devices will transition from pre-approval to a filing-based system, effective January 20, 2025. ICP service operators that provide medical device information shall complete the

filing with the relevant provincial-level medical products regulatory authority. Entities that previously obtained the Online Drug Information Service Certificate before the cancellation of the approval requirement may continue to provide online drug and medical device information services after the certificate expires, provided they complete the required filing procedures.

Imports and Exports of Medical Devices

Pursuant to the Customs Law of the PRC (《中華人民共和國海關法》) promulgated by the Standing Committee of the National People's Congress (the "**SCNPC**") on January 22, 1987, effective as of July 1, 1987, and most recently amended on April 29, 2021 — the Measures for Record Filing and Registration of Foreign Trade Operators (《對外貿易經營者備案登記辦法》), promulgated by the Ministry of Commerce of the PRC (the "**MOFCOM**") on June 25, 2004, effective as of July 1, 2004, and most recently amended on May 10, 2021 — and the Administrative Provisions of the Customs of the PRC on Record-Filing of Customs Declaration Entities (《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 (the "**GACC**") on November 19, 2021, and effective as of January 1, 2022, foreign trade operators engaged in the import and export of goods or technology are required to complete record-filing and registration procedures with the MOFCOM or its entrusted agencies.

Pursuant to the Administrative Regulations on the Export Sales Certificates of Medical Devices (《醫療器械產品出口銷售證明管理規定》) issued by the CFDA on June 1, 2015, and effective as of September 1, 2015, relevant drug regulatory authorities may issue a Medical Device Product Export Sales Certificate (《醫療器械產品出口銷售證明》) to medical device manufacturers only if the manufacturer has obtained a medical device registration certificate and a medical device production license, or has completed the record-filing procedures for medical device registration and production.

Advertisement of Medical Devices

The Advertising Law of the PRC (《中華人民共和國廣告法》), promulgated in 1994 and most recently amended in 2021, regulates advertising activities to ensure truthfulness, lawfulness, and the protection of consumer rights. It prohibits false or misleading content and the use of superlative terms such as "national level" or "highest level", and further restricts advertisements for medical devices from including the contents of: (i) assertations or guarantees regarding efficacy or safety; (ii) statements of cure rates or effectiveness rates; (iii) comparisons with the efficacy or safety of other types of drugs or medical devices; or (iv) the use of advertising endorsers for recommendations or testimonials.

Pursuant to the Regulations on the Supervision and Administration of Medical Devices, advertisements for medical devices must be truthful and lawful, and must not contain any false, exaggerated, or misleading content. Such advertisements are subject to review and approval by the authority designated by provincial-level government. Only after obtaining the corresponding medical device advertisement approval document may the advertisement be published.

Pursuant to the Administrative Measures on the Internet Drug Information Service (Amendments in 2017) (《互聯網藥品信息服務管理辦法(2017修正)》) promulgated by the CFDA, any medical device advertisement published on a website providing internet drug information services is subject to review and approval by the competent medical products authorities and must clearly display its advertisement approval number.

Pursuant to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food 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》), promulgated by the SAMR on December 24, 2019 and effective from March 1, 2020, the content of medical device advertisements shall be based on the registration certificates or filing documents approved by the drug regulatory authorities, as well as the content of the registered/filed product instructions. Where a medical device advertisement involves information such as the device name, scope of application, mechanism of action, or structure and composition, it shall not exceed the scope specified in the registration certificate, filing document, or registered/filed product instructions.

The Administrative Measures for Internet Advertising (《互聯網廣告管理辦法》) issued by the SAMR on February 25, 2023 and effective as of May 1, 2023 stipulates that medical device advertisements must undergo pre-release review by the competent authority, and shall not be published in the form of introducing health or wellness knowledge. Furthermore, when presenting general health and wellness information, the same page or interface must not simultaneously display the address, contact details of product operators or service providers, or any product purchase links.

Recall, Adverse Event Monitoring and Re-evaluation of Medical Devices

Pursuant to the Supervision and Administration of Medical Devices, medical registrants and filers must assume full lifecycle quality and safety responsibilities by establishing and implementing product traceability and recall systems, and by proactively conducting adverse event monitoring, and re-evaluation of products. Based on monitoring and re-evaluation results, they shall promptly implement control measures, improve products, and complete relevant registration or filing changes. Upon discovering that a medical device fails to comply with mandatory standards, registered or filed product technical requirements, the medical device registrant or filing party shall immediately cease production, notify relevant distributors, users and consumers, recall the medical devices on the market, and report the recall and handling to the drug regulatory authority and the health administration authority as required.

The Administrative Measures for Surveillance and Re-evaluation of Medical Device-related Adverse Events (《醫療器械不良事件監測和再評價管理辦法》) issued by the SAMR and the National Health Commission (the "**NHC**") on August 13, 2018 and effective from January 1, 2019 stipulates that the medical device marketing authorization holders shall, in accordance with the principle of "reporting when in doubt", report or evaluate individual medical device adverse events that causes or may cause serious injury or death within the prescribed time limit. The Administrative Measures for Surveillance and Re-evaluation of Medical Device-related Adverse Events also establishes a post-marketing monitoring system composed of: group medical device adverse events, regular risk assessment reports, key surveillance, risk control, and re-evaluation.

Special Review Procedures for Innovative Medical Devices

In October 2017, the General Office of the Communist Party of China Central Committee and the General Office of the State Council jointly issued the Opinions on Deepening the Reform of the Review and Approval Systems and Encouraging Innovation on Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》), which encourages the research and development of innovative medical devices. Innovative medical devices that are supported by major national science and technology programs or key national R&D initiatives, or those for which clinical trials are conducted by a National Clinical Medicine Research Center and accredited by its administrative department, shall be given priority in the review and approval process.

The Special Review Procedures for Innovative Medical Devices (《創新醫療器械特別審查程序》), promulgated by the NMPA on November 2, 2018 and effective from December 1, 2018, establishes special review procedures for innovative medical devices meeting the following criteria: (i) the applicant, through its leading role in technological innovation, legally owns core technical invention patents in China for the product, or has legally obtained such invention patents or the right to use them through patent transfers, and the application for special review is submitted within five years from the date of the patent authorization announcement; or the core technical invention patent application has been published by the Patent Administration Department of the State Council, and a search report issued by the Patent Search and Consultation Center of the State Intellectual Property Office confirms that the core technical solution of the product is novel and inventive; (ii) the applicant has completed preliminary research on the product, has a basically finalized product, and can demonstrate that the research process is authentic and controlled, with complete and traceable research data; (iii) the product's primary working principle or mechanism is pioneering in China, and its performance or safety represents fundamental improvement over similar products, with the relevant technology being internationally leading and the product having significant clinical application value. Upon receipt of a registration application, the Center for Medical Device Evaluation of the NMPA shall prioritize the technical review of such innovative medical devices, after which the NMPA shall grant priority in the administrative approval process.

According to the Regulations on the Supervision and Administration of Medical Devices, the government shall formulate industrial plans and policies for medical devices, focusing on innovation as a key development priority. Innovative medical devices shall be given priority in evaluation and approval, and the government shall support their clinical promotion and use to foster high-quality development of the medical device industry. The NMPA shall coordinate with relevant departments under the State Council to implement national industrial planning and guidance for medical devices. Furthermore, pursuant to the Regulations on the Supervision and Administration of Medical Devices, the government shall improve the innovation system for medical devices, support basic and applied research, promote the dissemination and application of new medical device technologies, and provide support in areas such as project initiation, financing, credit, public procurement bidding, and medical insurance. Enterprises are encouraged to cooperate with higher education institutions, research organizations, and medical institutions in medical device research and innovation, strengthen the protection of relevant intellectual property rights, and enhance the capacity for independent innovation.

