

REGULATORY OVERVIEW

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 on January 4, 2000 and most recently amended on December 6, 2024 (effective as of January 20, 2025), the drug administration departments under the State Council and the local people’s governments at various levels are in charge of the supervision and administration of medical devices in the PRC.

According to the Regulations on the Supervision and Administration of Medical Devices (2024 Revision), medical devices in the PRC are subject to a risk-based classification system comprising three categories — Class I, Class II, and Class III. 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. A medical device registration certificate shall be valid for five years. Where a renewal is required upon the expiry of the term of validity, an application for renewal of registration or a filing for record shall be submitted to the original drug administration department six months prior to the expiry of the certificate, in accordance with the adjusted category.

Clinical Trials for Medical Devices

According to the Administrative Measures for the Registration and Filing of Medical Devices, clinical trials are not required for the filing of Class I medical devices but are required for the application for registering Class II and Class III medical devices. Medical devices may be exempt from a clinical trial under any of the following circumstances: (i) with a clear working mechanism, established design, mature manufacturing processes, years of application of similar medical devices on the market with no record of material adverse events, and no change to the general purpose of the device; (ii) safety and effectiveness of the medical device proven through non-clinical evaluation; (iii) safety and effectiveness of the medical device proven through the analysis and evaluation of the data obtained from the clinical trial or application of similar medical devices. The National Medical Products Administration (the “NMPA”) shall prepare, adjust, and release the catalog of medical devices exempt from a clinical trial.

The Administrative Measures for the Registration and Filing of Medical Devices stipulates that, except for the circumstances exempt from clinical evaluation, clinical evaluation shall take place for the registration and filing of medical device products. On September 16, 2021, the NMPA issued the Notice on the Issuing the Catalog of Medical Devices Exempt from Clinical Evaluation (《關於發佈免於進行臨床評價醫療器械目錄的通告》), which came into effect on October 1, 2021, and last amended on May 12, 2025.

Jointly promulgated by the NMPA, and the National Health Commission (the “NHC”) on March 24, 2022, and effective from May 1, 2022, the Good Clinical Practice for Medical Devices (《醫療器械臨床試驗質量管理規範》) covers the entire process of a clinical trial of medical devices, including, among others, the protocol design, execution, monitoring, verification and inspection, as well as data collection, recording, analysis and conclusion and reporting procedure of a clinical trial. To carry out clinical trials of medical devices, the applicant shall organize to prepare a scientific and reasonable clinical trial protocol based on the categories, risks and intended

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uses of the medical devices for clinical experiments. Applicants for the clinical trials of medical devices are responsible for initiating, applying for, organizing and monitoring such clinical trials, and shall be responsible for the authenticity and reliability of the clinical trials.

Medical Devices Production License

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 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 life cycle of medical devices.

Unique Device Identification (UDI) System

Pursuant to the Rules for the Medical Device Unique Identification System (《醫療器械唯一標識系統規則》) promulgated by the NMPA on August 23, 2019, and the subsequent announcements regarding the implementation of the first, second, and third batches of Unique Device Identification (“UDI”), the regulatory framework mandates that registrants and filers are responsible for the creation and maintenance of UDIs, the affixation of data carriers, and the submission of relevant data to the UDI Database. This system ensures full-process traceability for medical devices from production to clinical use.

Medical Devices Operation License

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.

“Two Invoice System” (兩票制) for Medical Devices

Pursuant to the Notice on Opinions on the Implementation of the “Two Invoice System” in Drug Procurement by Public Medical Institutions (for Trial Implementation) (《關於在公立醫療機構藥品採購中推行“兩票制”的實施意見(試行)的通知》) (the “Notice”), issued on December 26, 2016, the “Two Invoice System” refers to one invoice from the pharmaceutical manufacturer to the distribution enterprise and one invoice from the distribution enterprise to the medical institution.

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According to the Notice on Consolidating the Achievements of Cancelling Pharmaceutical 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》) issued on March 5, 2018, high value medical consumables shall be subject to classified and centralized purchase, and the “Two Invoice System” in relation to high-value medical consumables shall be gradually implemented.

Pursuant to the Notice on Printing and Distributing the Reform Plan for the Management of High-value Medical Consumables (《國務院辦公廳關於印發治理高值醫用耗材改革方案的通知》) issued by the General Office of the State Council on July 19, 2019, local authorities are encouraged to reduce the processes for the circulation of high-value medical supplies and promote open and transparent purchase and sale through means such as the “Two Invoice System” after considering the actual situation.

At present, some provinces in the PRC have issued relevant regulations on the “Two Invoice System” for medical supplies. Nevertheless, there is no exact implementation timeline for the “Two Invoice System” for medical devices, with the reform still in progress.

Imports and Exports of Medical Devices

The Foreign Trade Law of the PRC (2022 Revision) (《中華人民共和國對外貿易法(2022修正)》) and the 2025 Revision (issued on December 27, 2025 and effective from March 1, 2026) have abolished the mandatory record-filing and registration requirements for foreign trade operators. Unless otherwise stipulated by applicable laws and regulations, the declaration of imported or exported goods and the payment of customs duties may be handled by the consignees or consignors themselves, or alternatively, by their entrusted customs brokers.

Pursuant to the Foreign Trade Law of the PRC (2025 Revision) and the Regulations of the PRC on the Administration of the Import and Export of Goods (《中華人民共和國貨物進出口管理條例》), the state allows the free import and export of goods, and maintains fair and orderly import and export trade of goods according to law. No entity or individual may establish or maintain prohibitive or restrictive measures over the import and export of goods, except for the goods which are explicitly prohibited or restricted by laws or administrative regulations.

