PRC LAWS AND REGULATIONS RELATING TO MEDICAL DEVICES

Classification of Medical Devices

Medical device industry of the PRC is subject to a large number of laws and regulations and extensive government supervision. Principal regulatory authorities of the industry are the NMPA and its local regulatory branches. In March 2018, the State Council Institutional Reform Proposal passed by the First Session of the Thirteenth National People's Congress decided the China Food and Drug Administration (國家食品藥品監督管理總局) shall cease to exist, and the NMPA was established to undertake the duties of the former China Food and Drug Administration.

Pursuant to the Regulations on Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) promulgated by the State Council, which took effect on June 1, 2021, the drug administration department of the State Council shall be responsible for the supervision of medical devices of the PRC. All relevant departments of the State Council shall be responsible for the supervision of medical devices within their respective scope of duties. The drug administration departments of the local people's governments at the county level and above are responsible for the supervision of medical devices within their own administrative jurisdictions. The relevant departments of the local people's governments at the county level and above are responsible for the supervision of medical devices within their respective scope of duties.

Although the newly revised Regulations on Supervision and Administration of Medical Devices has come into effect, amendment of specific supporting regulations has not been completed. According to the Announcement of the NMPA on Matters Concerning the Implementation of the Regulations on Supervision and Administration of Medical Devices (《國家藥監局關於貫徹實施<醫療器械監督管理條例>有關事項的公告》) promulgated by the NMPA on May 31, 2021, the NMPA is amending the supporting regulations, normative documents and technical guidelines for the new Regulations on Supervision and Administration of Medical Devices, which will be promulgated successively as per relevant procedures. Pursuant to this announcement, among others, from June 1, 2021, applicants for registration and filing of medical devices shall continue to make the application in accordance with existing regulations until relevant supporting regulations for the new Regulations on Supervision and Administration of Medical Devices are promulgated and implemented. The registrants and filing enterprises of medical devices shall apply for production permit and conduct filing or entrusted production in accordance with the existing regulations and normative documents until relevant supporting regulations on production permit and filing are revised.

In the PRC, medical devices are classified into three categories based on the degree of risk. Class I medical devices shall refer to those devices with low risk, and the safety and effectiveness of which can be ensured through routine administration. Class II medical devices shall refer to those devices with moderate risk, which are strictly controlled and administered to ensure their safety and effectiveness. Class III medical devices shall refer to those devices with high risk, which are strictly controlled and administered through special measures to ensure their safety and effectiveness. The classification of specific medical devices is stipulated in the Medical Device Classification Catalog (《醫療器械分類目錄》), which was latest amended on March 28, 2022.

Registration and Filings of Medical Device Products

Pursuant to the Administrative Measures for Registration and Filing of Medical Devices (《醫療器械註冊與備案管理辦法》) ("Medical Devices Registration Measures") promulgated by the SAMR on August 26, 2021, which came into effect on October 1, 2021 and replaced the Regulations on Supervision and Administration of Medical Devices and the Administrative Measures for Registration of Medical Devices (《醫療器械註冊管理辦法》) which came into effect on October 1, 2014, Class I medical devices are subject to filing, and the parties undergoing the filings of medical devices shall submit the filing materials to the drug administration departments of the local people's government at the districted city level. In case of any amendment to matters stated in the filings, such amendment shall be filed with the original filing department. Class II and Class III medical devices are subject to registration. Class II medical devices shall be examined by the drug administration departments of the people's governments of the provinces, autonomous regions or municipality where such applicants are located. A registration certificate for such medical device shall be issued upon approval. Class III medical devices shall be examined by the NMPA. A registration certificate for such medical device shall be issued upon approval. In case of any substantial change of the product name, model, specification, designs, raw materials, production technologies, scopes of application and application methods, etc., of the registered Class II or Class III medical device, which may affect the safety and effectiveness of such medical devices, the registrants shall apply to the original registration departments for change registration.

The registration certificate for a medical device is valid for five years and the registrant shall apply to the drug administration departments for renewal six months prior to its expiration date. Except for the circumstances set forth below, the drug administration department that receives the application shall make the decision to approve the extension before the expiration of the medical device registration certificate. If the decision is not made within the time limit, it is deemed as an approval. An application for renewal registration shall not be approved under any of the following circumstances: (1) the registrant fails to apply for extending the registration within the specific time limit; (2) where the compulsory standards for medical devices have been revised, the medical devices applied for extending the registration cannot meet the new requirements; and (3) for medical devices approved with conditions, the matters stipulated in the medical device registration certificate fail to be finished within the specific time limit.

According to the Medical Devices Registration Measures, clinical trials are not required for the filing of the Class I medical devices, but required for the application for the registration of the Class II and Class III medical devices. Medical devices may be exempt from clinical trials under any of the following circumstances: (1) the medical device has clear working mechanisms, finalized design and mature manufacturing processes, the medical devices of the same type that are available on the market have been used in clinical application for years without records of any serious adverse events, and the medical device will not change the general purposes; or (2) the safety and effectiveness of such medical device can be proved through non-clinical evaluation.

The catalog of medical devices that are exempted from clinical evaluation shall be formulated, amended and promulgated by the NMPA. On September 16, 2021, the NMPA issued the Notice on Issuing the Catalog of Medical Devices Exempted from Clinical Evaluation (《關於發佈免於臨床評價醫療器械目錄的通告》), which came into effect on October 1, 2021. Medical device products that are not included in the exemption catalog shall be analyzed and evaluated through the data obtained from the clinical trials or clinical application of the same categories of medical devices. Where the safety and effectiveness of such medical devices can be proved, applicants may specify in the course of registration application and submit relevant proof materials.

The applicants shall be an enterprise or development institution that can assume corresponding legal responsibilities, and are obliged to: (1) strengthen the quality management throughout the life cycle of medical devices, and assume liability for the safety, effectiveness and quality controllability of medical devices during the whole process of development, production, operation and use in accordance with the law; (2) establish quality management systems that are compatible with the products, and maintain their efficiency; (3) proactively carry out post-marketing research on medical devices, further confirm the safety, effectiveness and quality controllability of medical devices, and strengthen the continuous management of marketed medical device.

Medical Device Production Permit

According to the Regulations on Supervision and Administration of Medical Devices and the Administrative Measures for Supervision of the Production of Medical Devices (《醫療器械生產監督管理辦法》) promulgated by the NMPA on March 10, 2022, which became effective on May 1, 2022 and replaced the Administrative Measures for Supervision of the Production of Medical Devices issued on October 1, 2014 and amended on November 17, 2017, in addition to the required medical device registration certificates, a producer of medical devices shall file a record with or obtain a production license from drug administrative authorities at relevant level before commencing production. The medical device production license is valid for five years. Where the period of validity for the license needs to be extended upon expiry, the procedures for such extension shall be handled in accordance with the provisions of relevant laws on administrative licensing. For any changes to the contents or particulars stated in the production license, an application shall be submitted to relevant drug

administrative authorities for such changes. For any changes to the contents or particulars stated in the certificates for production filing of Class I medical devices, the certificates shall be filed with relevant drug administration authorities for filing of changes.

According to the Administrative Measures for Supervision of the Production of Medical Devices, an enterprise engaging in the production of Class I medical devices shall complete filing with the drug administration departments under the people's government of the city with districts where it is located and submit supporting materials evidencing its compliance with the criteria specified in the Regulations on Supervision and Administration of Medical Devices for engaging in the production of such medical devices and filing certificates of such medical devices; an enterprise engaging in the production of Class II and Class III medical devices shall apply for a production license from the drug administration departments under the people's government of the province, autonomous region or municipality where it is located and submit supporting materials evidencing its compliance with the criteria specified in the Regulations on Supervision and Administration of Medical Devices for engaging in the production of such medical devices and the product registration certificates of such medical devices.