Product Quality

Under the Product Quality Law of the PRC (《中華人民共和國產品質量法》), amended by the SCNPC on December 29, 2018 and effective on the same day, manufacturers and sellers engaged in the production or distribution of products within the PRC shall bear liability for product quality. Violations of the law may result in penalties such as fines, suspension of business operations, confiscation of unlawfully produced or sold goods and related proceeds, or revocation of business licenses. In serious cases, criminal liability may apply. If a defect in a product causes physical injury or damage to third party property, the injured party may claim compensation against the producer or may claim compensation against the seller.

The PRC Civil Code (《中華人民共和國民法典》), promulgated by the NPC in May 2020 and effective from January 1, 2021, establishes liability for manufacturers and sellers for harm caused by product defects. Where a patient suffers damage due to defects in medical devices, the patient may seek compensation from the drug marketing authorization holder or manufacturer, or also may seek compensation from the medical institution.

Two-Invoice System

Pursuant to the 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)》) issued jointly by eight government departments including the Deepen Medical and Healthcare System Reform Leading Group Office of the State Council on December 26, 2016, the "Two-Invoice System" allows only two invoices in the drug supply chain: one from the manufacturer to the distributor, and another from the distributor to the medical institution. The policy requires public medical institutions to phase in the "Two-Invoice System" in drug procurement and encourages its adoption by other healthcare institutions, with the goal of achieving nationwide implementation by 2018.

On March 5, 2018, six government departments including the Office of the Leading Group for Deepening the Reform of the Medical and Healthcare System of the State Council issued the Notice on Consolidating the Achievements of Canceling Drug Markups and Deepening Comprehensive Reforms in Public Hospitals (《關於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》), which mandates the implementation of centralized procurement and the gradual adoption of the "Two-Invoice System" for high-value medical consumables.

On July 19, 2019, the State Council issued the Reform Plan for the Control of High-value Medical Consumables (《治理高值醫用耗材改革方案》), which encourages local governments to adopt the "Two-Invoice System" according to the actual situation in order to reduce intermediates in the circulation of high-value medical consumables and promote the transparency of purchase and sales.

Furthermore, some provinces and municipal cities in China had promulgated local rules to require public medical institutions in their respective administrative regions to implement the two-invoice system in the procurement process of medical consumables.

Reform Plan on High-Value Medical Consumables and Centralized Procurement of Pharmaceuticals

The Notice on Strengthening Regional Coordination and Enhancing the Quality and Coverage of Centralized Procurement of Pharmaceuticals in 2024 (《關於加強區域協同做好2024年醫藥集中採購提質擴面的通知》) issued by the National Healthcare Security Administration (the "**NHSA**") in May 2024 aims to improve the centralized pharmaceutical procurement system, promote the quality and coverage of centralized volume-based procurement, and further enhance the capacity and scale of local procurement alliances, and hence achieving linkage and coordinated progress at the national and local levels, including but not limited to the following: (i) the centralized procurement of drugs and high-value medical consumables by national authorities (hereinafter referred to as "**National VBP**") shall be carried out by the Joint Procurement Office of drugs and consumables respectively, and all provinces shall participate in and earnestly implement such schemes. Provincial VBP will further strengthen coordination at the national level and shall be promoted to the national alliance for centralized procurement when certain conditions are met. Lead provinces will strengthen communication and coordination with the NHSA, and invite all provinces to participate in the formation of the national alliance for centralized value-based procurement (hereinafter referred to as the "**National Alliance VBP**"). The NHSA will coordinate and guide the National Alliance VBP; and (ii) the National VBP for drugs focuses on drugs that have been evaluated in terms of consistency of quality and efficacy, and the National VBP for high-value medical consumables focuses on those with high prices, representative significance and popularity from the masses. Potential provinces with relevant conditions are encouraged to take the lead in carrying out National Alliance VBP, focusing on chemical drugs, proprietary Chinese medicines and Chinese herbal decoction pieces that have not been evaluated for consistency, and "major drugs" for clinically used drugs and consumables that have large purchase amounts and cover a wide range of people, and drugs and consumables that can be substituted or related to the clinical use of the VBP drugs.

The Notice on Improving the Working Mechanism for Centralized Volume-based Procurement and Implementation for Medical Products (《關於完善醫藥集中帶量採購和執行工作機制的通知》) jointly issued by the NHSA and NHC on November 18, 2024 aims to further improve the working mechanism for centralized volume-based procurement, and guide medical institutions and pharmaceutical companies to comply with and support the centralized volume-based procurement system. Under the policy, the credit management system for drug suppliers shall be improved to punish the failure of selected enterprises to distribute drugs that affect clinical use of drugs, and enterprises failing to supply drugs in a timely or stable manner shall be punished as per procurement documents.

REGULATIONS ON CORPORATE GOVERNANCE AND FOREIGN INVESTMENT

The establishment, operation, and management of companies in China are primarily governed by the PRC Company Law (《中華人民共和國公司法》), originally enacted on December 29, 1993, and most recently amended on December 29, 2023, with the revisions effective July 1, 2024. Key amendments include: (i) optimization of corporate governance, confirming the board of directors as the company's executive body; (ii) enhancement of the company capital system through the introduction of an authorized capital system for companies limited by shares, specification of share classes eligible for issuance, reinforcement of capital maintenance principles, and permission to use capital reserves to cover losses; (iii) strengthening of fiduciary duties of the directors, supervisors and senior management, covering obligations such as maintaining adequate capital, disclosing related-party transactions, and assuming joint and several liability and liquidation responsibilities; and (iv) improvement of the company registration system by clarifying that equity interests and creditor rights can be contributed as capital, allowing the establishment of companies limited by shares with one shareholder, and introducing simplified procedures for capital reduction and de-registration of company to facilitate a company's operation.

China's foreign investment regulatory framework is established under the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the "**FIL**"), adopted by the National People's Congress (the "**NPC**") on March 15, 2019, and the Implementing Rules of FIL (《中華人民共和國外商投資法實施條例》) issued by the State Council on December 26, 2019. FIL defines "foreign investment" as direct or indirect investment within China by foreign investors — including individuals, enterprises, or other organizations — covering: (i) establishing foreign-invested enterprises, solely or jointly with other investors; (ii) acquiring shares, equity interests, property shares, or other similar rights and interests in Chinese enterprises; (iii) investing in new projects in the PRC, solely or jointly with other investors; or (iv) other forms of investment specified by laws, administrative regulations, or the State Council. The Implementing Rules of FIL introduce a "see-through" principle, clarifying that investments within China made by foreign-invested enterprises are also governed by the FIL and the Implementing Rules of FIL.

On December 30, 2019, the MOFCOM and the SAMR jointly issued the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which took effect on January 1, 2020. Foreign investors and foreign-invested enterprises are required to submit their investment information to the relevant commerce authorities through the enterprise registration system and the enterprise credit information publicity platform. An initial report must include basic enterprise details, investor and ultimate controller information, and key transaction data.

Foreign investment activities in the PRC are mainly regulated by the Special Administrative Measures (Negative List) for Access of Foreign Investment (2024 version) (《外商投資准入特別管理措施(負面清單)(2024年版)》) (the "**Negative List**") promulgated by the MOFCOM and the National Development and Reform Commission (the "**NDRC**") on September 6, 2024 and effective from November 1, 2024, and the Catalogue of Industries for Encouraging Foreign Investment (2025 version) (《鼓勵外商投資產業目錄(2025年版)》) (the "**Encouraging List**") promulgated by the MOFCOM and the NDRC and effective on February 1, 2026. The Negative List identifies sectors where foreign investment is restricted or prohibited, while the Encouraged Catalogue highlights industries eligible for support and incentives. Sectors not included in the Negative List grant foreign investors national treatment, subject to the same regulatory standards as domestic investors, unless otherwise stipulated by PRC laws or regulations.