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 NMPA on December 24, 2025, and effective as of May 1, 2026 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 for medical devices registered or filed in China 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, which constitutes the Certificate for Exportation of Medical Device (I). For medical devices intended solely for export without domestic registration or record filing in China, the Certificate for Exportation of Medical Device (II) may be issued where the manufacturer has obtained a medical device production license or completed production record filing procedures.

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) assertions 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 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.

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

Pursuant to Regulations on 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 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.

Product Safety

Pursuant to the Production Safety Law of the PRC (《中華人民共和國安全生產法》) promulgated by the Standing Committee of the National People’s Congress (the “SCNPC”) on June 29, 2002, and amended in August 2009, August 2014 and June 2021 respectively, to strengthen production safety supervision and management, and prevent and reduce production safety accidents to safeguard the lives and property of the people, and promote the sustained and sound economic and social development, the state has established systematic and principled provisions at the legislative level on production safety guarantees for production and business operation entities, the production safety rights and obligations of employees, production safety supervision and administration, emergency response and rescue, investigation and handling of production safety accidents, as well as corresponding legal liabilities.

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.

REGULATIONS ON PERSONAL INFORMATION SECURITY AND DATA PROTECTION

The Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》), which took effect on June 1, 2017. On October 28, 2025, the Standing Committee of the National People’s Congress revised the Cybersecurity Law, and the revised version came into force on January 1, 2026. The revised law has increased the liabilities of the network operators for violations, which stipulates that network operators must comply with laws and regulations and fulfill their obligations to safeguard cybersecurity while conducting business operations and providing services.

The PRC Data Security Law (《中華人民共和國數據安全法》), which was promulgated by the SCNPC on June 10, 2021 and took effect on September 1, 2021, provides that the conduct of data processing activities shall be in compliance with the provisions of laws and administrative regulations, establishing and completing a data security management system for the entire workflow, organizing and conducting data security education and training, adopting corresponding technical measures and other necessary measures to ensure data security, strengthening risk monitoring, taking immediate disposition measures and promptly reporting to relevant authorities when data security incidents occur.

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On August 20, 2021, the SCNPC promulgated the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), which took effect on November 1, 2021, which integrates the scattered rules with respect to personal information rights and privacy protection and aims at protecting the personal information rights and interests, regulating the processing of personal information, ensuring the orderly and free flow of personal information in accordance with the law, and promoting the reasonable use of personal information.

On September 24, 2024, the State Council promulgated the Administration Regulations on Cyber Data Security (《網絡數據安全管理條例》), which took effect on January 1, 2025. The Administration Regulations on Cyber Data Security provides that where the network data processing activities of a network data processor affect or may affect national security, a national security review shall be conducted in accordance with relevant national provisions.

Cybersecurity Review

On December 28, 2021, the Cyberspace Administration of China (the “CAC”), the National Development and Reform Commission of the PRC (the “NDRC”), the Ministry of Industry and Information Technology of the People’s Republic of China (the “MIIT”) and ten other Chinese regulatory authorities jointly promulgated the Cybersecurity Review Measures (《網絡安全審查辦法》), which took effect on February 15, 2022. The Cybersecurity Review Measures mandate cybersecurity reviews under the following three circumstances: (i) when critical information infrastructure operators procure network products or services that affect or may affect national security; (ii) when network platform operators carry out data processing activities that affect or may affect national security; and (iii) when network platform operators possessing personal information of more than 1,000,000 individuals pursue overseas [REDACTED].

Cross-border Data Transfer

On July 7, 2022, the CAC promulgated the Measures for the Security Assessment of Outbound Data Transfers (《數據出境安全評估辦法》), which became effective on September 1, 2022. Pursuant to Article 4 of such measures, data processors shall apply to the CAC for security assessment for the outbound transfer of data under several circumstances, including: (i) the transfer of important data; (ii) the transfer of personal information by critical information infrastructure operators; and (iii) other circumstances where a security assessment is required by the CAC.

Subsequently, on March 22, 2024, the CAC promulgated the Provisions on Promoting and Standardizing Cross-border Data Flows (《促進和規範數據跨境流動規定》) with effect from March 22, 2024, which further refined the regulatory framework for cross-border data transfers. These Provisions clarify the specific thresholds and application scenarios for the three major data export mechanisms, namely: (i) the security assessment of outbound data transfers; (ii) the execution of the standard contract for the outbound transfer of personal information; and (iii) the implementation of personal information protection certification.

CORPORATE GOVERNANCE AND OVERSEAS 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 but not limited to: (i) 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; (ii) 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 (iii) 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.

Pursuant to the Regulations on Foreign Exchange Administration of the Overseas Direct Investment of Domestic Institutions (《境內機構境外直接投資外匯管理規定》) promulgated by the State Administration of Foreign Exchange (the “SAFE”) on July 13, 2009 and effective from August 1, 2009, upon obtaining approval for relevant investment, a mainland Chinese enterprise shall apply for foreign exchange registration for its overseas direct investments. 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》) promulgated by SAFE on February 13, 2015 and amended on December 30, 2019, cancels the administrative approval

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requirements for foreign exchange registration of domestic direct investment and overseas direct investment, and simplifies foreign exchange-related registration procedures. Banks are entitled to review and carry out foreign exchange registration under overseas direct investment directly.

