The following is a brief summary of the laws and regulations in the PRC that currently materially affect our business operations. The principal objective of this summary is to provide potential investors with an overview of the key laws and regulations applicable to us. This summary does not purport to be a comprehensive description of all the laws and regulations applicable to our business and operations and/or which may be important to potential investors. Investors should note that the following summary is based on laws and regulations in force as of the date of this prospectus, which may be subject to change.

PRC REGULATORY OVERVIEW

Medical device industry of the PRC is subject to a large number of laws and regulations and extensive government supervision. Such laws and regulations encompass the areas including manufacturing, sales of medical devices, labor and intellectual property. Principal regulatory authorities of the industry are NMPA and its local regulatory branches. In March 2018, the State Council Institutional Reform Proposal passed by the First Session of the Thirteenth NPC decided the China Food and Drug Administration shall cease to exist, and the NMPA was established to undertake the duties of the former China Food and Drug Administration.

LAWS AND REGULATIONS RELATING TO MEDICAL DEVICES

Regulation and Classification of Medical Devices

Pursuant to the Regulations on the Supervision and Administration of Medical Devices (醫療器械監督管理條例) amended by the State Council and came into effect on May 4, 2017, the Food and Drug Administration 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. Food and drug supervision and 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.

In the PRC, medical devices have been classified into three categories based on the degree of risk. Class I medical devices shall refer to those devices with low risk and whose safety and effectiveness can be ensured through routine administration. Class II medical devices shall refer to those devices with medium risk and whose safety and effectiveness should be strictly controlled. Class III medical devices shall refer to those devices with high risk and whose safety and effectiveness must be strictly controlled with special measures.

Registration and Filings of Medical Device Products

Pursuant to the Regulations on the Supervision and Administration of Medical Devices (醫療器械監督管理條例) and the Administrative Measures for the Registration of Medical Devices (醫療器械註冊管理辦法) promulgated by the NMPA on July 30, 2014 and came into effect on October 1, 2014, for the filings of the medical device products of Class I, the parties undergoing the filings of medical devices shall submit the filing materials to the food and drug supervision and 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. The medical devices of Class II and Class III shall be subject to the product registration administration. Medical devices of Class II shall be examined by the food and drug supervision and 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. Medical devices of Class III shall be examined by the Food and Drug Administration of the State Council. A registration certificate for such medical device shall be issued upon approval. In case of any substantial change of the designs, raw materials, production technologies, scopes of application and application methods, etc., of the registered medical device products of Class II or Class III, which may affect the safety and effectiveness of such medical devices, the registrants shall apply to the original registration departments for changing registration.

The registration certificate for a medical device is valid for five years and the registrant shall apply to the food and drug supervision and administration departments for renewal six months prior to its expiration date. According to the latest Regulations on Supervision of Medical Devices (醫療器械監督管理條例), where the period of validity of the medical device registration certificate needs to be extended upon the expiration, an application for such extension shall be made to the original registration department six months before the expiration. Except for the circumstances set forth below, the food and drug supervision and 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: (i) the registrant fails to apply for extending the registration within the specific time limit; (ii) where the compulsory standards for medical devices have been revised, and the medical devices applied for extending the registration cannot meet the new requirements; and (iii) for medical devices in urgent demand used for treating rare diseases and responding to emergent public health events, the matters stipulated in the medical device registration certificate fail to be finished within the specific time limit.

Clinical trials are not required for the filing of the medical devices of Class I, but necessary for the application for the registration of the medical devices of Class II and Class III. However, medical devices listed in the Catalogue of Medical Device Exempted from Clinical Trials issued on September 28, 2018 (《免於進行臨床試驗醫療器械目錄（修訂）》) (the "**Exemption Catalog**") promulgated by the NMPA, as amended, are exempted from clinical trial requirements and 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, and 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;

(2) The safety and effectiveness of such medical devices can be proved through non-clinical evaluation;

(3) The safety and effectiveness of such medical devices can be proved through the analysis and evaluation of the data obtained from the clinical trials or clinical application of the same categories of medical devices.