REGULATIONS ON PERSONAL INFORMATION SECURITY AND DATA PROTECTION

Information Security

The PRC Civil Code establishes the fundamental legal principle for the protection of personal information. It prohibits the collection or use of personal information unrelated to services provided. Additionally, network operators are required to adopt appropriate technical and organizational measures to ensure the secure and stable operation of their networks, effectively respond to cybersecurity incidents, and protect the confidentiality, integrity, and availability of network data.

Pursuant to the Supreme People's Court and Supreme People's Procuratorate of Several Issues Concerning the Application of Laws to the Handling of Criminal Cases of Infringing on 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》) promulgated on May 8, 2017 and effective on June 1, 2017, the following activities may constitute crimes of infringement of citizens' personal information under Article 253-1 of the Criminal Law of the PRC: (i) providing citizens' personal information to specific persons or disclosing citizens' personal information on the Internet, etc., in violation of the relevant regulations, where the circumstances are serious; (ii) providing to others, without consent, lawfully collected citizens' personal information, unless such information has been anonymized and is irrecoverable, where the circumstances are serious; (iii) illegally collecting citizens' personal information through purchase, receipt or exchange, where the circumstances are serious; or (iv) illegally collecting citizens' personal information while performing duties or providing services.

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**"), enacted on August 20, 2021 and effective from November 1, 2021, establishes a comprehensive legal framework for personal data protection by consolidating previously dispersed provisions and introducing detailed processing rules, clarified liabilities, and enhanced penalties for violations. Notably, the Personal Information Protection Law designates health-related information as "sensitive personal information" and imposes stricter rules for consent, cross-border transfer, and security safeguards. Personal information handlers are obligated to implement appropriate security measures, or otherwise may face penalties including orders to rectification, suspension of services, confiscation of illegal gains, and monetary fines.

Data Protection

The Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》) (the "**Cybersecurity Law**"), revised on October 28, 2025 and effective from January 1, 2026, establishes the fundamental framework for cybersecurity governance in the PRC. The Cybersecurity Law requires network operators to implement appropriate technical and organizational measures to maintain secure and stable network operations, effectively respond to cybersecurity incidents, and ensure the confidentiality, integrity and availability of network data. The Cybersecurity Law further prohibits the collection or use of personal information unrelated to services provided and mandates compliance with applicable laws, regulations and user agreements.

The Data Security Law of the PRC (《中華人民共和國數據安全法》) (the "**Data Security Law**"), promulgated by the SCNPC on June 10, 2021 and effective from September 1, 2021, establishes a system for data classification and graded protection, risk assessment, monitoring and early warning, and emergency response. Pursuant to the Data Security Law, entities engaged in data processing activities must establish comprehensive data security management systems throughout the entire process, conduct data security education and training, and implement appropriate technical and organizational measures to ensure data security.

To strengthen supervision of data-related activities that may implicate national security, the Cybersecurity Review Measures (《網絡安全審查辦法》) was jointly issued by the Cyberspace Administration of China (the "**CAC**") and 12 other government departments on December 28, 2021, and became effective on February 15, 2022. The Cybersecurity Review Measures stipulates that the following circumstances shall undergo a cybersecurity review by the Cybersecurity Review Office under the CAC: (i) procurement of network products or services by critical information infrastructure operators (the "**CIIOs**"), or data processing by platform operators that affect or may affect national security; (ii) overseas [**REDACTED**] by platform operators holding personal information of over one million users; and (iii) other cases initiated by regulators where network products, services, or data processing are deemed to affect national security.

The Regulations on Network Data Security Management (《網絡數據安全管理條例》), promulgated by the State Council on September 30, 2024 and effective from January 1, 2025, further refines the regulatory framework for cyber data activities, specifying that data processing affecting or potentially affecting national security shall be subject to national security review under relevant regulations.

In respect of cross-border data transfer, the Measures for the Security Assessment of Data Export (《數據出境安全評估辦法》), promulgated by the CAC on July 7, 2022 and effective from September 1, 2022, combines prior self-assessment by data processors with mandatory security review organized by the CAC. It also adopts a supervision mechanism covering both pre-transfer review and post-transfer monitoring, to mitigate risks while facilitating lawful and orderly data flows.

Furthermore, the Provisions on the Prescribed Agreement on Cross-border Data Transfer of Personal Information (《個人信息出境標準合同辦法》) was promulgated by the CAC on February 22, 2023 and became effective on June 1, 2023. The Provisions on the Prescribed Agreement on

Cross-border Data Transfer of Personal Information provides a template that may be adopted by data processors as one of the lawful bases for cross-border transfers of personal information under Article 38 of the Personal Information Protection Law.

On March 22, 2024, the CAC issued the Provisions on Promoting and Regulating Cross-Border Data Flows (《促進和規範數據跨境流動規定》) (the "**Cross-Border Data Flows Provisions**"), effective upon promulgation, which streamlines compliance requirements by exempting eligible entities in specified cases. For instance, non-CIIOs transferring non-sensitive personal data of fewer than 100,000 individuals annually are exempt from security assessment, certification, or standard contract requirements. Transfers of non-sensitive data of 100,000 to one million individuals, or sensitive data of fewer than 10,000 individuals, may proceed via standard contract or certification.

REGULATIONS ON INTELLECTUAL PROPERTY RIGHTS

Patent

The Patent Law of the PRC (《中華人民共和國專利法》) promulgated by the SCNPC on March 12, 1984, most recently amended on October 17, 2020, and effective from June 1, 2021, and the Implementing Rules of the Patent Law (《中華人民共和國專利法實施細則》), which was promulgated on January 19, 1985, most recently amended by the State Council on December 11, 2023 and effective from January 20, 2024, provides for three types of patents, including "invention", "utility model" and "design". The validity periods of these patents are calculated from the date of application. An invention patent is valid for 20 years, a utility model for 10 years, and a design for 15 years.

Trademark

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》), which was promulgated on August 23, 1982, most recently amended on April 23, 2019, and effective as of November 1, 2019, and the Implementation Regulations of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》), which was issued on August 3, 2002 and most recently amended on April 29, 2014, the China National Intellectual Property Administration (the "**CNIPA**"), through its Trademark Office, is responsible for handling trademark registration matters. Under the Trademark Law, a registered trademark is valid for ten years from the date of registration. To maintain protection beyond this period, the registrant must apply for renewal within twelve months before expiry. Each renewal extends the trademark's validity for another ten years.

Copyright

Pursuant to the Copyright Law of the PRC (《中華人民共和國著作權法》) promulgated by the SCNPC on September 7, 1990, most recently amended on November 11, 2020, and effective from June 1, 2021, Chinese citizens, legal persons, or unincorporated organizations are entitled to copyright in their works under the law, regardless of whether the works are published. Authors and other copyright holders may complete work registration formalities with the registration agency recognized by the competent copyright authority of the PRC. Unless otherwise provided in the Copyright Law of the PRC and other related regulations, reproducing, distributing, performing, projecting, broadcasting or compiling a work or communicating the same to the public via an information network without permission from the owner of the copyright therein shall constitute infringements of copyrights. The infringer shall, according to the circumstances of the case, assume civil liability to stop infringement, eliminate impact, apologize, compensate losses, etc.

According to the Measures for the Registration of Computer Software Copyright (《計算機軟件著作權登記辦法》) issued on April 6, 1992, most recently amended on June 18, 2004, and became effective on July 1, 2004, and the Regulations on Protection of Computer Software (《計算機軟件保護條例》) promulgated by the State Council on June 4, 1991, most recently amended on

January 30, 2013, and effective from March 1, 2013, the State Copyright Administration shall be responsible for the administration of software copyright registration nationwide, and further certifies the China Copyright Protection Center as the institution responsible for software registration.