Pursuant to the Administrative Measures for Overseas Investment (《境外投資管理辦法》) promulgated by the MOFCOM on March 16, 2009, amended on September 6, 2014 and effective from October 6, 2014, the MOFCOM and its provincial counterparts are responsible for administering and supervising overseas investments. Overseas investments by enterprises involving sensitive countries or regions, or sensitive industries, shall be subject to approval administration. For other categories of overseas investments, enterprises shall file records with the competent commerce authorities.

Pursuant to the Administrative Measures for Overseas Investment of Enterprises (《企業境外投資管理辦法》) promulgated by the NDRC on December 26, 2017 and effective from March 1, 2018, domestic investing enterprises conducting overseas investments shall comply with the approval or filing procedures required by competent authorities. Where the direct investing entity is a local enterprise in mainland China and the Chinese investment amount is below USD300 million in a non-sensitive overseas investment project, the filing authority shall be the provincial-level department of the NDRC in the investing entity's place of registration.

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》), 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》), the China National Intellectual Property Administration, 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.

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 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.

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LAWS AND REGULATIONS ON ANTI-UNFAIR COMPETITION

According to the Anti-Unfair Competition Law of the People’s Republic of China (《中華人民共和國反不正當競爭法》) (the “**Anti-Unfair Competition Law**”) amended by the SCNPC on June 27, 2025 and came into effect on October 15, 2025, unfair competition refers to the conduct of an operator who, in the course of production and operation activities, violates the Anti-Unfair Competition Law, disrupts the order of market competition and harms the lawful rights and interests of other operators or consumers. According to the Interim Provisions of the State Administration for Industry and Commerce on Banning Commercial Bribery (《國家工商行政管理局關於禁止商業賄賂行為的暫行規定》) (the “**Provisions on Banning Commercial Bribery**”) promulgated by the State Administration for Industry and Commerce on November 15, 1996, commercial bribery refers to the use of money or other means by a business operator to bribe an entity or individual for the sale or purchase of goods. The term “**other means**” refers to the provision of any kind of domestic and overseas trips, study tours, and other means of benefit other than the payment of money. According to the Anti-Unfair Competition Law and the Provisions on Banning Commercial Bribery, the supervisory and inspection department may impose a fine according to the severity of the case and confiscate any illegal proceeds.

According to the Compliance Guidelines for Pharmaceutical Enterprises to Prevent Commercial Bribery Risks (《醫藥企業防範商業賄賂風險合規指引》) (the “**Compliance Guidelines**”) promulgated by the SAMR and became effective on January 10, 2025, medical device enterprises are required to establish and improve robust anti-commercial bribery mechanisms. The Compliance Guidelines emphasize that enterprises shall integrate anti-bribery requirements into their overall corporate governance, ensuring that internal control systems are sufficient to identify and mitigate risks throughout the entire lifecycle of business operations.

REGULATIONS ON ENVIRONMENT PROTECTION

Environmental Impact Assessment

Pursuant to the Ecological and Environmental Code (《中華人民共和國生態環境法典》), promulgated by the NPC on March 12, 2026, and effective on August 15, 2026, 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 November 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.

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 License (《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 License 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 License (《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.

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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.

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 and Housing Provident Fund

According to the Provisional Regulations on the Collection and Payment of Social Insurance Premium (《社會保險費徵繳暫行條例》), the Regulations on Work Injury Insurance (《工傷保險條例》), the Regulations on Unemployment Insurance (《失業保險條例》) and the Trial Measures on Employee Maternity Insurance of Enterprises (《企業職工生育保險試行辦法》), an enterprise in the PRC must provide a benefit plan for their employees, which include basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance. An enterprise must provide social insurance by processing social insurance registration with local social insurance agencies, and must pay or withhold relevant social insurance premiums for or on behalf of its employees.

The Social Insurance Law of the People’s Republic of China (《中華人民共和國社會保險法》) promulgated by the Standing Committee of the NPC on October 28, 2010, last amended and came into effect on December 29, 2018, regulates basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance, and has elaborated in detail the legal obligations and liabilities of an employer who does not comply with relevant laws and regulations on social insurance.

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, 1999, and last amended and came into effect on March 24, 2019, stipulates that an employer shall register with the Housing Provident Fund Management Centre for housing provident fund contributions and set up a housing provident fund account for its employees. The housing provident fund contributions paid by an individual employee and housing provident fund contributions paid by his/her employer shall vest to the individual employee.

Pursuant to the PRC Social Insurance Law (《中華人民共和國社會保險法》) and the Regulations on Administration of Housing Provident Fund (《住房公積金管理條例》), if an employer fails to make social insurance contributions in full, the relevant authorities could order the employer to pay, within a prescribed time limit, the outstanding amount with an additional late payment penalty at the daily rate of 0.05%, and if the employer fails to make the overdue contributions within such time limit, a fine equal to one to three times the outstanding amount may be imposed. If the employer engages third-party human resource agencies to pay the housing provident funds or fails to register and establish an account for housing provident funds, the authority could order the employer to correct it within a prescribed time limit, where failure to do so at the expiration of the time limit shall result in a fine of not less than RMB10,000 nor more than RMB50,000 being imposed. Where an employer is overdue in the payment and deposit of, or underpays, the housing provident funds, the authority could order it to make the payment and deposit within a prescribed time limit, and where the payment and deposit has not been made after the expiration of the time limit, an application may be made to a People’s Court of the PRC for compulsory enforcement.