According to the Regulations on Supervision and Administration of Medical Devices, apart from implantable medical devices with high risks, entities that register or file the medical devices may produce such medical devices by themselves or entrust other qualified enterprises for production. The drug administration department is responsible for issuing and adjusting the specific catalogues of implantable medical devices with high risks that may not be produced by entrusted producers. Medical devices included in the Catalogue of Medical Device Prohibited from Entrusted Production (《禁止委託生產醫療器械目錄》) issued on March 11, 2022 may not be produced on an entrustment basis.

Production and Quality Management of Medical Devices

Pursuant to the Administrative Measures for Supervision of the Production of Medical Devices and the Standards on Production and Quality Management of Medical Devices (《醫療器械生產質量管理規範》) promulgated by the NMPA on December 29, 2014, which came into effect on March 1, 2015, an enterprise engaging in the production of medical devices shall establish and effectively maintain a quality control system in accordance to the requirements of the Standards on Production and Quality Management of Medical Devices. The enterprise engaging in the production of medical devices shall regularly conduct comprehensive self-inspection on the operation of quality management system in accordance with the requirements of the Standards on Production and Quality Management of Medical Devices and submit a self-inspection report to the food and drug administration departments of the local people's governments of the provinces, autonomous regions, municipalities or at the districted city level before the end of every year. The enterprise shall establish its procurement control procedure and assess its suppliers by establishing an examination system to ensure the purchased products are in compliance with the statutory requirements. The enterprise shall record the procurement, production and inspection of raw materials. Such records shall be true, accurate, complete and traceable.

The enterprise shall apply risk management to the whole process of design and development, production, sales and after-sale services. The measures being adopted shall be applicable to risks of the related products.

Pursuant to The Notice of Four Guidelines including On-site Inspection Guidelines for the Standards on Production and Quality Management of Medical Devices (《關於印發<醫療器械生產質量管理規範現場檢查指導原則>等4個指導原則的通知》) promulgated by the NMPA with effect from September 25, 2015, during the course of on-site verification of the registration of medical devices and on-site inspection of production permit, including change production permit, the inspection team will, in accordance with the guidelines, issue recommended conclusions for on-site inspections, which shall be divided into "Passed," "Failed" and "Reassessment after rectification." During the supervision and inspection, if it is found that the requirements of the key items or ordinary items that may have direct impact on product quality are not satisfied, the enterprise shall suspend production and go through rectification. If it is found that the requirements of the ordinary items are not satisfied, and it does not directly affect product quality, the enterprise shall rectify in a prescribed time. The regulatory authorities will examine and verify the recommended conclusions and on-site inspection materials submitted by the inspection group, and issue the final inspection results.

Good Clinical Practice for Medical Devices

On March 24, 2022, the NMPA and the National Health Commission (國家衛生健康委員會) jointly promulgated the Good Clinical Practice for Medical Devices (《醫療器械臨床試驗質量管理規範》), which became effective as of May 1, 2022. The regulation includes full procedures of clinical trial of medical devices, including, among others, the protocol design, conduction, monitoring, verification, inspection, and data collection, recording, analysis and conclusion and reporting procedure of a clinical trial. Prior to commencement of a clinical trial, the applicant must complete the pre-clinical research of the medical device, including product performance verification and confirmation, product inspection report based on the technical requirements, risk-benefit analysis, the results of which should support the clinical trial. Approval by ethics committees of the relevant clinical trial organization should also be obtained before the clinical trial, and the applicant, the clinical trial organization and the principal investigators must enter into agreements in writing to arrange their rights and obligations during the trial.

On January 4, 2018, in order to further improve the quality of registration review, encourage R&D and innovation of medical devices, the NMPA promulgated the Guidelines for the Design of Clinical Practice for Medical Devices (《醫療器械臨床試驗設計指導原則》).

In November 2018, the NMPA promulgated the Main Points of Medical Device Clinical Trial Inspection and Judgment Principles (《醫療器械臨床試驗檢查要點及判定原則》), its purpose is to strengthen the supervision and management of the clinical trial process of medical devices.

The NMPA and the National Health and Family Planning Commission also released Medical Device Clinical Trial Institution Conditions and Filing Management Measures (《醫療器械臨床試驗機構條件和備案管理辦法》), which became effective as of January 1, 2018. According to the measures, medical device clinical trial institutions are required to submit information such as institution profile, professional technical level, organizational management capabilities, ethical review capabilities and other information to the drug administration department for archiving and reference.

Guidelines for Clinical Trials of Transcatheter Aortic Valve Implantation

In February 2019, the NMPA formally promulgated the Guidelines for Clinical Trials of Transcatheter Aortic Valve Implantation (《經導管植入式人工主動脈瓣膜臨床試驗指導原則》) (the "TAVI Clinical Trial Guidelines"). The purpose of the TAVI Clinical Trial Guidelines is to further standardize the premarketing clinical trials of transcatheter aortic valve implantation products and to guide the preparation of clinical trial data for applicants of such products when applying for the product registration.

The TAVI Clinical Trial Guidelines are the general requirements for the clinical trial of transcatheter aortic valve implantation. The applicant should enrich and refine the contents of clinical trial scheme according to the characteristics of the specific products.

Medical Device Operation Permit

According to the Regulations on Supervision and Administration of Medical Devices and the Administrative Measures for Supervision of the Operation of Medical Devices (《醫療器械經營監督管理辦法》) which was latest amended on March 10, 2022 and became effective on May 1, 2022, an enterprise engaging in the operation scale and scope, shall have quality control department or personnel suitable for the medical devices it operates. An enterprise engaging in the operations of Class I medical devices is not required to obtain approval or file a record. An enterprise engaging in the operations of Class II medical devices is required to file a record with the drug administration departments of the city with districts where it is located. An enterprise engaging in the operations of Class III medical devices shall obtain operation permit from the drug administration departments of the city with districts where it is located.

No operation permit or record filing is required for the registrant or record holder of medical devices to sell its medical devices at its domicile 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.

Special Procedures for Examination and Approval of Innovative Medical Devices

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

Pursuant to the Special Procedures for Examination and Approval of Innovative Medical Devices (《創新醫療器械特別審查程序》) promulgated by the NMPA on November 2, 2018, which came into effect on December 1, 2018, special procedures shall be applicable to the examination and approval for medical devices in the following circumstances: (1) the applicant legally owns the invention patent of the core technology of the product through its technological innovation activities in the PRC, or legally obtained the invention patent or the right of use thereof through transfer in the PRC, and the interval between the date of application for the special examination and approval of innovative medical devices to the date of authorized publication should not exceed five years; or the patent administration department of the State Council has disclosed the application for the invention patent of the core technology and the Patent Search and Consultation Center of the National Intellectual Property Administration of the PRC (國家知識產權局專利檢索諮詢中心) has issued the patent search report setting out the novelty and innovation of the core technology solution of the product; (2) the applicant has developed the prototype product and completed the preliminary research under a true and controllable process that generated complete and traceable data; (3) the product has major working mechanism or mechanism of action which is the first of its kind in the PRC, has fundamental improvement in product performance or safety compared with similar products, is of an internationally leading standard in terms of techniques and has significant clinical value. The Center for Medical Device Evaluation of the NMPA (國家藥品監督管理局醫療器械技術審評中心) should give priority to the innovative medical devices in their technical review upon receiving the registration application, after which the NMPA will give priority to the product in their administrative approval.

Two-Invoice System

On December 26, 2016, eight government departments including the NMPA issued Notice on Opinions on the Implementation of the "Two-Invoice System" in Drug Procurement by Public Medical Institutions (for Trial Implementation) (《印發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》). According to the Notice, the "Two-Invoice System" refers to issuing invoice at the time from a pharmaceutical manufacturer to a circulating enterprise, and issuing invoice again at the time from a circulating enterprise to a

medical institution. The Notice requires public medical institutions to gradually implement the "Two-Invoice System" for drug procurements and encourages other medical institutions to promote the "Two-Invoice System" so that the "Two-Invoice System" will strive to be widely promoted nationwide by 2018.