The Exemption Catalog shall be formulated, amended and promulgated by the NMPA. 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, applicant may specify in the course of registration application and submit relevant proofing materials.

According to the regulations mentioned above and as confirmed by our company, among our product candidates, the sheath and guidewire are exempted from clinical trial requirements in accordance with the Exemption Catalog, and balloon catheter II and balloon catheter III fall into the conditions that the safety and effectiveness of such medical devices can be proved through the analysis and evaluation of the data obtained from the clinical trials or clinical application of the same categories of medical devices, thus, these devices can apply for exemption from clinical trial for NMPA approval.

Medical Device Production Permit

According to the Regulations on Supervision of Medical Devices (醫療器械監督管理條例), 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 food and 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 food and drug administrative authorities for registration of 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 food and drug administrative authorities for registration of changes.

According to the Administrative Measures for the Supervision of the Production of Medical Devices (醫療器械生產監督管理辦法), which was promulgated by the NMPA on July 30, 2014 and became effective on October 1, 2014, and was amended on November 17, 2017, an enterprise engaging in the production of Class I medical devices shall complete record-filing with the food and drug supervision and 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 of Medical Devices for engaging in the production 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 food and drug supervision and administration departments under the people's government of the province, autonomous region or municipality directly under the central government where it is located and submit supporting materials evidencing its compliance with the criteria specified in the Regulations on Supervision of Medical Devices for engaging in the production of such medical devices and the product registration certificates of such medical devices.

The revised draft amendment to the Regulation on the Supervision and Administration of Medical Devices 《醫療器械監督管理條例修正案(草案)》 (the "Draft Amendment") has ended the stage for public consultation, from June 25, 2018 to July 24, 2018. As of the Latest Practicable Date, the Draft Amendment had not been formally promulgated and implemented. Compared with the

currently enforced Regulation on the Supervision and Administration of Medical Devices which was amended in 2017, the main changes are concentrated on the following aspects: (i) clarifying the system of "holders of medical device marketing license"; (ii) reforming the clinical trial management system; (iii) optimizing the approval process; and (iv) improving post-approval regulatory requirements. In terms of the clinical trial management system, the Draft Amendment has clarified the definition of "clinical evaluation" (臨床評價) and its application on different class of medical devices. Clinical trials are in principle required for medical devices of Class III that are intended to support or sustain life or clinical use with high risk. The Draft Amendment has also added the term of "clinical trial" (臨床試驗) approval of medical devices of Class III which may pose relatively high risks to human bodies according to the clinical trials thereof and has changed the explicit permission to implied permission; the clinical trial requirements of medical devices for the diseases that are seriously life-threatening while have no effective treatments have been reduced conditionally. In terms of medical device marketing, the Draft Amendment has clarified that the entity under either self-operating or authorized-operating model which shall be responsible for, among others, product quality and quality control system is the holder of medical device marketing license, and has added new requirements on online sales of medical devices. In terms of regulatory requirements, the Draft Amendment has expanded the scope of supervision to all aspects of development, production, operation and use, and has added extended inspection and monitoring methods. The Company considered that the implementation of the Draft Amendment if as presently drafted will not have material impacts on the Group's ongoing and planned clinical trials, sales and registration based on the scope of business and ongoing operation and other activities of our Group.

Production and Quality Management of Medical Devices

Pursuant to the Administrative Measures on the Supervision of the Production of Medical Devices (醫療器械生產監督管理辦法) 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 CFDA on December 29, 2014 and 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 supervision and 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 CFDA on September 25, 2015 and came into effect on 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 1, 2016, the NMPA and the National Health and Family Planning Commission 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 June 1, 2016. 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. For conducting clinical trials of medical devices, an applicant shall organize to formulate scientific and reasonable clinical trial protocol based on the categories, risks and intended use of the medical devices for the clinical study. The applicant shall be responsible for organizing to develop and revise the researcher's manual, clinical trial protocol, informed consent form, case report form, relevant standard operating procedures and other relevant documents, and shall be responsible for organizing necessary trainings for the clinical trials. The applicant shall select the clinical trial institutions and its researchers from the qualified medical device clinical trial institutions according to the characteristics of the medical devices to be used in the clinical study.