On July 31, 2025, the PRC Supreme People’s Court promulgated the Interpretation II by the Supreme People’s Court of the PRC on Legal Issues 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)》) (the “**Interpretation II**”), which took

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effect on September 1, 2025. Article 19(1) of Interpretation II stipulates that if an employer and an employee agree or the employee undertakes that social insurance contributions need not be paid, the People’s Court shall deem such agreement or undertaking invalid. Furthermore, where an employer fails to pay social insurance contributions in accordance with the law, and the employee seeks to terminate the labor contract and claims economic compensation from the employer pursuant to Article 38, Paragraph 1, Item (3) of the PRC Labor Contract Law, the People’s Court shall support such claims in accordance with the law, which clarifies that employees are entitled to request termination of their labor contracts and receive corresponding economic compensation under the PRC Labor Contract Law if the employer fails to make social insurance contributions in accordance with the law.

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, RMB is freely convertible for payments of current account items, such as trade-related and service-related foreign exchange transactions and dividend payments; however, conversion for capital account items, such as direct investment, loans, or investments in securities outside China, requires prior approval is obtained from SAFE or its local counterpart.

According to the Notice of the State Administration of Foreign Exchange on Issues concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局關於境外上市外匯管理有關問題的通知》) (the “**Notice Concerning the Management of Funds**”) issued by the SAFE on December 26, 2014, the domestic companies shall register the overseas [REDACTED] with the foreign exchange control bureau located at its registered address in 15 working days after completion of the overseas [REDACTED] and [REDACTED]. The funds raised by the domestic companies through overseas [REDACTED] may be repatriated to China or deposited overseas, provided that the intended use of the fund shall be consistent with the contents of the document and other public disclosure documents. While, according to the Notice by the People’s Bank of China and the State Administration of Foreign Exchange of Issues Concerning the Management of Funds for Domestic Enterprises Listing Abroad (《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》) (the “**New Notice Concerning the Management of Funds**”) promulgated by the PBOC and the SAFE on December 24, 2025 and will come into effect on April 1, 2026, which will replace Notice Concerning the Management of Funds. According to the New Notice Concerning the Management of Funds, domestic enterprises conducting overseas [REDACTED] shall, within 30 working days from the first [REDACTED] day of overseas [REDACTED] or after completion of the [REDACTED], apply for overseas listing registration at a bank within the province/municipality with independent planning status where they are registered. Funds raised by domestic enterprises through overseas [REDACTED] shall, in principle, be repatriated to China in a timely manner. If such funds are retained overseas for purposes such as overseas direct investment, overseas securities investment, or oversea lending, approval or filing documents from the competent business authorities must be obtained before the completion of the overseas issuance or the [REDACTED], and relevant cross-border fund management regulations must be complied with.

REGULATIONS ON TAXATION

Income Tax Law

According to the PRC Enterprise Income Tax Law (《中華人民共和國企業所得稅法》) (the “**EIT Law**”) 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稅法實施條例》) (the “**Implementation Regulations for the EIT Law**”) 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%.

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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 (《國家稅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稅有關問題的通知》), 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

The PRC Value-Added Tax Law (《中華人民共和國增值稅法》) has been promulgated by the SCNPC on December 25, 2024, and became effective on January 1, 2026. Entities and individuals (including individual industrial and commercial households) that sell goods, services, intangible assets, or immovables, or import goods within the territory of the People’s Republic of China are taxpayers of VAT, and shall pay VAT in accordance with this Law. Pursuant to the VAT Law, the VAT rate will be: (1) 13%, for taxpayers’ sale of goods, labor services of processing, repairs or replacement, or tangible movable property leasing services or import of goods, except for those specified in subparagraphs 2, 4 and 5 herein; (2) 9%, for taxpayers’ sale of transportation, postal, basic telecommunications, construction, or immovable leasing services, sale of immovables, transfer of the rights to use land, or sale or import of the following goods, except for those specified in subparagraphs 4 and 5 herein; (3) 6%, for taxpayers’ sale of services or intangible assets, except for those specified in subparagraphs 1, 2 and 5 herein; (4) Zero, for taxpayers’ export of goods, except it is otherwise provided for by the State Council; (5) Zero, for the sale of services or intangible assets within the scope as prescribed by the State Council by domestic entities and individuals across national borders.

REGULATIONS ON SECURITIES ISSUANCE AND OVERSEAS [REDACTED] AND [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 [REDACTED] of securities, takeovers by [REDACTED] companies, securities exchanges, securities companies and the duties and responsibilities of securities [REDACTED] authorities. The Securities Law further regulates that a domestic enterprise [REDACTED] and [REDACTED] overseas directly or indirectly or [REDACTED] and [REDACTED] their securities overseas shall comply with the relevant provisions of the State Council and for subscription and [REDACTED] 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 Regulations, 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 the 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.

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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 Management Work Related to the 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**”), 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] and [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.

REGULATIONS RELATED TO THE “FULL-CIRCULATION” OF H-SHARE

“Full circulation” means [REDACTED] and [REDACTED] on the Stock Exchange of the domestic unlisted shares of an H-share [REDACTED] company (the “**H-share [REDACTED] company**”), including unlisted domestic shares held by domestic shareholders prior to overseas [REDACTED], unlisted domestic shares additionally issued after overseas [REDACTED], and unlisted shares held by foreign shareholders. On August 10, 2023, the CSRC announced the Guidelines for the “Full Circulation” Program for Domestic Unlisted Shares of H-share Listed Companies (2023 Revision) (《H股公司境內未上市股份申請“全流通”業務指引(2023修訂)》) (the “**Guidelines for the ‘Full Circulation’**”).

According to the Guidelines for the “Full Circulation”, shareholders of domestic unlisted shares may determine by themselves through consultation on 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 company may be entrusted to file with the CSRC. Domestic companies limited by shares that have not been [REDACTED] may file with the CSRC for the “Full circulation” at the time of their [REDACTED] and [REDACTED] overseas.