On March 5, 2018, six government departments including the National Health and Family Planning Commission 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 stipulates the implementation of the centralized purchase of high-value medical consumables, and that the "Two-Invoice System" in relation to high-value medical consumables shall be gradually implemented.

On July 19, 2019, the General Office of the State Council issued the Circular on Reform Plan on Managing High-Value Medical Consumables (《關於印發<治理高值醫用耗材改革方案>的通知》), which encourages local governments to adopt the "Two-Invoice System" according to actual situation in order to reduce intermediates in the circulation of high-value medical consumables and promote the transparency of purchase and sales. This task is expected to be completed by the end of 2020.

Pursuant to the Reply of the National Healthcare Security Administration to Recommendation No. 1209 of the Second Session of the 13th National People's Congress (《國家醫療保障局對十三屆全國人大二次會議第1209號建議的答覆》) issued by National Healthcare Security Administration on July 23, 2019, "Two-Invoice System" for high-value consumables needs to be further discussed given the huge differences between high-value consumables and pharmaceuticals and the complexity of clinical use and after-sales service.

As of the Latest Practicable Date, 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, such as Two-invoice System Implementation Opinions on the Procurement of Medical Consumables in Public Medical Institutions in Anhui Province (Trial) (安徽省公立醫療機構醫用耗材採購"兩票制"實施意見(試行)) promulgated on November 20, 2017, the Notice on Further Promoting the "Two Invoice System" for Medicines and Medical Consumables (關於進一步推進藥品和醫用耗材"兩票制"的通知) in Shaanxi promulgated on July 23, 2018 and the Notice from the Office of Fujian Province Medical Security Management Committee on the Province-wide Sharing of the Results of Medical Equipment (Medical Consumables) Open Procurement Implementation (福建省醫療保障管理委員會辦公室關於開展醫療器械(醫用耗材)陽光採購結果全省共享工作的通知) promulgated on July 23, 2018. According to such local rules, if the manufacturers or distributors of medical consumables fail to implement the two-invoice system, they may lose the qualification to participate in the procurement or distribution of medical consumables, and they may also be included in the bad credit record for medical consumables procurement.

Reform Plan on High-Value Medical Consumables

According to the Notice of Ministry of Health on Further Strengthening the Administration of Centralized Procurement of Medical Devices (《衛生部關於進一步加強醫療器械集中採購管理的通知》) issued on June 21, 2007, all not-for-profit medical institutions under all levels of government and state-owned enterprises from different industries shall participate in the centralized procurement of medical devices.

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

According to the Administrative Norms on Centralized Procurement of High-value Medical Consumables (for Trial Implementation) (《高值醫用耗材集中採購工作規範(試行)》) issued on December 17, 2012, high-value medical consumables are defined as medical consumables directly used on human body, with strict requirement on safety and strong social response, in great demand clinically, and relatively highly-priced. The online centralized procurement works of high-value medical consumables (the "Centralized Procurement") will be led by government and conducted by each province (region and municipality). Medical institutions and medical consumables production and operation enterprises shall make procurement through the Centralized Procurement platform established by each province (region and municipality). The administrative authorities in charge of the Centralized Procurement in each province (region and municipality) shall be responsible for formulating and preparing a Centralized Procurement list of high-value medical devices within its administrative region. High-value medical consumables listed on the Centralized Procurement list may be procured by way of public tenders, invitational tenders or by other means stipulated by PRC laws and regulations. After the procurement prices are determined, public medical institutions within relevant regions shall make procurement strictly at bidding prices.

On July 19, 2019, the General Office of the State Council issued the Circular on Reform Plan on Managing High-value Medical Consumables (《關於印發<治理高值醫用耗材改革方案>的通知》(the "Circular"). According to the Circular, high-value medical consumables are defined as medical consumables directly used on human body, with strict requirement on safety, in great demand clinically, relatively highly-priced, and that can pose heavy burdens on patients. The Circular releases several reform initiatives aiming at managing high-value medical consumables, including: (1) the classification and codes of high-value medical consumables in the national medical insurance system will be unified gradually, and rules on unique device identification in full life cycle of the high-value medical consumables, including but not limited to registration, procurement and usage, will be implemented by the National Healthcare Security Administration, the National Medical Products Administration, and the National Health Commission of the PRC by the end of 2020; (2) The mechanism for including

high-value medical consumables in basic medical insurance shall be built, and a list of high-value medical consumables shall be compiled, to strengthen the dynamic adjustment mechanism. The access regulations shall be promulgated by the National Health Commission and the Ministry of Finance as of the end of June 2020; (3) the price markups placed on medical consumables at public hospitals will be abolished, and all medical consumables, including high-value medical consumables will be sold at procurement price at all public hospitals as of the end of 2019; (4) the medical insurance payment policy shall be formulated and implemented by the National Healthcare Security Administration, the Ministry of Finance and the National Health Commission of the PRC. Meanwhile, the medical insurance payment standards on high-value medical consumables will be formulated and the dynamic adjustment mechanism will be established. The medical insurance funds and patients will share the cost of high-value medical consumables according to the medical insurance payment standards, and medical institutions shall further reduce procurement prices under the guidance of the Circular.

Sampling and Collecting Human Genetic Resources Filing

The Ministry of Science and Technology is responsible for the administration of human genetic resources at the national level. On July 2, 2015, the Ministry of Science and Technology issued the Service Guide for Administrative Licensing Items concerning Examination and Approval of Sampling, Collecting, Trading, or Exporting Human Genetic Resources or Taking Such Resources out of the PRC (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》), which clarified that the sampling and collection of human genetic resources through clinical trials shall be required to be filed with the China Human Genetic Resources Management Office through the online system. On October 26, 2017, the Ministry of Science and Technology promulgated the Circular on Optimizing the Administrative Examination and Approval of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》), which became into effect on December 1, 2017, simplifying the approval of sampling and collecting human genetic resources for the purpose of listing a drug in the PRC.

On May 28, 2019, the State Council promulgated the Administrative Regulations on Human Genetic Resources of the PRC (《中華人民共和國人類遺傳資源管理條例》), which came into effect on July 1, 2019, and the Standing Committee of the NPC promulgated the Biosecurity Law of the PRC (《中華人民共和國生物安全法》) on October 17, 2020, which came into effect on April 15, 2021. According to the provisions therein, the PRC shall support the rational utilization of human genetic resources to carry out scientific research, develop the biomedical industry, improve diagnosis and treatment technologies, improve the biosafety guarantee capabilities of China, and improve people's health protection level. Foreign organizations, individuals and the institutions established or actually controlled thereby shall not collect or preserve China's human genetic resources within the territory of China, nor shall they take China's human genetic resources out of the country; while they are allowed to utilize human genetic resources of China to conduct scientific research activities through cooperation with scientific research institutions, higher education institutions, medical institutions or enterprises of China. Such international cooperative scientific research utilizing human genetic

resources of China is subject to approval by the Ministry of Science and Technology. However, provided that human genetic resources of China are utilized in the international cooperative clinical trials for the purpose of obtaining product registration of relevant medicine and medical device in China, without providing such human genetic resources to any overseas persons, such international cooperation is subject to filing with the Ministry of Science and Technology instead of approval. Furthermore, the collection, preservation, utilization, and external provision of China's human genetic resources shall comply with the ethical principles of human genetic resources providers and be subject to ethical review in accordance with relevant regulations of the PRC.