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.

Permit for Medical Device Operation

According to the Regulations on Supervision of Medical Devices (醫療器械監督管理條例) 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 promulgated by the NMPA on July 30, 2014 and became effective on October 1, 2014, and was amended and implemented on November 17, 2017 respectively, 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 food and drug supervision and 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 food and drug supervision and administration departments of the city with districts where it is located.

No operation permit or record filing is required for the registrant, record holder or manufacturer of medical devices to sell its medical devices at its domicile or production sites; 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 and the General Office of the State Council 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 and the National Key R&D Program of China, and the clinical trials of which having been conducted by the National Clinical Research Center, 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), which were promulgated by the NMPA on November 2,2018 and 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) (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 National Health Commission of the PRC 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 Notice on Printing and Distributing the Reform Plan for the Management of 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" combined with actual situation in order to reduce 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.

As of the Latest Practicable Date, "Two Invoice System" had not been implemented across all provinces in China and only some provinces mainly including Fujian Province, Shanxi Province and Anhui Province have implemented the "Two Invoice System" in the field of medical consumables.

Overseas Clinical Trial Data of Medical Devices

On January 10, 2018, NMPA issued the Technical Guidelines for Accepting Overseas Clinical Trial Data of Medical Devices (接受醫療器械境外臨床試驗數據技術指導原則, "Technical Guidelines"). According to the Technical Guidelines, the overseas clinical trial data refers to all research data or research data of the same stage which generated from the confirmation process of the safety and effectiveness of the medical devices to be registered in China under normal use conditions in the overseas clinical trial institutions with the requirements of the country (region) where the clinical trial is conducted.

The three basic principles to accept overseas clinical trial data are as follow: (i) ethical principle: Overseas clinical trials shall follow the ethical guidelines established by the Declaration of Helsinki. Applicants are also required to state the ethics of the country (region) in which the clinical trial is conducted and codes and standards established by laws and regulations of the aforesaid country (region) or international codes and standards; (ii) legal principle: Overseas clinical trials shall be conducted in a country (region) with clinical trial quality management, and are in accordance with the regulatory requirements for clinical trials of medical devices (including IVD) in China; and (iii) scientific principle: Overseas clinical trial data shall be true, scientific, reliable and traceable. Applicants shall provide complete trial data and shall not filter.

According to the Technical Guidelines, the overseas clinical trial data submitted by the applicant shall at least include clinical trial protocol, ethical opinions, and clinical trial report which shall

include analysis and conclusions on the complete clinical trial data. If the overseas clinical trial data meets the relevant requirements of registration in China, and the data is scientific, complete and sufficient, it will be accepted. If the overseas clinical trial data meets the basic requirements of the Technical Guidelines, but additional information needs to be supplemented according to the relevant technical requirements for registration in China, supplementary clinical trials can be conducted within or outside China. As the supplementary clinical trial data and original overseas clinical trial data are in accordance with the relevant technical requirements of registration in China after comprehensive evaluation, overseas clinical trial data will be accepted.

Sampling and Collecting Human Genetic Resources Filing

On June 10, 1998, the Ministry of Science and Technology and the Ministry of Health promulgated the Interim Administrative Measures on Human Genetic Resources (人類遺傳資源管理暫行辦法), which established the rules for protecting and utilizing human genetic resources in the PRC. 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 became effective on October 1, 2015 according to the Circular on Implementing the Approval of Sampling, Collecting, Trading or Exporting Human Genetic Resources (關於實施人類遺傳資源採集、收集、買賣、出口、出境行政許可的通知), which clarified that the sampling and collection of human genetic resources though 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. According to the provisions therein, the State 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. And 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. 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 State.