On December 31, 2019, China Securities Depository and Clearing Corporation Limited (the “**CSDC**”) and Shenzhen Stock Exchange jointly announced the Measures for Implementation of the H share “Full Circulation” business (《H股“全流通”業務實施細則》) (the “**Measures for Implementation**”). The businesses of cross-border transfer registration, maintenance of deposit and holding details, transaction entrustment and instruction transmission, settlement, management of settlement participants, services of nominal holders, etc. in relation to the H-share “full circulation business”, are subject to the Measures for Implementation. Unlisted shares in the PRC once [REDACTED] and [REDACTED] on the Hong Kong Stock Exchange may not be transferred back to the PRC.

In order to fully promote the reform of H-shares “Full Circulation” and clarify the business arrangement and procedures for the relevant shares’ registration, custody, settlement and delivery, CSDC has promulgated the Notice on the issuance of the “Full Circulation” Pilot Business Guide for H Shares (Trial) (關於發佈《H股“全流通”試點業務指南(試行)》的通知) in May 22, 2018, which specified the business preparation, account arrangement, cross-border share transfer registration and overseas centralized custody, etc.

OVERVIEW OF LAWS AND REGULATIONS IN EUROPEAN UNION

EEA Regulations of Medical Devices

Since the full application of the EU MDR on May 26, 2021, all new medical devices seeking CE marking for the first time must demonstrate full compliance with Regulation (EU) 2017/745 (“**MDR**”).

Medical devices may be placed on the market in the member states of the European Economic Area (the “**EEA**”), comprising the 27 EU Member States together with Norway, Iceland and Liechtenstein, only if they meet the applicable requirements of the MDR and bear the CE (Conformité Européenne) marking. Devices covered by certificates issued under the EU MDD, and

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certain other devices lawfully placed on the market before May 26, 2021 (together, “legacy devices”), may continue to be placed on the market or put into service during the transitional period provided for in Article 120 of the MDR, as amended by Regulation (EU) 2023/607, subject to the conditions set out in that Article.

On May 26, 2021, the Medical Device Directive (“EU MDD”) 93/42/EEC was repealed and replaced by the EU MDR which has become a regulation versus a former directive, for the manufacturers who plan to commercialize medical devices in this region. The MDR is subject to a transition period during which manufacturers of medical devices must update their technical information and processes. While the original transition period was initially set to end in May 2024, Regulation (EU) 2023/607 has formally extended these timelines. The MDR has the same basic requirements as the EU MDD, but is generally more stringent, especially in terms of risk classes and the oversight provided by notified bodies, and more vigilance and post-market surveillance (“PMS”).

The EU MDR aims to ensure the smooth functioning of the internal market with respect to medical devices, taking as a base a high level of protection of health for patients and users, and considering the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products.

Certification System of Medical Devices

Before a device may be placed on the EU market, the manufacturer must carry out the applicable conformity assessment procedure, draw up an EU declaration of conformity in accordance with Article 19 of the MDR and affix the CE marking in accordance with Article 20. The CE marking signifies that the device conforms to the MDR. Depending on the classification of the device and the conformity assessment route followed, the involvement of a notified body is required, in which case the notified body issues one or more of the certificates listed in Annex XII to the MDR. Class I devices, other than those which are placed on the market in sterile condition, have a measuring function or are reusable surgical instruments, do not require the involvement of a notified body and are self-certified by the manufacturer. A certificate issued by a notified body under Chapter I of Annex IX to the MDR relates to the manufacturer’s quality management system and identifies the devices covered by it; there is no single certificate under the MDR which of itself constitutes an approval of a device. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the EU MDR within their jurisdiction. Coordination between the Member States and the European Commission is carried out through the Medical Device Coordination Group established under Article 103 of the MDR. The means for achieving the requirements for CE mark varies according to the nature of the device. Pursuant to the MDR, devices are classified into Class I, Class IIa, Class IIb, and Class III.

Classification is risk-based and is determined by the manufacturer by applying the rules set out in Annex VIII to the MDR, having regard in particular to the intended purpose of the device, its duration of use, whether and in what manner it is invasive, whether it is an active device, and whether it is intended to administer or remove medicinal products, body liquids or other substances to or from the body. The classification applied by the manufacturer is verified by the notified body as part of the conformity assessment. The class of a product determines the requirements to be fulfilled before CE mark can be placed on a product, known as a conformity assessment.

Notified bodies are designated by the authority responsible for notified bodies of a Member State in accordance with Articles 38 and 39 of the MDR, following a joint assessment involving the European Commission and assessors from other Member States, and are listed, together with the scope of their designation, in the European Commission’s NANDO database. Where a notified body established in one Member State has issued the certificates required for a device, no further conformity assessment is required in order for that device to be placed on the market in other Member States. Member States nevertheless retain competence in certain respects, including as regards the language in which the label and the instructions for use are to be supplied under Article 10(11) of the MDR, national registration and notification requirements under Articles 29 and 31 of the MDR, and market surveillance and safeguard measures under Chapter VII of the MDR.