Domain Names

Pursuant to the Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) promulgated by the Ministry of Industry and Information Technology (the "**MIIT**") on August 24, 2017 and effective from November 1, 2017, the MIIT supervises and administers domain services nationwide. Domain name registration services shall in principle implement "first apply, first register". A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

REGULATIONS ON ENVIRONMENT PROTECTION

On March 12, 2026, the NPC promulgated the Code of the PRC on the Ecological Environment (《中華人民共和國生態環境法典》). The Code of the PRC on the Ecological Environment will take effect on August 15, 2026 and supersede 10 existing environmental protection laws, serving as the comprehensive and unified fundamental law governing ecological and environmental protection in the PRC.

Environmental Impact Assessment

Pursuant to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) promulgated by the SCNPC on December 26, 1989, amended on April 24, 2014, and effective as of January 1, 2015, entities that cause environmental pollution or other public hazards are required to adopt effective measures to prevent and control pollution and related risks. Pollution prevention facilities in construction projects shall be designed, constructed and put into use simultaneously with the main project. Pollution prevention facilities shall comply with the requirements of the approved environmental impact assessment document, and shall not be arbitrarily removed or left idle.

Pursuant to the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》), promulgated by the SCNPC on October 28, 2002 and most recently amended on December 29, 2018, and the Provisions on Classified Examination and Approval of Environmental Impact Assessment Documents for Construction Projects (2009 Revision) (《建設項目環境影響評價文件分級審批規定(2009修訂)》) enacted by the Ministry of Environmental Protection on January 16, 2009 and effective from March 1, 2009, construction projects are subject to classified environmental impact assessments based on the degree of environmental impact. Projects with possible significant impacts must submit a comprehensive assessment of the environmental impact; projects with moderate impacts are required to provide an environmental impact statement for analysis or assessment of specific items relating to the environmental impact; while projects with minimal impacts may submit an environmental impact registration form.

Under the Regulations on the Environmental Protection Management of Construction Projects (《建設項目環境保護管理條例》), promulgated by the State Council on December 29, 1998, revised on July 16, 2017, and effective on October 1, 2017, construction projects requiring environmental impact reports or statements must obtain approval from competent authorities before commencement. Furthermore, complementary environmental protection facilities must pass acceptance inspection prior to being put into production or use; where the environmental protection facilities have not undergone acceptance inspection or do not pass acceptance inspection, the construction project shall not be put into production or use.

Pollution Prevention and Control

Pursuant to the Law on the Prevention and Control of Water Pollution of the PRC (《中華人民共和國水污染防治法》), promulgated by the SCNPC on May 11, 1984 and most recently amended on June 27, 2017, enterprises that directly or indirectly discharge industrial wastewater or medical sewage into water bodies must obtain a pollutant discharge permit.

Pursuant to the Law on the Prevention and Control of Air Pollution of the PRC (《中華人民共和國大氣污染防治法》), promulgated on September 5, 1987 and last revised on October 26, 2018, local ecological environmental protection authorities at or above the county level are responsible for unified supervision of air pollution prevention and control. Enterprises which emit industry waste gases or hazardous atmospheric pollutants are required to obtain pollutant discharge permits and install automatic monitoring equipment.

The Law on the Prevention and Control of Noise Pollution of the PRC (《中華人民共和國噪聲污染防治法》), promulgated on December 24, 2021 and effective on June 5, 2022, requires enterprises and other business operators that emit industrial noise to take effective measures to reduce vibration and noise and obtain a pollutant discharge permit or fill in a pollutant discharge registration form.

Pursuant to the Prevention and Control of Environmental Pollution by Solid Wastes of the PRC (《中華人民共和國固體廢物污染環境防治法》), promulgated on October 30, 1995, amended on April 29, 2020, and implemented on September 1, 2020, entities producing, collecting, storing, transporting, utilizing, or treating solid wastes must adopt pollution prevention measures and bear liability for any resulting environmental pollution.

Pollutant Discharge

Pursuant to the Environmental Protection Law of the PRC, as well as three key regulatory documents as follows: (i) the Regulation on Administration for Pollutant Discharge Licensing (《排污許可管理條例》), which was promulgated by the State Council in January 2021 and entered into force in March 2021; (ii) the Catalog of Classified Management of Pollutant Discharge Licensing for Stationary Pollution Sources (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》), issued by the Ministry of Ecology and Environment ("**MEE**") in December 2019 and taking effect on the same date; (iii) the Administrative Measures for Pollutant Discharge Licensing (《排污許可管理辦法》), which was promulgated by MEE on April 1, 2024 and scheduled to be implemented on July 1, 2024, Pollutant discharge permits are categorized into three tiers — key management, simplified management, and registration management — based on criteria such as the volume of pollutants generated, the quantity discharged, and the extent of environmental impact. Entities falling under registration management are exempt from applying for a formal permit; instead, they need to complete and submit a pollutant discharge registration form via the national pollutant discharge permit administration information platform.

Pursuant to the Guidelines for the Registration of Pollutant Discharge for Stationary Pollution Sources (Trial Implementation) (《固定污染源排污登記工作指南(試行)》) issued by the MEE on January 6, 2020 and taking effect on the same date, pollutant discharge registration applies to enterprises that are specifically exempted from applying for a formal pollutant discharge permit due to factors such as their small-scale pollutant generation, limited discharge volume, and minor environmental impact, and are instead required to complete the registration process in accordance with applicable provisions.

Under the Measures for the Administration of Permits for the Discharge of Urban Sewage into the Drainage Network (《城鎮污水排入排水管網許可管理辦法》), promulgated in January 2015, amended in December 2022, and effective in February 2023, enterprises, public institutions, and

individual business operators engaged in industries such as manufacturing, construction, catering, and medical services (or other activities involving sewage generation) that need to discharge sewage into urban drainage facilities shall apply for a drainage license.

REGULATIONS ON EMPLOYMENT AND SOCIAL WELFARE

Employment

The PRC Labor Law (《中華人民共和國勞動法》), which was promulgated by the NPC in 1994, and most recently amended in 2018, stipulates the relationship between employers and employees. Pursuant to the PRC Labor Law, employers must establish and improve the system for occupational safety and healthcare, provide training on occupational safety and healthcare to employees, comply with national and local regulations on occupational safety and healthcare, and provide necessary labor protective supplies to employees.

The PRC Labor Contract Law (《中華人民共和國勞動合同法》), which was promulgated by the NPC in 2007, amended in 2012 and came into effect in 2013, and the Implementation Regulations on Labor Contract Law (《中華人民共和國勞動合同法實施條例》) which was promulgated by the State Council and came into effect in 2008, specifies the terms and conditions included in labor contracts to protect the rights and interests of the employees.

Social Insurance

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》), promulgated by the NPC in 2010, effective in 2011 and most recently amended on December 29, 2018, all employers and employees in China are required to participate in pension insurance, medical insurance, unemployment insurance, maternity insurance and occupational injury insurance. Contributions to maternity and occupational injury insurance are fully borne by the employer, while contributions to pension, medical and unemployment insurance are jointly borne by both the employer and the employee. Any employer who fails to make the required contributions may be fined and ordered to compensate the deficit within a prescribed time limit.

According to the Social Insurance Law 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 most recently amended on March 24, 2019, enterprises are required to make social insurance contributions for their employees in a timely and full manner.

On July 31, 2025, the Supreme People's Court of the PRC promulgated the Interpretation II of the Supreme People's Court on Several Issues Concerning the Application of Law in Labor Dispute Cases (the "**Interpretation II in 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）》), which took effect from September 1, 2025. Pursuant to the Interpretation II in Labor Dispute Cases, any arrangement for non-payment of social insurance contributions, whether through unilateral undertaking by employees or mutual agreement between the employers and the employees, shall be deemed invalid. If the employee terminates the labor contract on the grounds that the employer has failed to make social insurance contributions in accordance with applicable laws and regulations, and claims economic compensation from the employer, such claims shall be upheld by the people's court.