Export Registration

Pursuant to the Rules on the Application and Issuance of Medical Device Exporting Certificate (《醫療器械產品出口證明申辦規定》) promulgated by the NMPA with effect from January 6, 1996, the NMPA represents the PRC government to conduct inspections of safety and legality of the products manufactured by domestic enterprises (including the PRC enterprises, sino-foreign equity joint ventures and foreign-owned enterprises) in accordance with the spirit of the Notice of the General Office of the State Council on Printing and Distributing the Functional Configuration, Internal Institutions and Staffing Plans of the State Administration of Medicine (《國務院辦公廳關於印發國家醫藥管理局職能配置、內設機構和人員編制方案的通知》), and to grant exporting certificate in accordance with the international conventions so as to prove that such products have obtained legitimate production permit within Chinese territory. Medical device exporting certificate granted by the NMPA must be used with the safety and quality assurance disclaimer issued by the manufacturers of such products at the same time, and such certificate shall not be used separately. Chinese version of the exporting certificate is regarded as the original copy and its English translation is deemed as a copy. Such certificate, except being specified for one time use, is valid for a term of two years.

If any of the following circumstances occurs to a production enterprise of medical device product that has obtained the exporting certificate, the NMPA will revoke such exporting certificate and inform the relevant exporting country on a timely basis: (1) the application document is found forfeited or the validity period has expired; or (2) the product received complaints from customers and such quality issue has been proved.

Advertisements of Medical Devices

Pursuant to the Regulations on Supervision and Administration of Medical Devices and the Interim Administrative Measures for Censorship of Advertisements for Drugs, Medical Devices, Dietary Supplements and Foods for Special Medical Purpose (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) promulgated by the SAMR on December 24, 2019, which came into effect on March 1, 2020, an enterprise qualified for engaging in the production or operation of medical devices shall apply for the publication of any medical device advertisement with the market regulation, drug administration departments of the local people's governments of the provinces, autonomous regions or municipalities, and

obtain an approval of such advertisement of medical device. The validity term of such advertisement approval shall be consistent with that of the registration certificate or record-filing certificate or the production permit of the product, whichever is the shortest. Where no validity term is set forth in the registration certificate, record-filing certificate or the production permit of the product, the advertisement approval shall be valid for two years. The content of the medical device advertisements shall be based on the registration certificate or the recordation proof. Medical device advertisement involving the name, scope of application, mechanism of action, or structure and composition of the medical device must not exceed the scope of the registration certificate or the recordation proof.

The advertisement of a medical device shall be true and lawful, and its content shall not be false, exaggerated or misleading. A publisher of a medical device advertisement shall verify approval documents and their authenticity prior to the publication. If no approval document was obtained or the authenticity of any approval document has not been verified or the content of the advertisement is inconsistent with the approval documents, such medical device advertisement shall not be published.

National Medical Insurance Program

The national medical insurance program was adopted pursuant to the Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program (《國務院關於建立城鎮職工基本醫療保險制度的決定》) issued by the State Council on December 14, 1998, under which all employers in urban cities are required to enroll their employees in the Urban Employee Basic Medical Insurance Program and the insurance premium is jointly contributed by the employers and employees. Pursuant to the Opinions on the Establishment of the New Rural Cooperative Medical System (《關於建立新型農村合作醫療制度意見的通知》) forwarded by the General Office of the State Council on January 10, 2003, China launched the New Rural Cooperative Medical System to provide medical insurance for rural residents in selected areas which has since spread to the whole nation. The State Council promulgated the Guiding Opinions of the State Council about the Pilot Urban Resident Basic Medical Insurance (《國務院關於開展城鎮居民基本醫療保險試點的指導意見》) on July 10, 2007, under which urban residents of the pilot district, rather than urban employees, may voluntarily join Urban Resident Basic Medical Insurance. In 2015, the General Office of the State Council announced the Outline for the Planning of the National Medical and Health Service System (2015-2020) (《全國醫療衛生服務體系規劃綱要(2015-2020年)》) which aims to establish a basic medical and health care system that covers both rural and urban residents by 2020.

On January 3, 2016, the State Council issued the Opinions on Integrating the Basic Medical Insurance Systems for Urban and Rural Residents (《國務院關於整合城鄉居民基本醫療保險制度的意見》) to integrate the Urban Resident Basic Medical Insurance and the New Rural Cooperative Medical System and to establish a unified Basic Medical Insurance System for Urban and Rural Residents, which will cover all urban and rural non-working residents except for rural migrant workers and persons in flexible employment arrangements who participate in the Urban Employee Basic Medical Insurance Program.

With regard to reimbursement for medical devices and diagnostic tests, the Notice of Opinion on the Diagnosis and Treatment Management, Scope and Payment Standards of Medical Service Facilities Covered by the Urban Employee Basic Medical Insurance Program (《關於印發城鎮職工基本醫療保險診療項目管理、醫療服務設施範圍和支付標準意見的通知》) prescribes the coverage of diagnostic and treatment devices and diagnostic tests where part of the fees is paid through the basic medical insurance program. It also includes a negative list that precludes certain devices and medical services from governmental reimbursement. Detailed reimbursement coverage and rate for medical devices and medical services (including diagnostic tests and kits) are subject to each provinces' local policies.

Product Liability and Protection of Consumers' Rights

Pursuant to the Product Quality Law of the PRC (《中華人民共和國產品質量法》) amended by the Standing Committee of the National People's Congress (the "NPC") and came into effect on December 29, 2018, producers and sellers shall have their own proper regulations for the management of product quality, rigorously implementing postoriented quality regulations, quality liabilities and relevant measures for their assessment. Producers and sellers are responsible for the product quality according to the provisions of the laws.

The product quality supervision and administration departments of the State Council are responsible for the supervision and administration of the quality of products of the whole country. All relevant departments of the State Council shall be responsible for the supervision of product quality within their own functions and duties.

Quality of products shall pass standard examinations and no substandard products shall be used as standard ones. Industrial products which may be hazardous to the health of the people and the safety of lives and property shall conform to the State and trade standards for ensuring the health of the human body and safety of lives and property. In absence of such State or trade standards, the products shall conform to the minimum requirements for ensuring the health of the human body and the safety of lives and property. It shall be prohibited to produce or sell industrial products that do not come to the requirements and demands for physical health and safety of body and property. Producers or sellers shall be responsible for any compensation arising from their unlawful acts such as production or sales of defective, eliminated or ineffective products, faking the place of origin or quality marks, mixing or adulterating products or passing off imitations as genuine, substandard products as quality ones or non-conforming products as conforming. Proceeds from the sales may be confiscated, the business license may be revoked and penalties may be imposed. If the case is serious, criminal responsibilities shall be investigated. Producers or sellers shall be liable for any damage to any person or property due to the defects of products resulting from the default of the producers or sellers.

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

Medical Device Recalls

Pursuant to the Administrative Measures for Medical Device Recalls (《醫療器械召回管理辦法》) promulgated on January 25, 2017, which came into effect on May 1, 2017, in light of the severity of harm, medical device recalls are divided into: (1) Class I recall where the circumstances leading to the recall may cause or have caused serious health hazards; (2) Class II recall where the circumstances leading to the recall may cause or have caused temporary or reversible health hazards; or (3) Class III recall where the circumstances leading to the recall are not likely to cause harm.

Medical device manufacturers shall determine the recall class based on the specific situation and properly design and implement the recall plan based on the recall class and the sale and use of the medical devices. In terms of Class I recall, the recall notice shall be published on the NMPA website and major media of the central government. In terms of Class II and Class III recalls, the recall notice shall be published on the website of the food and drug administrative authority of the provinces, autonomous regions or municipalities.