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 and came into effect on 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 (Guo Ban Fa No. [1994] 66) (《國務院辦公廳關於印發國家醫藥管理局職能配置、內設機構和人員編製方案的通知》(國辦發[1994]66號)), 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 such exporting country on a timely basis:

(1) the application document is found forfeited or the validity period has expired;

(2) the product received complaints from customers and such quality issue has been proved.

Advertisements of Medical Devices

Pursuant to the Regulations on the Supervision and Administration of Medical Devices (醫療器械監督管理條例) 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 State Administration for Market Regulation (國家市場監督管理總局) on December 24, 2019, and 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 supervision and 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 license of the product, whichever is the shortest. Where no validity term is set forth in the registration certificate, record-filing certificate or the production license of the product, the advertisement approval shall be valid for two years.

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 PRC government 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 citizens 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 the establishment of a unified Basic Medical Insurance 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 basic medical insurance for urban employees.

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 National Urban Employees Basic Medical Insurance Scheme (Lao She Bu Fa [1999] No. 22) (《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》) (勞社部發[1999]22號)) prescribes the coverage of diagnostic and treatment devices and diagnostic tests where part of the fees is paid through the basic medical insurance scheme. 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 province's local policies.

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 formation can be guided by measures such as limiting the price difference rate in circulation links and publishing market price information.

According to the Administrative Norms on Centralized Procurement of High Value Medical Consumables (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, with strict requirement on safety, in great demand clinically, relatively highly-priced, and strongly reflected by the society. The online centralized procurement (the "**Centralized Procurement**") works of high value medical consumables 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 and invitational tenders or by other means stipulated by laws and regulations of the State. 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 (Guo Ban Fa No.[2019]37) (關於印發治理高值醫用耗材改革方案的通知(國辦發[2019]37號, the "Circular"). According to the Circular, high-value medical consumables are defined as medical consumables directly used on human, 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.

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 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 post-oriented 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 Tort Law of the PRC (《中華人民共和國侵權責任法》) promulgated by the Standing Committee of the NPC on December 26, 2009 and came into effect on July 1, 2010, 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.

LAWS AND REGULATIONS ON 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 "**PRC Company Law**"), which was issued by the Standing Committee of the National People's Congress (the "**SCNPC**") on December 29, 1993, last revised and became effective on October 26, 2018. Limited liability companies and stock limited companies established in the PRC shall be subject to the PRC Company Law. A foreign-invested company is also subject to the PRC Company Law unless otherwise provided by the foreign investment laws.

On March 15, 2019, the National People's Congress (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 (i) 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, (ii) for any sector restricted by the negative list, Foreign Investors shall conform to the investment conditions provided in the negative list, and (iii) 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 PRC 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

Investments in the PRC by foreign investors and foreign-invested enterprises were regulated by the Catalog for The Guidance of Foreign Investment Industries (外商投資產業指導目錄), last repealed by the Special Administrative Measures (Negative List) for the Access of Foreign Investment (2020 Version)（外商投資准入特別管理措施（負面清單（2020年版）, the "**Negative List 2020**") and the Catalog of Industries for Encouraging Foreign Investment (2019 Version)（鼓勵外商投資產業目錄（2019年版）） (the "**Encouraging Catalog 2019**") which were promulgated by the National Development and Reform Commission and the MOFCOM on June 30, 2019 and became effective on July 30, 2019. Pursuant to the Encouraging Catalog and the Negative List, foreign-invested projects are categorized as encouraged, restricted and prohibited. Foreign-invested projects that are not listed in the Negative List are permitted foreign invested projects.

According to the Encouraging Catalog 2019 and the Negative List 2020, the industry in which our PRC subsidiaries are primarily engaged does not fall into the category of restricted or prohibited industries.