Person Responsible for Regulatory Compliance (PRRC)

Under Article 15 of the MDR, manufacturers must have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices, demonstrated either by a diploma or other formal qualification in law, medicine, pharmacy, engineering or another relevant scientific discipline together with at least one year of professional experience in regulatory affairs or in quality management systems relating to

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medical devices, or by four years of such professional experience. Micro and small enterprises are not required to have such a person within their organisation but must have such a person permanently and continuously at their disposal. An authorised representative must likewise have permanently and continuously at its disposal at least one person responsible for regulatory compliance meeting the same requirements. The person responsible for regulatory compliance is responsible at least for ensuring that the conformity of the devices is appropriately checked in accordance with the quality management system before a device is released; that the technical documentation and the EU declaration of conformity are drawn up and kept up to date; that the post-market surveillance obligations under Article 10(10) of the MDR are complied with; that the reporting obligations referred to in Articles 87 to 91 of the MDR are fulfilled; and, in the case of investigational devices, that the statement referred to in Section 4.1 of Chapter II of Annex XV to the MDR is issued. Such person must not suffer any disadvantage within the manufacturer’s organisation in relation to the proper fulfilment of those duties.

EUDAMED and Registration

In accordance with the MDR, the European Database on Medical Devices (“**EUDAMED**”) has been established to enhance market transparency. Pursuant to the applicable registration obligations, manufacturers must obtain a Single Registration Number through the Actor Registration module and record the Unique Device Identifier (“**UDI**”) in the Device Registration module.

Post-Market Clinical Follow-up (PMCF)

In accordance with the continuous clinical evaluation requirements under the MDR, a Post-Market Clinical Follow-up (“**PMCF**”) plan must be implemented for Class IIb active devices. Pursuant to this plan, clinical data must be proactively collected to confirm the long-term safety and performance of the devices.

Post Market Surveillance and Vigilance for Medical Devices

Pursuant to the EU MDR, the PMS and vigilance of a medical device shall have a PMS system to actively gather and analyze the PMS data throughout the device’s lifetime. Proactive PMS plan and report shall be performed at an appropriate frequency based on the device’s risk-based class. As a key element of this proactive approach, a Post-Market Clinical Follow-up (PMCF) plan is required to continuously update the clinical evaluation and verify the long-term safety and performance of the device. For Class IIa, IIb and III medical devices, as a result of the PMS plan and PMCF findings, a Periodic Safety Update Report (“**PSUR**”) will be generated either biennially (for IIa) or annually (for IIb and III) and made available to the notified body and competent authorities. The medical device manufacturers are also requested by the regulation to report serious incidents and field safety corrective actions, additionally the trend report for any statistical significant increase in the frequency or severity of the non-serious incidents. The aforementioned reporting and PSUR submission shall follow the electronic system established by the European Commission.

Clinical Evaluation and Clinical Data

Under Article 61 of the MDR, a manufacturer must plan, conduct and document a clinical evaluation for each device in accordance with Article 61 and Part A of Annex XIV to the MDR, and must demonstrate conformity with the relevant general safety and performance requirements set out in Annex I on the basis of sufficient clinical evidence.

Clinical data supporting a clinical evaluation may be derived from clinical investigations of the device concerned, from clinical investigations or other studies reported in scientific literature relating to a device for which equivalence to the device in question can be demonstrated, from reports published in peer-reviewed scientific literature on other clinical experience of either the device in question or an equivalent device, or from clinically relevant information obtained from post-market surveillance, in particular post-market clinical follow-up. Where equivalence is relied upon, the manufacturer must demonstrate equivalence in accordance with Section 3 of Part A of Annex XIV and must have a sufficient level of access to the data relating to the device with which equivalence is claimed.

Clinical investigations must be performed in the case of implantable devices and class III devices, subject to the exemptions set out in Article 61(4) to (6) of the MDR. For devices of other classes, including class IIb devices, the MDR does not require the manufacturer to conduct, or to act as sponsor of, a clinical investigation, provided that the clinical evaluation is supported by sufficient clinical evidence.

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Where a clinical evaluation relies on the results of clinical investigations, Article 61(3)(b) of the MDR requires the manufacturer to take due consideration of whether those investigations were performed in accordance with Articles 62 to 80 of, the acts adopted pursuant to Article 81 of, and Annex XV to, the MDR. Chapter VI of the MDR governs clinical investigations carried out within the European Union. Clinical investigations conducted outside the European Union are governed by the law of the country in which they are conducted; where data from such investigations are used to support a clinical evaluation, the notified body assesses, as part of the conformity assessment, the methodological soundness and ethical conduct of the investigation and the relevance and transferability of the resulting data to the European target population and to the device under assessment.

The clinical evaluation and the clinical data on which it is based are documented in a clinical evaluation report, which forms part of the technical documentation and which must be updated throughout the lifecycle of the device with data obtained from post-market surveillance and post-market clinical follow-up.

Clinical Investigations of Medical Devices

Chapter VI of the MDR (Articles 62 to 82) and Annex XV set out the requirements applicable to clinical investigations carried out in the European Union. Article 2(49) of the MDR defines the “sponsor” of a clinical investigation as any individual, company, institution or organisation which takes responsibility for the initiation, for the management and for setting up the financing of the clinical investigation. The sponsor bears the principal obligations under Chapter VI.

A clinical investigation carried out for the purpose of demonstrating conformity of a device may be commenced only after the Member State concerned has authorised it in accordance with Articles 70 to 72 of the MDR and after the investigation has been the subject of a favourable review by an ethics committee, the composition and procedures of which are determined by national law. Applications are submitted through the electronic system for clinical investigations referred to in Article 73 of the MDR, which forms part of EUDAMED. Where a clinical investigation is to be conducted in more than one Member State, the sponsor may make use of the coordinated assessment procedure under Article 78 of the MDR.