PRC LAWS AND REGULATIONS RELATING TO COMPANY ESTABLISHMENT AND FOREIGN INVESTMENT

The establishment, operation and management of corporate entities in the PRC is governed by the Company Law of PRC (《中華人民共和國公司法》) (the "Company Law"), which was issued by the Standing Committee of the NPC on December 29, 1993, latest revised and became effective on October 26, 2018. Limited liability companies and stock limited companies established in the PRC shall be subject to the Company Law. A foreign-invested company is also subject to the Company Law unless otherwise provided by the foreign investment laws.

On March 15, 2019, the NPC approved the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) (the "Foreign Investment Law"), which became effective on January 1, 2020, replaced the Sino-Foreign Equity Joint Venture Enterprise Law of the PRC (《中華人民共和國中外合資經營企業法》), the Sino-Foreign Cooperative Joint Venture Enterprise Law of the PRC (《中華人民共和國中外合作經營企業法》) and the Wholly Foreign-Invested Enterprise Law of the PRC (《中華人民共和國外資企業法》), and becomes the legal foundation for foreign investment in the PRC. On December 26, 2019, the State Council issued the Regulations on Implementing the Foreign Investment Law of the PRC (《中華人民共和國外商投資法實施條例》), which came into effect on January 1, 2020 and replaced

the Regulations on Implementing the Sino-Foreign Equity Joint Venture Enterprise Law of the PRC (《中華人民共和國中外合資經營企業法實施條例》), Provisional Regulations on the Duration of Sino-Foreign Equity Joint Venture Enterprise Law of the PRC (《中外合資經營企業合營期限暫行規定》), the Regulations on Implementing the Wholly Foreign- Invested Enterprise Law of the PRC (《中華人民共和國外資企業法實施細則》) and the Regulations on Implementing the Sino-foreign Cooperative Joint Venture Enterprise Law of the PRC (《中華人民共和國中外合作經營企業法實施細則》).

The Foreign Investment Law sets out the basic regulatory framework for foreign investments and proposes to implement a management system of pre-establishment national treatment with a negative list for foreign investments, pursuant to which (1) foreign natural persons, enterprises or other organizations (collectively the "Foreign Investors") shall not invest in any sector forbidden by the negative list for access of foreign investment, (2) for any sector restricted by the negative list, Foreign Investors shall conform to the investment conditions provided in the negative list, and (3) sectors not included in the negative list shall be managed under the principle that domestic investment and foreign investment shall be treated equally. The Foreign Investment Law also sets forth necessary mechanisms to facilitate, protect and manage foreign investments and proposes to establish a foreign investment information report system in which Foreign Investors or foreign-invested enterprises shall submit the investment information to competent departments of commerce through the enterprise registration system and the enterprise credit information publicity system. The organization form and structure and operating rules of foreign-invested enterprises are subject to the provisions of the Company Law, the Partnership Enterprise Law of the PRC (《中華人民共和國合夥企業法》) and other applicable laws, if applicable.

On December 30, 2019, the Ministry of Commerce (the "MOFCOM") and the State Administration for Market Regulation issued the Measures for the Reporting of Foreign Investment Information (《外商投資信息報告辦法》), which came into effect on January 1, 2020 and replaced the Interim Administrative Measures for the Record-filing of the Incorporation and Change of Foreign- invested Enterprises (《外商投資企業設立及變更備案管理暫行辦法》). Since January 1, 2020, for carrying out investment activities directly or indirectly in China, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce administrative authorities through the Enterprise Registration System and the National Enterprise Credit Information Publicity System pursuant to these measures.

The Catalog for the Guidance of Foreign Investment Industries

Investment activities in the PRC by foreign investors and foreign-invested enterprises shall comply with the Special Administrative Measures (Negative List) for Foreign Investment Access (2021 version) (《外商投資准入特別管理措施(負面清單)(2021年版)》)(the "Negative List 2021") and the Catalog of Industries for Encouraging Foreign Investment (2020 Version) (《鼓勵外商投資產業目錄(2020年版)》) (the "Encouraging Catalog 2020") which were promulgated by the National Development and Reform Commission and the MOFCOM.

Pursuant to the Encouraging Catalog 2020 and the Negative List 2021, foreign-invested projects are categorized as encouraged, restricted and prohibited. Foreign-invested projects that are not listed in the Negative List 2021 are permitted foreign invested projects.

According to the Encouraging Catalog 2020 and the Negative List 2021, the industry in which we are primarily engaged does not fall into the category of restricted or prohibited industries.

PRC LAWS AND REGULATIONS RELATING TO INTELLECTUAL PROPERTY

The Trademark Law

Trademarks are protected by the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated on August 23, 1982 and latest amended on April 23, 2019 as well as the Implementation Regulation of the PRC Trademark Law (《中華人民共和國商標法實施條例》) adopted by the State Council on August 3, 2002 and amended on April 29, 2014. In China, registered trademarks include commodity trademarks, service trademarks, collective marks and certification marks.

The Trademark Office under the CNIPA, handles trademark registrations and grants a term of 10 years to registered trademarks. Trademarks are renewable every 10 years where a registered trademark needs to be used after the expiration of its validity term. A registration renewal application shall be filed within 12 months prior to the expiration of the term. A trademark registrant may license its registered trademark to another party by entering into a trademark license contract. Trademark license agreements must be filed with the Trademark Office for record. The licensor shall supervise the quality of the commodities on which the trademark is used, and the licensee shall guarantee the quality of such commodities. As with trademarks, the PRC Trademark Law has adopted a "first come, first file" principle with respect to trademark registration. Where trademark for which a registration application has been made is identical or similar to another trademark which has already been registered or been subject to a preliminary examination and approval for use on the same kind of or similar commodities or services, the application for registration of such trademark may be rejected. Any person applying for the registration of a trademark may not prejudice the existing right first obtained by others, nor may any person register in advance a trademark that has already been used by another party and has already gained a "sufficient degree of reputation" through such party's use.

The Patent Law

Pursuant to the Patent Law of the PRC (《中華人民共和國專利法》) which was amended by the Standing Committee of the NPC on October 17, 2020 and came into effect on June 1, 2021 and the Implementation Rules of The Patent Law of the PRC (《中華人民共和國專利法實施細則》) which was amended by the State Council on January 9, 2010 and came into effect on February 1, 2010, patents in China are divided into invention patent, utility patent and

design patent. Invention patent refers to new technical solutions for a product, method or its improvement; utility patent refers to new technical solutions for the shape, structure or the combination of both shape and structure of a product, which is applicable for practical use; design patent refers to new designs of the shape, pattern or the combination of shape and pattern, or the combination of the color, the shape and pattern of a product with esthetic feeling and industrial application value. Any design for which patent right may be granted shall not be an existing design, nor has any entity or individual filed before the date of filing with the patent administration department under the State Council an application relating to the identical design disclosed in patent documents announced after the date of filing. The protection period is 20 years for an invention patent, 10 years for a utility patent and 15 years for design patent, commencing from their respective application dates. The patent right entitled to its owner shall be protected by the laws. Any person shall be licensed or authorized by the patent owner before using such patent. Otherwise, the use constitutes an infringement of the patent right.

The Copyright Law

Pursuant to the Copyright Law of the PRC (《中華人民共和國著作權法》) which was amended by the Standing Committee of the NPC on November 11, 2020 and came into effect on June 1, 2021, Chinese citizens, legal persons or other organizations shall, whether published or not, enjoy copyright in their works, which include, among others, works of literature, art, natural science, social science, engineering technology and computer software created in writing or oral or other forms. A copyright holder shall enjoy a number of rights, including the right of publication, the right of authorship and the right of reproduction.