Provisions on Merger and Acquisition of Domestic Enterprises by Foreign Investors

The Provisions on Merger and Acquisition of Domestic Enterprises by Foreign Investors (關於外國投資者併購境內企業的規定, the "**M&A Rules**"), promulgated by six PRC ministries including MOFCOM, the State-owned Assets Supervision and Administration Commission of the State Council, the State Administration of Taxation (the "**SAT**"), the SAIC, the China Securities Regulatory Commission (the "**CSRC**"), and the SAFE on August 8, 2006, effective from September 8, 2006, amended and became effective on June 22, 2009. The M&A Rules stipulate that foreign investors' merger and acquisition of domestic enterprises shall comply with the requirements stipulated by laws, administrative regulations and rules of China, and policies concerning industry, land and environment. A foreign investor is required to obtain necessary approvals when it: (i) acquires the equity of a domestic enterprise so as to convert the domestic enterprise into a foreign-invested enterprise; (ii) subscribes for the increased capital of a domestic enterprise so as to convert the domestic enterprise into a foreign-invested enterprise; (iii) establishes a foreign-invested enterprise through which it purchases the assets of any domestic enterprise and operates these assets; or (iv) purchases the assets of a domestic enterprise, and then invests such assets to establish a foreign-invested enterprise.

REGULATIONS RELATING TO INTELLECTUAL PROPERTY

The Trademark Law

Trademarks are protected by the Trademark Law of the PRC (Revised in 2019) (中華人民共和國商標法(2019年修訂)) which was promulgated on August 23, 1982 and subsequently amended on February 22, 1993, October 27, 2001, August 30, 2013 and April 23, 2019, respectively as well as the Implementation Regulation of the PRC Trademark Law (Revised in 2014) (中華人民共和國商標法實施條例(2014年修訂)) 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 SAIC, handles trademark registrations and grants a term of ten years to registered trademarks. Trademarks are renewable every ten years where a registered trademark needs to be used after the expiration of its validity term. A registration renewal application shall be filed within twelve 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》) amended by the Standing Committee of the NPC on December 27, 2008 and came into effect on October 1, 2009 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》) 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. Invention patent shall be valid for 20 years from the date of application while utility patent and design patent shall be valid for ten years from the date of application. 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 Patent Law of the PRC (revised in 2020) (中華人民共和國專利法（2020年修訂）) has been promulgated by the SCNPC on October 17, 2020 and will come into effect on June 1, 2021. Compared with the valid Patent Law which was amended on December 27, 2008 and come into effect on October 1, 2009, the main changes of the Patent Law of the PRC (revised in 2020) are concentrated on the following aspects: (i) clarifying the incentive mechanism for inventor or designer relating to service inventions; (ii) extending the duration of design patent; (iii) establishing a new system of "open licensing" (開放許可); (iv) improving the distribution of burden of proof in patent infringement cases; and (v) increasing the compensation for patent infringement.

The Copyright Law

Pursuant to the Copyright Law of the PRC (《中華人民共和國著作權法》) amended by the Standing Committee of the NPC on February 26, 2010 and came into effect on April 1, 2010, 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 on February 20, 2002 and the Regulation on Computers Software Protection (《計算機軟件保護條例》) amended by the State Council on January 30, 2013 and came into effect on 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 Regulation on Computers Software Protection.

Domain Names

Pursuant to the Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》) promulgated by the Ministry of Industry and Information Technology on August 24, 2017 and coming 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 and coming into effect on January 1, 2018 specifies the obligation of anti-terrorism and maintaining network security of internet information service providers.