Clinical investigations must be designed and conducted in such a way that the rights, safety, dignity and well-being of the subjects are protected and prevail over all other interests, and must comply with the informed consent requirements of Articles 63 to 65 of the MDR, with the requirements applicable to specific groups of subjects set out in Articles 64 to 66, and with Annex XV. In practice, clinical investigations of medical devices are conducted in accordance with the international standard ISO 14155 on good clinical practice for clinical investigations of medical devices for human subjects, and in accordance with the ethical principles of the Declaration of Helsinki.

Substantial modifications to a clinical investigation are subject to notification and, where applicable, authorisation under Article 75 of the MDR. Under Article 80 of the MDR, the sponsor must record and report serious adverse events, device deficiencies that might have led to a serious adverse event, and new findings in relation to any such event. Under Article 77 of the MDR, the sponsor must notify the end of the clinical investigation and, within the periods specified in that Article, submit a clinical investigation report together with a summary presented in terms that are easily understandable to the intended user.

A clinical investigation carried out on a device already bearing the CE marking, within its intended purpose, is subject to Article 74 of the MDR. Where such an investigation would submit subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are invasive or burdensome, the sponsor must notify the Member States concerned in advance and a number of the requirements applicable to clinical investigations conducted for conformity assessment purposes apply. Clinical investigations that are not conducted for any of the purposes listed in Article 62(1) of the MDR are governed by Article 82 of the MDR and by national law.

Data Protection

The processing of personal data in connection with the development, clinical evaluation, registration, distribution and post-market surveillance of medical devices in the European Union is governed principally by Regulation (EU) 2016/679 (the “GDPR”), as supplemented by the national data protection legislation of the Member States.

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Data concerning health constitute a special category of personal data under Article 9(1) of the GDPR. Their processing is prohibited unless one of the conditions in Article 9(2) is satisfied, in addition to a lawful basis under Article 6(1). The conditions most commonly relied upon in the medical device context are the explicit consent of the data subject, processing necessary for scientific research purposes on the basis of Union or Member State law under Article 9(2)(j), and processing necessary for reasons of public interest in the area of public health, including ensuring high standards of quality and safety of medical devices, under Article 9(2)(i). Article 9(4) of the GDPR permits Member States to maintain or introduce further conditions, including limitations, with regard to the processing of data concerning health, with the result that requirements in this area continue to differ between Member States.

Controllers must comply with the principles set out in Article 5 of the GDPR, provide the information required by Articles 13 and 14, respond to requests from data subjects under Articles 15 to 22, implement appropriate technical and organisational measures under Article 32, put in place written data processing agreements with processors under Article 28, and notify personal data breaches to the competent supervisory authority and, where required, to affected data subjects under Articles 33 and 34. A data protection impact assessment under Article 35 is generally required for processing of data concerning health on a large scale.

Transfers of personal data to a country outside the European Economic Area may take place only in accordance with Chapter V of the GDPR, on the basis of an adequacy decision under Article 45, appropriate safeguards under Article 46 (in practice most frequently the standard contractual clauses adopted by the European Commission, supported by an assessment of the legal framework of the destination country), or a derogation under Article 49. A manufacturer established outside the European Union may be subject to the GDPR under Article 3(2) where it offers goods or services to, or monitors the behaviour of, data subjects in the Union, and may be required to designate a representative in the Union under Article 27 of the GDPR.

The MDR itself also contains provisions relevant to information handling, including Article 109 on confidentiality and Article 110 on the protection of personal data processed pursuant to the MDR.

Environmental Compliance and Extended Producer Responsibility (EPR)

In accordance with the WEEE Directive (2012/19/EU), manufacturers of active medical devices are subject to Extended Producer Responsibility (“EPR”) requirements regarding the collection, treatment, and recycling of waste electrical and electronic equipment. Pursuant to the RoHS Directive (2011/65/EU), manufacturers must also ensure that the restricted hazardous substances in the electronic components of their devices do not exceed the mandated concentration limits, thereby ensuring environmental safety throughout the product lifecycle.

Anti-Bribery and Ethical Business Practices

In accordance with the national anti-corruption laws of the EU Member States and the MedTech Europe Code of Ethical Business Practice, all commercial interactions with healthcare professionals and healthcare organizations must adhere to strict standards of transparency and integrity. Pursuant to these ethical guidelines, the provision of improper inducements to influence the procurement, recommendation or prescription of medical devices is strictly prohibited, and any interactions, such as educational grants or consulting arrangements, must be documented and conducted on an arms’ length basis.

Import Requirements of Medical Devices

Under the MDR, strict requirements on manufacturers, importers and distributors of medical devices in the EEA are imposed. Failure to comply with the regulatory requirements may render medical device manufacturers to lose their marketing approvals or be subject to fines or other sanctions. Medical device manufacturers must also have a named person responsible for regulatory compliance, who possesses the requisite expertise in the field of medical devices. Medical device manufacturers must assign a Basic UDI-DI code to the device and provide the code to the UDI database.

Pursuant to article 16 of the MDR, an importer, distributor or any natural or legal person is the one who must assume the obligations incumbent on manufacturers if it does any of the following: (a) it makes available on the EEA market a device under its own name, registered trade name or registered trademark, except if the manufacturer agreed to be identified as such on the label

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and to be responsible for the MDR manufacturers obligations; (b) it changes the intended purpose of a device already placed on the market or put into service; and (c) it modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

OVERVIEW OF LAWS AND REGULATIONS IN THE UNITED STATES

U.S. Federal and State Regulations of Medical Devices

The U.S. Food and Drug Administration (“FDA”) regulates medical devices and products intended for diagnostic use under the Federal Food, Drug, and Cosmetic Act and its implementing regulations (“FDCA”). In the United States, a company that manufactures, imports, or distributes a medical device, would be subject to FDA pre- and post-market requirements, including obtaining a 510(k) clearance or pre-market approval (“PMA”), registering its manufacturing facilities, listing the products it manufactures.