The Regulation on the Administration of Housing Provident Funds (《住房公積金管理條例》) issued by the State Council in 1999 and last revised in 2019 provides that enterprises must register with the competent managing center for housing funds and shall contribute to the Housing Provident Fund for any employee on its payroll. Where an employer fails to pay up housing provident funds within the prescribed time limit, the employer may be fined and ordered to make payment within a certain period. Where the contribution has not been made after the expiration of the time limit, the enterprises may be subject to compulsory enforcement by the People's Court.

REGULATIONS ON FOREIGN EXCHANGE

The principal regulations governing foreign exchange in China are the Foreign Exchange Administration Regulations of the PRC (《中華人民共和國外匯管理條例》), which was promulgated by the State Council on January 29, 1996 and most recently amended on August 5, 2008. Pursuant to this regulation and other PRC rules and regulations on currency conversion, Renminbi is freely convertible for payments of current account items, such as trade-related and service-related foreign exchange transactions and dividend payments; however, it is not freely convertible for capital account items, such as direct investment, loan or investment in securities outside China unless prior approval is obtained from the State Administration of Foreign Exchange ("**SAFE**") or its local counterpart.

The Notice on Further Simplifying and Improving the Direct Investment-related Foreign Exchange Administration Policies (《關於進一步簡化和改進直接投資外匯管理政策的通知》) (the "**SAFE Circular 13**") promulgated by SAFE on February 13, 2015 and amended on December 30, 2019, cancels the administrative approval requirements for foreign exchange registration of domestic direct investment and overseas direct investment, and simplifies foreign exchange-related registration procedures. Pursuant to SAFE Circular 13, investors shall complete registration with qualified banks for both domestic direct investment and overseas direct investment.

The Circular on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《關於改革和規範資本項目結匯管理政策的通知》) (the "**SAFE Circular 16**") was promulgated by SAFE on June 9, 2016 and amended on December 4, 2023. Pursuant to SAFE Circular 16, enterprises registered in the PRC may convert their foreign debts into Renminbi at their own discretion. The circular further reiterates the principle that Renminbi converted from a company's foreign currency-denominated capital shall be used for expenditures under the current account within its business scope or the expenditure under the capital account permitted by laws and regulations.

According to the Circular of the State Administration for Foreign Exchange on Optimizing Foreign Exchange Administration to Support the Development of Foreign-related Business (《國家外匯管理局關於優化外匯管理支持涉外業務發展的通知》), promulgated and effective on April 10, 2020, the SAFE has promoted nationwide reforms to facilitate payments under capital accounts. Eligible enterprises are permitted to use funds from capital account income (including capital contributions, foreign debts, and overseas [**REDACTED**]) for domestic payments, and are no longer required to provide banks with supporting documents to prove the authenticity of such transactions in advance. This permission is subject to the requirement that the enterprises' fund use is genuine, compliant, and in line with current administrative regulations governing the use of capital account income. In accordance with relevant requirements, the involved banks shall conduct ex post random checks, while local branches of SAFE shall strengthen both in-process and post-process oversight.

According to the "Guidelines for Foreign Exchange Business under Capital Accounts (2024 Edition)" (《資本項目外匯業務指引》(2024年版)) issued by the SAFE on April 3, 2024, in principle, funds raised by domestic companies through overseas [**REDACTED**] should be repatriated to China in a timely manner, and may be repatriated in RMB or foreign currency. The use of such funds shall be consistent with the relevant contents set out in the document, corporate bond offering documents, shareholder circulars, board resolutions, shareholders' meeting resolutions, and other publicly disclosed materials. Domestic companies that use funds raised from overseas [**REDACTED**] to conduct overseas direct investment, overseas securities investment, overseas lending, or other related activities shall comply with the relevant foreign exchange management regulations.

On September 12, 2025, the SAFE issued the Circular of the State Administration for Foreign Exchange on Deepening of Reform in the Administration of Foreign Exchange for Cross-border Investment and Financing (《關於深化跨境投融資外匯管理改革有關事宜的通知》) (the "**SAFE Circular 43**"), cancels the registration requirements for domestic reinvestment by foreign-invested enterprises stipulated by the Circular on Further Deepening the Reform to Facilitate Cross-border Trade and Investment (《國家外匯管理局關於進一步深化改革促進跨境貿易投資便利化的通知》) (the "**SAFE Circular 28**"). Additionally, it further narrows the negative list governing the use of capital account income originally stipulated under the SAFE Circular 28. Pursuant to the SAFE Circular 43, the restriction about funds "shall not be used to purchase residential properties for non-self-use purposes (except for enterprises engaged in real estate development or leasing operations)" has been removed from the negative list.

According to the Circular of the People's Bank of China and the State Administration for Foreign Exchange on Issues Concerning the Administration of Funds Raised by Domestic Enterprises Listed Overseas (《中國人民銀行國家外匯管理局關於境內企業境外上市資金管理有關問題的通知》) issued on December 24, 2025 and became effective from April 1, 2026, domestic enterprises conducting overseas listings shall, within 30 working days from the first trading date of their overseas listing or the completion of the over-allotment, apply to the banks at the provincial level of their place of registration for overseas listing registration formalities.

REGULATIONS ON TAXATION

Income Tax and Dividend Tax

According to the PRC Enterprise Income Tax Law (《中華人民共和國企業所得税法》) promulgated by the NPC on March 16, 2007, and most recently amended on December 29, 2018 and effective from the same date and the Enterprise Income Tax Implementation Regulations of the PRC (《中華人民共和國企業所得税法實施條例》) promulgated by the State Council on December 6, 2007, and most recently amended on December 6, 2024 and effective from January 20, 2025, enterprises are classified as either "resident enterprises" and "non-resident enterprises". Resident enterprises are enterprises incorporated in China under the PRC law, or enterprises incorporated under the law of a foreign country (region) but are with its de facto management located within China. Non-resident enterprises are enterprises which are incorporated in accordance with the law of a foreign country (region) with its actual management located outside China, but which either maintains an office or place of business in China, or derives China-sourced income despite having no such office or place of business in China. Resident enterprises are subject to a standard enterprise income tax rate of 25% on their global income. Key advanced and new technology enterprises supported by the State are eligible for a preferential enterprise income tax rate of 15%.

Pursuant to the Circular on Issues Relating to the Withholding of Enterprise Income Tax by Mainland China Resident Enterprises on Dividends Paid to Overseas Non-mainland China Resident Enterprise Shareholders of H Shares (《國家税務總局關於中國居民企業向境外H股非居民企業股東派發股息代扣代繳企業所得税有關問題的通知》), issued by the State Taxation Administration (the "**STA**") on November 6, 2008, a Chinese resident enterprise distributing dividends to its overseas non-resident enterprise shareholders holding H-shares for fiscal years commencing in or after 2008 is required to withhold Enterprise Income Tax at a uniform rate of 10%.

Value-Added Tax

Pursuant to the PRC Value-Added Tax Law (《中華人民共和國增值税法》), which was promulgated by the SCNPC on December 25, 2024 and became effective from January 1, 2026, and the Detailed Rules for the Implementation of the Interim Regulations of the PRC on Value-added Tax (《中華人民共和國增值税暫行條例實施細則》) which was promulgated by the Ministry of Finance (the "**MOF**") on December 25, 1993 and most recently amended on October 28, 2011, and effective from November 1, 2011, all entities or individuals in the PRC engaged in the sale of goods, services, lease of tangible movables or importation of goods are required to pay value-added tax ("**VAT**") at the rate of 13%. Unless otherwise provided, taxpayers engaged in the provision of services and sales of intangible assets are subject to a tax rate of 6%.