REGULATIONS RELATING TO FOREIGN EXCHANGE

General Administration of Foreign Exchange

Under the PRC Foreign Currency Administration Rules (中華人民共和國外匯管理條例), promulgated on January 29, 1996 and last amended on August 5, 2008 which is formulated to strengthen the administration of foreign exchange, maintain the balance of international payments, and promote the healthy development of the national economy, and various regulations issued by the SAFE and other relevant PRC government authorities, Renminbi is convertible into other currencies for the purpose of current account items, such as trade related receipts and payments, payment of interest and dividends. The conversion of Renminbi into other currencies and remittance of the converted foreign currency outside the PRC territory for the purpose of capital account items, such as direct equity investments, loans and repatriation of investment, requires the prior approval from the SAFE or its regional office. Payments for transactions that take place within the PRC territory must be made in Renminbi. Unless otherwise approved, PRC companies may repatriate foreign currency payments received from abroad or retain the same abroad. Foreign-invested enterprises may retain foreign exchange in accounts with designated foreign exchange banks under the current account items subject to a cap set by the SAFE or its regional office. Foreign exchange proceeds under the current accounts may be either retained or sold to a financial institution engaging in settlement and sale of foreign exchange pursuant to relevant rules and regulations of the State. For foreign exchange proceeds under the capital accounts, approval from the SAFE is required for its retention or sale to a financial institution engaging in settlement and sale of foreign exchange, except where such approval is not required under the relevant laws and regulations of the PRC.

REGULATIONS ON FOREIGN EXCHANGE REGISTRATION OF OVERSEAS INVESTMENT BY PRC RESIDENTS

The Circular of the State Administration of Foreign Exchange on Issues concerning Foreign Exchange Administration over the Overseas Investment and Financing and Round-trip Investment by Domestic Residents via Special Purpose Vehicles (國家外匯管理局關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知, the "**Circular 37**"), which was promulgated by SAFE on

July 4, 2014 and became effective on the same date, requires PRC residents or entities to register with SAFE or its regional local branch with respect to their establishment or control of an offshore entity established for the purpose of overseas investment or financing. In addition, such PRC residents or entities must update their SAFE registrations when the offshore special purpose vehicle undergoes material events relating to any change of basic information (including change of such PRC citizens or residents, name and operation term), increases or decreases in investment amount, transfers or exchanges of shares, or mergers or divisions.

The SAFE promulgated the Circular of the State Administration of Foreign Exchange on Further Simplifying and Improving the Direct Investment-related Foreign Exchange Administration Policies (國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知, the "**Circular 13**") on February 13, 2015, which became effective on June 1, 2015 and was amended on December 30, 2019. The Circular 13 allows PRC residents or entities to register with qualified banks with respect to their establishment or control of an offshore entity established for the purpose of overseas investment or financing. However, remedial registration applications made by PRC residents that previously failed to comply with the Circular 37 continue to fall under the jurisdiction of the relevant local branch of SAFE. In the event that a PRC shareholder holding interests in a special purpose vehicle fails to fulfill the required SAFE registration, the PRC subsidiaries of that special purpose vehicle may be prohibited from distributing profits to the offshore parent and from carrying out subsequent cross-border foreign exchange activities, and the special purpose vehicle may be restricted in its ability to contribute additional capital into its PRC subsidiary. Moreover, failure to comply with the various SAFE registration requirements described above could result in liability under PRC law for evasion of foreign exchange controls.

REGULATIONS RELATING TO EMPLOYMENT AND SOCIAL WARFARE

The Labor Contract Law

Pursuant to the Labor Contract Law of the PRC (中華人民共和國勞動合同法), issued on June 29, 2007, amended on December 28, 2012 and newly effective on July 1, 2013, labor contracts shall be concluded in writing if labor relationships are to be or have been established between enterprises or institutions and the laborers. Enterprises and institutions are forbidden to force laborers to work beyond the time limit and employers shall pay laborers for overtime work in accordance with national regulations. In addition, labor wages shall not be lower than local standards on minimum wages and shall be paid to laborers in a timely manner.

According to the Labor Law of the PRC (中華人民共和國勞動法) promulgated on July 5, 1994 and last amended and newly effective on December 29, 2018, enterprises and institutions shall establish and improve their system of workplace safety and sanitation, strictly abide by state rules and standards on workplace safety, educate laborers in labor safety and sanitation in the PRC. Labor safety and sanitation facilities shall comply with state-fixed standards. Enterprises and institutions shall provide laborers with a safe workplace and sanitation conditions which are in compliance with state stipulations and the relevant articles of labor protection.