Pursuant to the Measures for the Registration of Computer Software Copyright (《計算機軟件著作權登記辦法》) promulgated by the National Copyright Administration (國家版權局) on February 20, 2002 and the Regulations on Computers Software Protection (《計算機軟件保護條例》) amended by the State Council on January 30, 2013 with effect from March 1, 2013, the National Copyright Administration is mainly responsible for the registration and management of software copyright in China and recognizes the China Copyright Protection Center as the software registration organization. The China Copyright Protection Center shall grant certificates of registration to computer software copyright applicants in compliance with the regulations of the Measures for the Registration of Computer Software Copyright and the Regulations on Computers Software Protection.

Domain Names

Pursuant to the Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》) which was promulgated by the Ministry of Industry and Information Technology (工業和信息化部) on August 24, 2017 and came into effect on November 1, 2017, the establishment of any domain name root server and institution for operating domain name root servers, managing the registration of domain name and providing registration services in relation to domain name within the territory of China shall be subject to the approval of the Ministry of Industry and Information Technology or provincial, autonomous regional and municipal communications administration. The registration of domain name shall follow the

principle of "first apply first register." The Notice of the Ministry of Industry and Information Technology on Regulating the Use of Domain Names in Internet Information Services (《工業和信息化部關於規範互聯網信息服務使用域名的通知》) promulgated by the Ministry of Industry and Information Technology on November 27, 2017 with effect from January 1, 2018 specifies the obligation of anti-terrorism and maintaining network security of internet information service providers.

PRC LAWS AND REGULATIONS RELATING TO LABOR

Pursuant to the PRC Labour Law (《中華人民共和國勞動法》) promulgated on July 5, 1994 with effect from January 1, 1995, and latest revised on December 29, 2018, as well as the PRC Labour Contract Law (《中華人民共和國勞動合同法》) promulgated on June 29, 2007, revised on December 28, 2012 with effect from July 1, 2013, if an employment relationship is established between an entity and its employees, written labour contracts shall be executed between them. The relevant laws stipulate the maximum number of working hours per day and per week, respectively. Furthermore, the relevant laws also set forth the minimum wage. The entities shall establish and develop systems for occupational safety and sanitation, implement the rules and standards of the PRC government on occupational safety and sanitation, educate employees on occupational safety and sanitation, prevent accidents at work and reduce occupational hazards.

Pursuant to the Interim Regulations on Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) promulgated on January 22, 1999, and last revised on March 24, 2019, Decisions of the State Council on Modifying the Basic Endowment Insurance System for Enterprise Employees (《國務院關於完善企業職工基本養老保險制度的決定》) promulgated on December 3, 2005, Decision of the State Council on the Establishment of the Urban Employee Basic Medical Insurance Program, the Regulations on Unemployment Insurance (《失業保險條例》) effective from January 22, 1999, Regulations on Work-Related Injury Insurance (《工傷保險條例》) promulgated on April 27, 2003 with effect from January 1, 2004, and latest amended on December 20, 2010, and the Interim Measures concerning the Maternity Insurance for Enterprise Employees (《企業職工生育保險試行辦法》) promulgated on December 14, 1994 with effect from January 1, 1995, employers are required to register with the competent social insurance authorities and provide their employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, work-related injury insurance and medical insurance.

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》), which was promulgated on October 28, 2010 and latest amended with effect from December 29, 2018, all employees are required to participate in basic pension insurance, basic medical insurance schemes and unemployment insurance, which must be contributed by both the employers and the employees. All employees are required to participate in work-related injury insurance and maternity insurance schemes, which must be contributed by the employers. Employers are required to complete registrations with local social insurance authorities.

Moreover, the employers must timely make all social insurance contributions. Except for mandatory exceptions such as force majeure, social insurance premiums may not be paid late, reduced or be exempted. Where an employer fails to make social insurance contributions in full and on time, the social insurance contribution collection agencies shall order it to make all or outstanding contributions within a specified period and impose a late payment fee at the rate of 0.05% per day from the date on which the contribution becomes due. If such employer fails to make the overdue contributions within such time limit, the relevant administrative department may impose a fine equivalent to one to three times the overdue amount.

Pursuant to the Administrative Regulations on Housing Provident Fund (《住房公積金管理條例》) effective from April 3, 1999, and latest amended on March 24, 2019, enterprises are required to register with the competent administrative centers of housing provident fund and open bank accounts for housing provident funds for their employees. Employers are also required to timely pay all housing fund contributions for their employees. Where an employer fails to submit and deposit registration of housing provident fund or fails to go through the formalities of opening housing provident fund accounts for its employees, the housing provident fund management center shall order it to go through the formalities within a prescribed time limit. Failing to do so at the expiration of the time limit will subject the employer to a fine of not less than RMB10,000 and up to RMB50,000. When an employer fails to pay housing provident fund due in full and in time, housing provident fund center is entitled to order it to rectify, failing to do so would result in enforcement exerted by the court.

Furthermore, according to the Notice of the General Office of the SAT on Conducting the Relevant Work Concerning the Collection and Administration of Social Insurance Premiums in a Steady, Orderly and Effective Manner (《國家税務總局辦公廳關於穩妥有序做好社會保險費徵管有關工作的通知》) issued on September 13, 2018 and the Urgent Notice of the General Office of the Ministry of Human Resources and Social Security on Implementing the Spirit of the Executive Meeting of the State Council in Stabilizing the Collection of Social Insurance Contributions (《人力資源社會保障部辦公廳關於貫徹落實國務院常務會議精神切實做好穩定社保費徵收工作的緊急通知》) issued on September 21, 2018, all the local authorities responsible for the collection of social insurance are strictly forbidden to conduct self-collection of historical unpaid social insurance contributions from enterprises. The Notice of the SAT on Implementing Measures to Further Support and Serve the Development of Private Economy (《國家税務總局關於實施進一步支持和服務民營經濟發展若干措施的通知》) issued on November 16, 2018 further underlines that tax authorities at all levels may not organize self-collection of arrears of taxpayers including private enterprises in the previous years. The Notice of the General Office of the State Council on Promulgating the Comprehensive Plan for the Reduction of Social Insurance Premium Rate (《國務院辦公廳關於印發降低社會保險費率綜合方案的通知》) issued on April 1, 2019 generally reduces the social insurance contribution burden of enterprises, and re-emphasizes that local authorities shall not conduct self-collection of historical unpaid social insurance contributions from enterprises.

PRC LAWS AND REGULATIONS RELATING TO ENVIRONMENTAL PROTECTION

According to the Environmental Protection Law of the PRC (《中華人民共和國環境保護法》) which was latest amended on April 24, 2014 and became effective on January 1, 2015; the Law of the PRC on Environment Impact Assessment (《中華人民共和國環境影響評價法》) which was revised and became effective on December 29, 2018; the Rules on the Environmental Protection of Construction Projects (《建設項目環境保護管理條例》) which was revised on July 16, 2017 and became effective on October 1, 2017; the Interim Measures on the Environmental Protection Acceptance Check on Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) promulgated with effect from November 20, 2017, for a construction project for which an environmental impact report or environmental impact statement shall be prepared, the construction unit shall submit the environmental impact report or environmental impact statement to the competent administrative department of the environmental protection for approval before starting construction. For a construction project for which an environmental impact registration form shall be filled in according to the law, the construction unit shall submit the environmental impact registration form to the competent administrative department of the environmental protection for record. For a construction project for which an environmental impact report or environmental impact statement shall be prepared, before starting to operate, the construction unit shall organize the inspection and acceptance, after passing the acceptance check, the project can go into production or be delivered for use.