REGULATIONS ON SECURITIES ISSUANCE AND OVERSEAS [REDACTED]

Laws and Regulations on Securities Issuance

The Securities Law of the PRC (《中華人民共和國證券法》) (the "**Securities Law**"), which was promulgated by the SCNPC on December 29, 1998, most recently amended on December 28, 2019 and took effect on March 1, 2020, comprehensively regulating activities in the PRC securities market including issuance and trading of securities, takeovers by listed companies, securities exchanges, securities companies and the duties and responsibilities of securities regulatory authorities. The Securities Law further regulates that a domestic enterprise [**REDACTED**] overseas directly or indirectly or [**REDACTED**] their securities overseas shall comply with the relevant provisions of the State Council and for subscription and trading of shares of domestic companies using foreign currencies, detailed measures shall be stipulated by the State Council separately. The CSRC is the securities regulatory authority set up by the State Council to supervise and administer the securities market according to law, maintain order in the market, and ensure the market operates in a lawful manner.

CSRC Filing Requirements for Overseas [REDACTED] and [REDACTED]

On February 17, 2023, 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 "**Overseas Listing Trial Measures**") and five supporting guidelines (together with the Overseas Listing Trial Measures, collectively referred to as the "**Overseas Listing Regulations**"). Under the Overseas Listing Measures and its supporting guidelines, PRC domestic companies that seek to [**REDACTED**] or [**REDACTED**] securities overseas, either directly or indirectly, shall file with the CSRC within 3 working days after its [**REDACTED**] for overseas [**REDACTED**] is submitted.

Pursuant to the Overseas Listing Trial Measures, no overseas [**REDACTED**] and [**REDACTED**] shall be made under any of the following circumstances: (i) such securities [**REDACTED**] and [**REDACTED**] are explicitly prohibited by PRC laws and regulations; (ii) such securities [**REDACTED**] and [**REDACTED**] constitute a threat to or endanger national security; (iii) the PRC domestic company, or its controlling shareholder(s) and the actual controller, have committed relevant 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 PRC domestic company is 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 controlling shareholder(s) or by other shareholder(s) that are controlled by the controlling shareholder(s) and/or the actual controller.

CSRC Requirements on Confidentiality and Archives Administration for Overseas [REDACTED] and [REDACTED]

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》) (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 [**REDACTED**] subjects, documents and materials involving state secrets and working secrets of state agencies, it shall apply to the competent authority for approval, and file the same with the secrecy administration department at the same level for the record. To provide accounting records or photocopies of accounting records to entities and individuals such as the relevant securities companies, securities service agencies and overseas regulatory authorities, a domestic enterprise shall perform the corresponding procedures in accordance with the relevant provisions of the State.

RELEVANT LAWS AND REGULATIONS IN CERTAIN OVERSEAS JURISDICTIONS

U.S. Federal and State Regulations of Medical Devices

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

In the United States, for a company that manufactures, imports, or distributes a medical device, it would be subject to FDA pre- and post-market requirements, such as, for many medical devices, obtaining a 510(k) clearance or premarket approval prior to marketing, registering its manufacturing facility, listing the products it manufactures, following FDA's good manufacturing practices, and having a required quality system, which includes adverse event reporting and recall policies. If a company acts as an importer or distributor in the United States of an FDA regulated medical device, it would be required to register as an importer and have quality systems, including recall policies and related post-marketing requirements in place.

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

U.S. Labor Laws and Employment Laws

The employment of individuals in the United States is governed by federal, state and sometimes local laws. Federal laws set the minimum legal standard for employee rights; state and local laws may set different standards. Most employees in the United States are hired "at-will," meaning that their employment can be terminated at any time, with or without notice or cause. At-will employment can be modified by an employment agreement between an employee and employer, but in no event may an employee be terminated for an illegal reason (such as discrimination or harassment), nor may an employee be terminated or retaliated against for engaging in a legally protected activity. Individual verification of eligibility to work in the United States is required.

U.S. Intellectual Property Law

The United States has both federal and state laws that govern intellectual property rights. Some intellectual property rights are governed exclusively by federal law, while others are governed by both federal and state laws.

Copyrights. Copyrights are exclusively governed by federal law. A copyright is a set of exclusive rights owned by the creator of an original work that is fixed in tangible form. A copyright (i) covers expressions, not ideas; (ii) cannot be purely functional; and (iii) must be an original work. U.S. copyright law is governed by the Copyright Act of 1976, codified at 17 U.S.C. 101 et seq.

Patents. Patents are exclusively governed by federal law. A patent is a government grant providing the patent owner with the right to exclude others from manufacturing, using, or selling a claimed invention within the United States or practicing a claimed method within the United States. A patent is obtained by filing an application with the U.S. Patent and Trademark Office

("USPTO") claiming a useful, novel invention. The application must comply with various requirements set forth in the Patent Act (codified at 35 U.S.C.§1etseq) and regulations established by the USPTO, which is an agency within the U.S. Department of Commerce. A patent owner can bring an infringement action in a U.S. federal court or, where the importation of infringing goods is involved, before the International Trade Commission. A patent owner may be entitled to remedies against an infringing party including preliminary and permanent injunctions, direct damages (including lost profits or royalties), and, in exceptional cases, treble damages and attorneys' fees.

Trademarks and Service Marks. Trademarks and service marks are governed by both federal and state laws. A "mark" is the use of one or more words, symbols, or logos to identify and distinguish the mark owner's goods and/or services. A trademark is a mark used for goods; a service mark is a mark used in connection with providing services. U.S. trademarks and service marks generally must (i) be different from prior marks, (ii) not be generic, and (iii) not be descriptive. U.S. federal trademark law is governed by the Lanham Act, codified at 15 U.S.C. § 1051 et seq. The USPTO is responsible for examining trademark and service mark applications and either granting or rejecting applications to register marks. Once granted, a trademark or service mark provides its owner with nationwide exclusivity within one or more particular fields of use. State law is an alternative basis for trademark and service mark rights, either under specific state laws or under common law. States generally provide common law rights in trademarks and service marks upon their first use in commerce, without requiring registration. Some states have registries for trademarks and service marks. The rights inherent in such marks are limited to the state where they are used. The owner of a trademark generally has a cause of action for infringement against a defendant who uses a mark that is likely to cause confusion in the relevant marketplace about the source of goods or services, or likely to cause consumers to falsely infer some association or affiliation between the trademark owner and the defendant. A plaintiff may be entitled to preliminary and permanent injunctions (including destruction of infringing articles), actual monetary damages, accounting of the defendant's profits, and in some cases, attorneys' fees.

Trade Secrets. Trade secrets are governed by both federal and state laws. A trade secret is information that (i) has independent economic value from being generally unknown by the public and (ii) is the subject of reasonable efforts under the circumstances to maintain its secrecy. Trade secrets are governed by both federal and state law. The Defend Trade Secrets Act, codified at 18 U.S.C. § 1836, et seq. ("**DTSA**"), is the federal trade secret law. Enacted recently in 2016, the DTSA applies only to trade secrets used in interstate or foreign commerce. The DTSA provides specific remedies for trade secret misappropriation, including ex parte seizure in specific and generally rare instances. The DTSA is similar to the Uniform Trade Secret Act ("UTSA"), a model set of laws enacted by almost all fifty states within the U.S. A trade secret owner may often have a choice in enforcing its trade secret rights under the DTSA or a relevant state's version of the UTSA.