Nonclinical (bench and animal) testing of a device is generally conducted in accordance with the FDA’s Good Laboratory Practice regulations. Where clinical data are required to support a marketing submission, a clinical investigation of a significant-risk device in the United States may only be conducted after the sponsor has obtained an Investigational Device Exemption (“IDE”) from the FDA, in support of which the sponsor must submit, among other things, the results of nonclinical testing, manufacturing information, the investigational plan and any available clinical data. An IDE application is deemed approved 30 days after the FDA receives it unless the FDA notifies the sponsor that the investigation may not begin or may begin only subject to conditions. Clinical investigations must also be approved by an institutional review board and conducted in accordance with the FDA’s regulations on informed consent and good clinical practice.

Beyond clinical trials, the regulatory pathway to market depends on the device classification. Class I devices are subject to general controls and are mostly exempt from premarket review. Most Class II devices, including many active devices, require 510(k) clearance, which demonstrates that the device is “substantially equivalent” to a legally marketed predicate device (or, for certain low-to-moderate risk devices without a predicate, a De Novo classification request). In contrast, Class III or high-risk devices typically require PMA, a more rigorous process requiring independent evidence of safety and effectiveness. Medical device manufacturers are also subject to the FDA’s Quality Management System Regulation (“QMSR”), which replaced the former Quality System Regulation and incorporates ISO 13485:2016 by reference, with effect from February 2, 2026.

The FDA operates a Q-Submission program under which a sponsor may request a Pre-Submission meeting with the FDA to obtain feedback on matters such as the proposed regulatory pathway, the evidence required to support a marketing submission and the design of nonclinical and clinical studies, before making a marketing submission. Feedback provided by the FDA at a Pre-Submission meeting is advisory, is not binding on the FDA and does not constitute a commitment by the FDA to accept, review or approve any subsequent submission, although the FDA generally intends to follow such feedback unless circumstances change, such as the availability of new scientific information.

Products that comprise both a device constituent part and a drug constituent part may be regulated as combination products under applicable FDA requirements. The FDA assigns a combination product to a lead center (the Center for Devices and Radiological Health for device-led products or the Center for Drug Evaluation and Research for drug-led products) based on the product’s primary mode of action, and the lead center consults with the other center in the review. A device-led combination product is reviewed through the device premarket pathways described above, but remains subject to applicable drug requirements in respect of its drug constituent part.

Transition to Quality Management System Regulation (QMSR)

The FDA’s Quality Management System Regulation (“QMSR”), which replaced the former Quality System Regulation and incorporates ISO 13485:2016 by reference, became effective on February 2, 2026.

Medical Device Reporting (U.S. MDR)

In accordance with 21 CFR Part 803, the Medical Device Reporting (“U.S. MDR”) framework mandates strict adverse event reporting obligations. Pursuant to these regulations, a report must be submitted to the FDA within 30 calendar days of becoming aware of a reportable death, serious injury, or malfunction, or within 5 work days if remedial action is required to prevent substantial harm to public health.

REGULATORY OVERVIEW

Unique Device Identification (UDI) and Global Unique Device Identification Database (GUDID)

In accordance with 21 CFR Part 801 and Part 830, medical devices distributed in the U.S. must bear a Unique Device Identifier (“**UDI**”). Pursuant to these requirements, identification data must be submitted to the Global Unique Device Identification Database (“**GUDID**”) to facilitate supply chain traceability.

Recently Passed Law by the U.S. Government: The BIOSECURE Act

On January 25, 2024, the BIOSECURE Act (H.R. 7085) was introduced to the U.S. House of Representatives. The proposed legislation was referred to the House Committee on Oversight and Accountability, and passed by a vote of 306-81 in the House.

At the time, the BIOSECURE Act (H.R. 7085), as proposed, generally would prohibit U.S. executive branch agencies from:

1. procuring or obtaining any biotechnology equipment or service produced or provided by a “biotechnology company of concern;”
2. entering into or renewing a contract with an entity that uses such biotechnology equipment or enters into a contract requiring the use of such biotechnology equipment after the applicable effective date of the prohibition; or
3. providing loan or grant funds to perform either of these functions.

On October 9, 2025, the U.S. Senate passed a revised version of the BIOSECURE Act as an amendment to the NDAA for the year of 2026. The final version of the NDAA containing this legislative language was passed by the Senate and House of Representatives and signed into law by President Trump on December 18, 2025. This version of the Act materially mitigates potential impacts, specifically, the Act eliminates the prior, explicit designation of “BCC” (which had included Wuxi AppTec) and instead adopts a dynamic identification framework tied to the U.S. Department of Defense’s annual List of Chinese Military Companies, also known as the 1260H List, and the U.S. Government also has the ability to designate entities as BCCs through a separate designation process. The 1260H List currently includes, among others, BGI and MGI, and was updated in June 2026 to include additional PRC life sciences companies, including WuXi AppTec, which has challenged its designation in the U.S. federal courts and obtained a preliminary injunction against enforcement of the designation pending the outcome of that litigation. The designation framework remains subject to ongoing legal and regulatory developments. In addition, the legislation narrows the definition of restricted “biotechnology equipment or services,” expressly excluding certain core technologies, including mass spectrometry and PCR instruments, from the scope of prohibitions.