PRC LAWS AND REGULATIONS RELATING TO FIRE SECURITY

Pursuant to the Fire Protection Law of the PRC (《中華人民共和國消防法》) which was latest revised on April 29, 2021, and the Measure for Supervision on and Inspection of Fire Protection (《消防監督檢查規定》) amended in 2012, enterprises shall implement a fire safety accountability system, install firefighting facilities and equipment, conduct a yearly comprehensive inspection of firefighting facilities and keep the inspection records for future reference, and perform other fire safety measures as well as other fire safety and protection responsibilities. Pursuant to Interim Provisions on the Administration of Fire Protection Design Review and Final Inspection of Construction Projects (《建設工程消防設計審查驗收管理暫行規定》) ("Interim Provisions Regarding Fire Protection") effective on June 1, 2020, a special construction project as stipulated in the Interim Provisions Regarding Fire Protection shall be subject to fire protection design review before such project was commenced construction and shall be subject to fire protection inspection before such project was put into used. Other construction projects other than a special construction project shall be subject to fire protection inspection recordation, and the competent department of housing and urban-rural development shall conduct a random fire protection inspection thereof. If the project fails to pass the random fire protection inspection, such project shall be ceased to use.

PRC LAWS AND REGULATIONS RELATING TO PRODUCTION SAFETY

Pursuant to the Production Safety Law of the PRC (《中華人民共和國安全生產法》) amended by the Standing Committee of the NPC on August 31, 2014 and coming into effect on December 1, 2014, an enterprise shall (1) provide production safety conditions as stipulated in this law and other relevant laws, administrative regulations, national and industry standards, (2) establish a comprehensive production safety accountability system and production safety rules, and (3) develop production safety standards to ensure production safety. Any entity that fails to provide required production safety conditions is prohibited from engaging in production activities. The person-in-charge of an enterprise shall be fully responsible for the safety of production of the enterprise. An enterprise having more than 100 employees shall establish a department or engage in personnel managing production safety specifically. Personnel who is responsible for managing production safety shall inspect the safety of production regularly based on the characteristics of production of the enterprise and shall deal with any safety issue identified during the inspection in a timely manner. Any unsolved issue shall be reported to the person-in-charge in a timely manner and the person-in-charge shall solve such issue immediately. The inspection and measures taken shall be duly recorded. Enterprises and institutions shall provide their employees with training on production safety and shall truthfully inform their employees of any potential risks in relation to the workplace and duties, preventive measures and emergency measures. In addition, an enterprise shall provide its employees with protective equipment that meet the national or industry standards and supervise and train them to use such equipment.

On June 10, 2021, the Standing Committee of the NPC amended the Production Safety Law of the PRC, which will come into effect on September 1, 2021. Pursuant to the latest amended Production Safety Law of the PRC, an enterprise shall implement the production safety responsibility system with full participation of all staff, and establish a dual prevention mechanism consisting of graded management and control of risks and investigation and handling of hidden dangers. The latest amended law also imposes heavier penalties for illegal acts by raising the upper and lower limits of fines and continuously calculating fines on a daily basis.

PRC LAWS AND REGULATIONS RELATING TO TAXATION

Enterprises Income Tax

According to the Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得税法》) promulgated by the NPC on March 16, 2007, which took effect on January 1, 2008 and was latest amended on December 29, 2018, and its implementing rules, a unified enterprise income tax rate of 25% is applied equally to both domestic enterprises and foreign invested enterprises excluding non-resident enterprises.

Value-added Tax

The Circular on Comprehensively Promoting the Pilot Program of the Collection of Value-added Tax in Lieu of Business Tax (《關於全面推開營業税改徵增值税試點的通知》) was promulgated by SAT and Ministry of Finance on March 23, 2016 and effective from May 1, 2016, the pilot program of the collection of value-added tax in lieu of business tax shall be promoted nationwide in a comprehensive manner as of May 1, 2016.

Pursuant to the Interim Regulations on Value-Added Tax of the PRC (《中華人民共和國增值税暫行條例》) promulgated by the State Council on December 13, 1993 and latest amended on November 19, 2017 and its implementing rules promulgated on December 25, 1993 and latest amended by Ministry of Finance on November 28, 2011, tax payers engaging in selling goods, labor services, or tangible movable property leasing services or importing goods within the territory of the PRC shall pay value-added tax (the "VAT") at the tax rate of 6%, 11% or 17%. Taxpayers engaged in selling services or intangible assets shall pay VAT at the tax rate of 6%. Unless otherwise provided by the State Council, the tax rate of VAT shall be zero on goods exported by taxpayers.

According to the Interim Regulations of the PRC on Business Tax (《中華人民共和國營業税暫行條例》) (the "BT Regulations") promulgated by the State Council on December 13, 1993 and amended on November 10, 2008, all units and individuals providing taxable services as prescribed in the BT Regulations, transferring intangible assets or selling immovable properties within the territory of the PRC shall be taxpayers of business tax, and shall pay business tax in accordance with these regulations. For taxpayers providing services, transferring intangible assets or selling immovable properties under different tax items, the turnover, transfer and sales volume under different tax items shall be accounted for respectively. Where the turnover has not been accounted for respectively, a higher tax rate shall apply. The BT Regulations has been abolished by the State Council on November 19, 2017.

According to the Notice of the Ministry of Finance and the State Administration of Taxation on the Adjustment to VAT Rates (《財政部、國家税務總局關於調整增值税税率的通知》) which was promulgated by Ministry of Finance and SAT on April 4, 2018 and came into effect on May 1, 2018, the VAT rates of 17% and 11% applicable to the general VAT payers who have VAT taxable sales activities or imported goods are adjusted to 16% and 10%, respectively. According to the Announcement on Policies for Deepening the VAT Reform (《關於深化增值税改革有關政策的公告》) jointly which was promulgated by Ministry of Finance, SAT and General Administration of Customs on March 20, 2019, which became effective on April 1, 2019, for general VAT payers' sales activities or imports that are subject to VAT at an existing applicable rate of 16% or 10%, the applicable VAT rate is adjusted to 13% or 9% respectively.

Dividend Withholding Tax

Pursuant to the Enterprise Income Tax Law of the PRC and its implementation rules, if a non-resident enterprise has not set up an organization or establishment in the PRC, or has set up an organization or establishment but the income derived has no actual connection with such organization or establishment, it will be subject to a withholding tax on its PRC-sourced income at a rate of 10%. Pursuant to the Arrangement between Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Tax Evasion on Income (《內地和香港特別行政區關於對所得避免雙重徵税和防止偷漏税的安排》), the withholding tax rate in respect to the payment of dividends by a PRC enterprise to a Hong Kong enterprise is reduced to 5% from a standard rate of 10% if the Hong Kong enterprise is the beneficial owner of the dividends and directly holds at least 25% of the PRC enterprise.

Pursuant to the Notice of the State Administration of Taxation on the Issues concerning the Application of the Dividend Clauses of Tax Agreements (《國家税務總局關於執行税收協定股息條款有關問題的通知》), if the relevant PRC tax authorities determine, in their discretion, that a company benefits from such reduced income tax rate due to a structure or arrangement that is primarily tax-driven, such PRC tax authorities may adjust the preferential tax treatment. Furthermore, the Administrative Measures for Non-Resident Taxpayer to Enjoy Treatments under Tax Treaties (《非居民納税人享受税收協定待遇管理辦法》) (the "SAT Circular 60"), which became effective in November 2015, require that non-resident enterprises which satisfy the criteria for entitlement to tax treaty benefits may, at the time of tax declaration or withholding declaration through a withholding agent, enjoy the tax treaty benefits, and be subject to ongoing administration by the tax authorities. In the case where the non-resident enterprises do not apply to the withholding agent to claim the tax treaty benefits, or the materials and the information stated in the relevant reports and statements provided to the withholding agent do not satisfy the criteria for entitlement to tax treaty benefits, the withholding agent should withhold tax pursuant to the provisions of the PRC tax laws. The SAT issued the Announcement of State Taxation Administration on Promulgation of the Administrative Measures on Non-resident Taxpayers Enjoying Treaty Benefits (《國家税務總局關於發佈<非居民納税人享受協定待遇管理辦法>的公告》) (the "SAT Circular 35") on October 14, 2019, which became effective on January 1, 2020. The SAT Circular 35 further simplified the procedures for enjoying treaty benefits and replaced the SAT Circular 60. According to the SAT Circular 35, no approvals from the tax authorities are required for a non-resident taxpayer to enjoy treaty benefits, where a non-resident taxpayer self-assesses and concludes that it satisfies the criteria for claiming treaty benefits, it may enjoy treaty benefits at the time of tax declaration or at the time of withholding through the withholding agent, but it shall gather and retain the relevant materials as required for future inspection, and accept follow-up administration by the tax authorities. There are also other conditions for enjoying the reduced withholding tax rate according to other relevant tax rules and regulations. According to the Circular of the State Administration of Taxation on Several Issues regarding the "Beneficial Owner" in Tax Treaties (《國家税務總局關於税收協定中"受益所有人"有關問題的公告》), which was issued on February 3, 2018 by the SAT, effective as of April 1, 2018, when determining the applicant's status of the "beneficial owner" regarding tax treatments in