U.S.-Based Data Privacy Regulations

The U.S. federal government and various states and governmental agencies also have adopted or are considering adopting various laws, regulations, and standards regarding the collection, use, retention, security, disclosure, transfer, and other processing of sensitive and personal information, including, without limitation and in each case as amended from time to time, the Fair Credit Reporting Act, 15 U.S.C. 1681; the Federal Trade Commission Act, 15 U.S.C. § 45; the CAN-SPAM Act, 15 U.S.C. § 7701 et seq.; the Telephone Consumer Protection Act, 47 U.S.C. § 227; the Telemarketing and Consumer Fraud and Abuse Prevention Act, 15 U.S.C. § 6101 et seq.; the Health Insurance Portability and Accountability Act of 1996; the Electronic Communications Privacy Act, 18 U.S.C. §§ 2510-22; and the Stored Communications Act, 18 U.S.C. § 2701-12. In addition, many states have laws that protect the privacy and security of sensitive and personal information. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international, or other state laws, and such laws may differ from each other, which may complicate compliance efforts. For example, in 2018, California enacted the California Consumer Privacy Act, which came into effect on January 1, 2020, and has since been amended by the California Privacy Rights Act which came into effect on January 1, 2023 (collectively, the "CCPA"). The CCPA creates individual privacy rights for California residents, including rights to opt out of certain processing such as the transfer of personal information for the purpose of cross contextual behavioral advertising, the processing of sensitive personal information for certain purposes, as well as "sales" of personal information, and increases the privacy and security obligations of entities handling personal information of California consumers and meeting certain thresholds. The CCPA is currently enforceable by the California Attorney General, and provides for civil penalties for violations as well as a private right of action for certain data breaches that result in the unauthorized access to, or exfiltration, theft or disclosure of certain types of personal information. This private right of action is expected to increase the likelihood of, and risks associated with, class action data breach litigation. Though regulatory fines have been imposed, the CCPA has not been subject to significant litigation and judicial interpretation and it remains unclear how various provisions will be enforced. Additionally, the CCPA's further expansion under the California Privacy Rights Act may impact our business particularly given its establishment of a new regulatory agency dedicated to enforcing the CCPA's requirements in addition to the California Attorney General, potentially resulting in further uncertainty and requiring us to incur additional costs and expenses, and potentially change our business practices, in an effort to comply.

In addition, many similar laws have been proposed at the federal level and in other states. For instance, the state of Nevada recently enacted a law that went into force on October 1, 2019 and requires companies to honor consumers' requests to no longer sell their data. Violators may be subject to injunctions and civil penalties of up to $5,000 per violation. New legislation proposed or enacted in Illinois, Massachusetts, New Jersey, New York, Rhode Island, Washington, and other states, and a proposed right to privacy amendment to the Vermont Constitution, imposes, or has the potential to impose, additional obligations on companies that collect, store, use, retain, disclose, transfer, and otherwise process confidential, sensitive, and personal information, and will continue to shape the data privacy environment throughout the United States. Currently, there are no United

States (federal or state) privacy laws that explicitly mandate data localization, requiring businesses to store personal information locally within the United States. State laws are changing rapidly and there is discussion in the U.S. Congress of a new federal data protection and privacy.

EEA Regulations of Medical Devices

The two main regulations for medical devices and *in vitro* diagnostics in the EEA are the Regulations (EU) 2017/745 on medical devices and (EU) 2017/746 on *in vitro* diagnostic medical devices. The regulations' main principle is that a manufacturer is legally responsible for ensuring the safety and efficacy of devices. Devices that meet the requirements are labeled with the CE mark and can be freely circulated within the EEA area. Medical devices do not require approval from national authorities before they can be marketed. Depending on the risk classes of devices, a notified body must conduct a conformity assessment before the devices can be freely marketed. This involves the notified body evaluating whether the product complies with the safety requirements in the regulations. Manufacturers based outside the EEA have to appoint an authorised representative, i.e. a party who has received and accepted a written mandate from the manufacturer to act on the manufacturer's behalf in relation to specified tasks with regard to the manufacturer's obligations. The regulations allows for national authorities to introduce national provisions.

EU Regulations of Product Compliance and Product Liability

As a general rule, according to product-related EU law, every product must be designed, manufactured and usable in a way that it does not pose inadequate risks to its user. In addition, electrical and electronic products and equipment must comply with definite technical specifications, specific environmental standards, waste management requirements, eco-design and energy labeling requirements for energy-using products and compatibility requirements in order to avoid inadequate interference with other products (e.g. in terms of electromagnetic compatibility and radio waves). The applicable provisions depend on the specifications of the individual product. In particular, the following non-conclusive product-related regulations may be relevant to our products: Directive 2014/35/EU (Low Voltage Directive), Directive 2014/30/EU (EMC-Directive), Directive 2014/53/EU (Radio Equipment Directive), Directive 2011/65/EU (RoHS Directive), Directive 2012/19/EU (WEEE-Directive), regulations for batteries and accumulators (e.g. Regulation 2023/1542/EU), Directive 2009/125/EC (Eco-design Directive), Regulation (EU) 2017/1369 (Energy Labelling Regulation), Directive 2006/42/EC (Machinery Directive), which has been replaced by Regulation 2023/1230/EU and is already partially applicable, Directive 2001/95/EC (General Product Safety Directive) and Regulation 2023/988 (General Product Safety Regulation coming into force on 13 December 2024), each as amended. In addition, Regulation (EU) 2019/1020 (Market Surveillance Regulation) introduces provisions that supplement, further develop and strengthen the existing market surveillance concept and the official tasks and competences of market surveillance authorities.

Briefly summarized those aforementioned regulations, amongst others, provide for requirements regarding (i) product properties (e.g. restrictions on substances, requirements regarding product construction and design, technical standards, radio or electromagnetic frequencies or other material product qualities), (ii) product labeling (e.g. regarding product and manufacturer/importer identification, applicable markings, e.g. CE-marking and energy efficiency labeling), (iii) registration and notification obligations (e.g. the obligation to register electrical and electronic equipment or batteries/accumulators in public registers and participate in a recycling system), (iv) take-back obligations at end of product's life (e.g. taking back electronic equipment or batteries/accumulators), (v) procedural obligations, such as drawing up specific documentation (e.g. technical obligation comprising testing reports, expert opinions and design drawings, declaration of conformity), and (vi) proper instruction and information to users (e.g. user manual in the language of the country where the product is made available, warnings affixed to the product).

Generally, product-related EU laws are applicable when a product is placed, made available on or imported to the European market. In principle, the acting legal or natural person is considered legally responsible if it acts as manufacturer, authorized representative, importer, distributor or – as expressly provided for in the Market Surveillance Regulation – "fulfillment service provider", i.e. any natural or legal person offering, in the course of commercial activity, at least two of the services warehousing, packaging, addressing and dispatching. A product is placed or made available when it is supplied on the European market for distribution, consumption or use without the need for a transfer of ownership or possession, as it is sufficient for the product to be made available or offered (including online distribution) in a way that merely requires acceptance by another market participant.

Products that do not comply with the aforementioned product compliance requirements cannot be marketed in the EU. The competent authorities are entitled and obliged to take appropriate measures when they have reason to suspect that a product does not fulfill these requirements. Such measures include, but are not limited to: (i) prohibiting the exhibition of such product; (ii) ordering that such products be withdrawn or recalled; and (iii) seizing such products, destroying or having them destroyed or otherwise rendered unusable. Furthermore, non-compliance with product safety regulations is subject to fines.

EU Regulations of Data Protection

European companies are subject to the General Data Protection Regulation (EU) 2016/679 (GDPR), which is promulgated by the European Union. Under certain circumstances, companies established outside the EU also fall under the scope of the GDPR. The GDPR prescribes a risk-based approach to the processing of personal data, i.e. that entities need to establish appropriate risk management practices in order to be able to document and demonstrate compliance, for instance, by conducting regular and ad-hoc risk assessments in various contexts related to the processing of personal data, or risk mitigation.

The GDPR requires entities to process personal data in compliance with a set of general principles that are reflected in specific compliance requirements stipulated by them, for instance: (i) before processing personal data, an entity must ensure that the processing will comply with the general principles set out in the GDPR. These general principles are mainly related to the principle of lawfulness, transparency, purpose limitation, data minimization, accuracy, storage limitation, data security and accountability; (ii) once the entity has assessed the specific intended processing activity, a legal basis for processing the personal data must be identified, and the bases are stipulated in the GDPR; (iii) the GDPR confers data subjects a number of rights with respect to the entity that is processing their personal data and, at the same time, imposes corresponding obligations on the entity; (iv) the GDPR does not mandate that personal data must be stored within the EU. However, it requires that organizations can only transfer personal data to third countries if they ensure an adequate level of protection, either through an adequacy decision by competent authorities or appropriate safeguard measures; (v) the GDPR requires an entity to maintain a record of its processing activities under its responsibility. This record must contain a list of information, such as the purposes of the processing, categories of personal data, categories of recipients etc.; (vi) the GDPR also imposes a requirement to have data processing agreements with companies to whom processing of personal data is outsourced (the "data processor"). The purpose of the data processing agreement is to ensure that the data processor is contractually bound to implement appropriate technical and organizational measures that ensure compliance with the requirements in the GDPR and protect the rights of the data subjects; (vii) the GDPR imposes specific rules and requirements for the transfer of personal data to countries outside the European Union; and (viii) the GDPR allows member states of the European Union to maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.

Non-compliance with the GDPR can result in fines of up to EUR 20 million or 4% of the company's or group's total worldwide annual turnover, whichever is higher. Penalties such as imprisonment may also be imposed. Furthermore, an entity may be held liable for the damages suffered by the data subjects as a result of the non-compliant processing of personal data.

U.S. AND INTERNATIONAL LAWS AND REGULATIONS ON SANCTIONS, EXPORT CONTROL AND TARIFFS

Sanctions Laws and Regulations

United States

The Office of Foreign Assets Control ("OFAC") is the primary agency responsible for administering U.S. sanctions programmes against targeted countries, entities, and individuals. "Primary" U.S. sanctions apply to "U.S. persons" or activities involving a U.S. nexus (e.g., funds transfers in U.S. currency even if performed by non-U.S. persons), and "secondary" U.S. sanctions apply extraterritorially to the activities of non-U.S. persons even when the transaction has no U.S. nexus. Generally, U.S. persons are defined as entities organized under U.S. law (such as companies and their U.S. subsidiaries); any U.S. entity's domestic and foreign branches (sanctions against Iran and Cuba also apply to U.S. companies' foreign subsidiaries or other non-U.S. entities owned or controlled by U.S. persons); U.S. citizens or permanent resident aliens ("green card" holders), regardless of their location in the world; individuals physically present in the United States; and U.S. branches or U.S. subsidiaries of non-U.S. companies.

Depending on the sanctions program and/or parties involved, U.S. law also may require a U.S. company or a U.S. person to "block" (freeze) any assets/property interests owned, controlled or held for the benefit of a sanctioned country, entity, or individual when such assets/property interests are in the United States or within the possession or control of a U.S. person. Upon such blocking, no transaction may be undertaken or effected with respect to the asset/property interest – no payments, benefits, provision of services or other dealings or other type of performance (in case of contracts/agreements) – except pursuant to an authorization or license from OFAC.

OFAC's comprehensive sanctions programmes currently apply to Cuba, Iran, North Korea, the Crimea region of Russia/Ukraine, and the self-proclaimed Luhansk People's Republic (LPR) and Donetsk People's Republic (DPR) regions (the comprehensive OFAC sanctions programme against Sudan was terminated on October 12, 2017). OFAC also prohibits virtually all business dealings with persons and entities identified in the SDN List. Entities that a party on the SDN List owns (defined as a direct or indirect ownership interest of 50% or more, individually or in the aggregate) are also blocked, regardless of whether that entity is expressly named on the SDN List. Additionally, U.S. persons, wherever located, are prohibited from approving, financing, facilitating, or guaranteeing any transaction by a non-U.S. person where the transaction by that non-U.S. person would be prohibited if performed by a U.S. person or within the United States.

United Nations

The United Nations Security Council (the "UNSC") can take action to maintain or restore international peace and security under Chapter VII of the United Nations Charter. Sanctions measures encompass a broad range of enforcement options that do not involve the use of armed force. Since 1966, the UNSC has established 30 sanctions regimes. The UNSC sanctions have taken a number of different forms, in pursuit of a variety of goals. The measures have ranged from comprehensive economic and trade sanctions to more targeted measures such as arms embargoes, travel bans, and financial or commodity restrictions. The UNSC has applied sanctions to support peaceful transitions, deter non-constitutional changes, constrain terrorism, protect human rights and promote nonproliferation.

There are 14 ongoing sanctions regimes which focus on supporting political settlement of conflicts, nuclear non-proliferation, and counter-terrorism. Each regime is administered by a sanctions committee chaired by a non-permanent member of the UNSC. There are ten monitoring groups, teams and panels that support the work of the sanctions committees. United Nations sanctions are imposed by the UNSC, usually acting under Chapter VII of the United Nations Charter. Decisions of the UNSC bind members of the United Nations and override other obligations of United Nations member states.

European Union and United Kingdom

Under European Union sanction measures, there is no "blanket" ban on doing business in or with a jurisdiction targeted by sanctions measures. It is not generally prohibited or otherwise restricted for a person or entity to do business (involving non-controlled or unrestricted items) with a counterparty in a country subject to European Union sanctions where that counterparty is not a Sanctioned Person and not engaged in prohibited activities, such as exporting, selling, transferring or making certain controlled or restricted products available (either directly or indirectly) to, or for use in a jurisdiction subject to sanctions measures, provided that no funds and economic resources are made available to the Sanctioned Persons.

As of January 1, 2021, the United Kingdom was no longer an EU member state. EU law including EU sanctions measures continued to apply to and in the United Kingdom until December 31, 2020. EU sanctions measures had also been extended by the United Kingdom on a regime-by-regime basis to apply in the United Kingdom overseas territories, including the Cayman Islands. Starting from January 1, 2021, the United Kingdom applies its own sanctions programs and has extended its autonomous sanctions regimes to apply to and in the United Kingdom overseas territories.

U.S. Export Controls

The United States has increased export controls restrictions on China through the Export Administration Regulations (the "EAR"), administered by the Bureau of Industry and Security of the U.S. Department of Commerce (the "BIS"), which includes a list of foreign persons on which certain trade restrictions are imposed, including businesses, research institutions, government and private organizations, individuals and other types of legal persons (the "Entity List"). Where a foreign person is included on the Entity List, the export, re-export and/or transfer (in-country) of items which are subject to the EAR generally is prohibited unless the specified license requirements are met. In addition, EAR also maintains a list of items, software, and technology that are subject to export controls (the "Commerce Control List"). The Commerce Control List is primarily based on multilateral export control lists, such as the Wassenaar Arrangement's List of Dual-Use Goods and Technologies and Munitions List, BIS can also implement unilateral licensing requirements and other controls on items subject to U.S. export controls jurisdiction that can restrict exports and reexports to certain countries, as well as transfers within a country to a different end-user or end-use. The Commerce Control List is divided into ten categories, represented by the first digit of the Export Control Classification Number ("ECCN"). Each ECCN is subject to the respective control(s) and licensing requirement applicable for sales to controlled countries and/or entities.

U.S. Tariffs

On May 14, 2024, the Office of the United State Trade Representative announced a plan to raise the tariff rate applicable to U.S. imports of electric vehicles from China from 25% to 100%. On September 13, 2024, the United States Trade Representative announced the final Section 301 tariff increases on imports from China, which imposed a tariff rate of 100% effective from September 27, 2024. China responded with increased tariffs. Since February 2025, both countries raised reciprocal tariffs on each other's imported goods to 125%. However, on May 12, 2025, both the U.S. and China modified these tariff measures: the U.S. removed the 125% tariff and temporarily reduced tariffs on Chinese goods to 10% by suspending a 24% duty for 90 days. The PRC government announced the same tariff adjustments, removing the 125% retaliatory tariff and cutting tariffs on U.S. goods from 34% to 10% for the same period. On August 12, 2025, the US-China tariff truce got extended for another 90 days until November 10, 2025, which was extended to a longer period to November 10, 2026 on November 2, 2025.