connection with dividends, interests or royalties in the tax treaties, several factors, including without limitation, whether the applicant is obligated to pay more than 50% of its income in 12 months to residents in third country or region, whether the business operated by the applicant constitutes the actual business activities, and whether the counterparty country or region to the tax treaties does not levy any tax or grant tax exemption on relevant incomes or levy tax at an extremely low rate, will be taken into account, and it will be analyzed according to the actual circumstances of the specific cases. This circular further provides that applicants who intend to prove his or her status of the "beneficial owner" shall submit the relevant documents to the relevant tax bureau according to the Administrative Measures for Non-Resident Taxpayers to Enjoy Treatments under Tax Treaties.

PRC LAWS AND REGULATIONS RELATING TO FOREIGN EXCHANGE

The principal regulations governing foreign currency 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 latest amended on August 5, 2008. Pursuant to these regulations and other PRC rules and regulations on currency conversion, Renminbi is freely convertible for payments of current account items, such as trade and service-related foreign exchange transactions and dividend payments, but not freely convertible for capital account items, such as direct investment, loan or investment in securities outside China unless prior approval of the SAFE or its local counterpart is obtained.

On February 13, 2015, SAFE promulgated 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》), according to which, entities and individuals may apply for such foreign exchange registrations from qualified banks. The qualified banks, under the supervision of SAFE, may directly review the applications and conduct the registration. On March 30, 2015, SAFE promulgated the Circular on Reforming the Management Approach regarding the Settlement of Foreign Capital of Foreign-invested Enterprise (《關於改革外商投資企業外匯資本金結匯管理方式的通知》) (the "SAFE Circular 19"). According to the SAFE Circular 19, the foreign exchange capital of foreign-invested enterprises shall be subject to the Discretionary Foreign Exchange Settlement, which means that the foreign exchange capital in the capital account of a foreign-invested enterprise for which the rights and interests of monetary contribution have been confirmed by the local foreign exchange bureau (or the book-entry registration of monetary contribution by the banks) can be settled at the banks based on the actual operational needs of the foreign-invested enterprise, and if a foreign-invested enterprise needs to make further payment from such account, it still needs to provide supporting documents and proceed with the review process with the banks. Furthermore, the SAFE Circular 19 stipulates that the use of capital by foreign-invested enterprises shall follow the principles of authenticity and self-use within the business scope of enterprises. The capital of a foreign-invested enterprise and capital in Renminbi obtained by the foreign-invested enterprise from foreign exchange settlement shall not be used for the following purposes: (1) directly or indirectly used for payments beyond the business scope of the enterprises or payments as prohibited by relevant laws and regulations;

(2) directly or indirectly used for investment in securities unless otherwise provided by the relevant laws and regulations; (3) directly or indirectly used for granting entrust loans in Renminbi (unless permitted by the scope of business), repaying inter enterprise borrowings (including advances by the third-party) or repaying the bank loans in Renminbi that have been sub-lent to third parties; or (4) directly or indirectly used for expenses related to the purchase of real estate that is not for self-use (except for the foreign-invested real estate enterprises).

The Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《關於進一步改進和調整直接投資外匯管理政策的通知》) (the "SAFE Circular 59") which became effective on December 17, 2012 and was amended on December 30, 2019, cancels the administrative approvals of foreign exchange registration of direct domestic investment and direct overseas investment and simplifies the procedure of foreign exchange-related registration. Pursuant to SAFE Circular 59, investors should register with banks for direct domestic investment and direct overseas 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. Pursuant to SAFE Circular 16, enterprises registered in the PRC may also convert their foreign debts from foreign currency to Renminbi on a self-discretionary basis. The SAFE Circular 16 reiterates the principle that Renminbi converted from foreign currency-denominated capital of a company may not be directly or indirectly used for purposes beyond its business scope or prohibited by PRC Laws, while such converted Renminbi shall not be provided as loans to its non-affiliated entities.

On January 26, 2017, SAFE promulgated the Circular on Further Improving Reform of Foreign Exchange Administration and Optimizing Genuineness and Compliance Verification (《關於進一步推進外匯管理改革完善真實合規性審核的通知》), which stipulates several capital control measures with respect to the outbound remittance of profit from domestic entities to offshore entities, including: (1) banks should check board resolutions regarding profit distribution, the original version of tax filing records, and audited financial statements pursuant to the principle of genuine transactions; and (2) domestic entities should hold income to account for previous years' losses before remitting the profits. Moreover, pursuant to this circular, domestic entities should make detailed explanations of the sources of capital and utilization arrangements, and provide board resolutions, contracts, and other proof when completing the registration procedures in connection with an outbound investment.

On October 23, 2019, the SAFE promulgated the Notice for Further Advancing the Facilitation of Cross-border Trade and Investment (《關於進一步促進跨境貿易投資便利化的通知》), which, among other things, allows all FIEs to use Renminbi converted from foreign currency denominated capital for equity investments in China, as long as the equity investment is genuine, does not violate applicable laws, and complies with the negative list on foreign investment. However, since this circular is newly promulgated, it is unclear how the SAFE and competent banks will carry it out in practice.

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》) (the "SAFE Circular 8") promulgated with effect from April 10, 2020 by the SAFE, the reform of facilitating the payments of incomes under the capital accounts shall be promoted nationwide. Under the prerequisite of ensuring true and compliant use of funds and compliance and complying with the prevailing administrative provisions on use of income from capital projects, enterprises which satisfy the criteria are allowed to use income under the capital account, such as capital funds, foreign debt and overseas listing, etc., for domestic payment, without the need to provide proof materials for veracity to the bank beforehand for each transaction.

On December 30, 2020, the SAFE promulgated the Circular on Further Optimizing Cross-border Renminbi Policies to Support the Stabilization of Foreign Trade and Foreign Investment(《關於進一步優化跨境人民幣政策支持穩外貿穩外資的通知》), effective as of February 4, 2021, which promotes the facilitation of Renminbi settlement for trade and investment based on the needs of the real economy, further simplifies the cross-border Renminbi settlement process, optimizes the administration of cross-border Renminbi investment and financing, facilitates the cross-border Renminbi receipt and payment under individual current accounts and the use of Renminbi bank settlement accounts by overseas institutions.

SANCTIONS LAWS AND REGULATIONS

Hogan Lovells, our International Sanctions Legal Advisors, have provided the following summary of the sanctions regimes imposed by their respective jurisdictions. This summary does not intend to set out the laws and regulations relating to the United States, the United Nations and the European Union sanctions in their entirety.

United States

Treasury Regulations

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 or activities involving U.S.-origin goods, software, technology or services 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, Syria, the Crimea region of Russia/Ukraine and the self-proclaimed Luhansk People's Republic and self-proclaimed Donetsk People's Republic 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 non-proliferation.

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 10 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

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 or 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.