Social Insurance and Housing Fund

As required under the Regulation of Insurance for Labor Injury (工傷保險條例) promulgated on April 27, 2003, implemented on January 1, 2004 and amended on December 20, 2010, the Provisional

Measures for Maternity Insurance of Employees of Corporations (企業職工生育保險試行辦法) promulgated on December 14, 1994 and implemented on January 1, 1995, the Decisions on the Establishment of a Unified Program for Basic Old-Aged Pension Insurance of the State Council (國務院關於建立統一的企業職工基本養老保險制度的決定) issued on July 16, 1997, the Decisions on the Establishment of the Medical Insurance Program for Urban Workers of the State Council (國務院關於建立城鎮職工基本醫療保險制度的決定) promulgated on December 14, 1998, the Unemployment Insurance Measures (失業保險條例) promulgated on January 22, 1999 and the Social Insurance Law of the PRC (中華人民共和國社會保險法) promulgated on October 28, 2010 and implemented on July 1, 2011 and amended on December 29, 2018, enterprises are obliged to provide their employees in the PRC with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, labor injury insurance and medical insurance. These payments are made to local administrative authorities and if employers fail to contribute, they may be ordered to make up within a prescribed time limit and may be liable for a late payment fee equal to 0.05% of the outstanding contribution amount for each day of delay.

In accordance with the Regulations on the Management of Housing Funds (住房公積金管理條例) which was promulgated by the State Council on April 3, 1999 and amended on March 24, 2002 and March 24, 2019, enterprises must register at the competent managing center for housing funds and upon the examination by such managing center of housing funds, these enterprises shall complete procedures for opening an account at the relevant bank for the deposit of employees' housing funds. Enterprises are also required to pay and deposit housing funds on behalf of their employees in full and in a timely manner. If an employer fails to undertake contribution 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; where failing to do so at the expiration of the time limit, a fine of not less than 10,000 yuan nor more than 50,000 yuan shall be imposed. Furthermore, if an employer is overdue in the contribution of, or underpays, the housing provident fund, the housing provident fund management center shall order it to make the contribution within a prescribed time limit; where the contribution has not been made after the expiration of the time limit, an application may be made to a people's court for compulsory enforcement.

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) promulgated on December 26, 1989 and latest amended on April 24, 2014; the Law of the PRC on Environment Impact Assessment (中華人民共和國環境影響評價法) 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) 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 on November 20, 2017 and became effective on the same day, 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.

REGULATIONS RELATING TO TAX

Enterprise Income Tax

According to the Law of the PRC on Enterprise Income Tax (中華人民共和國企業所得税法), enacted on March 16, 2007, effective from January 1, 2008 and amended on February 24, 2017 and December 29, 2018 and the Implementation Regulations for the Enterprise Income Tax Law of the PRC (中華人民共和國企業所得税法實施條例), which was enacted on December 6, 2007 by the State Council, became effective on January 1, 2008 and was amended on April 23, 2019 (collectively, the "**EIT Law**"), and its relevant implementation regulations, taxpayers consist of resident enterprises and non-resident enterprises. Resident enterprises are defined as enterprises that are established in China in accordance with PRC laws, or that are established in accordance with the laws of foreign countries but whose actual or de facto control is administered from within the PRC. Non-resident enterprises are defined as enterprises that are set up in accordance with the laws of foreign countries and whose actual administration is conducted outside the PRC, but have established institutions or premises in the PRC, or have no such established institutions or premises but have income generated from inside the PRC. Under the EIT Law and relevant implementing regulations, a uniform Enterprise income tax rate of 25% is applicable. However, if non-resident enterprises have not formed permanent establishments or premises in the PRC, or if they have formed permanent establishment institutions or premises in the PRC but there is no actual relationship between the relevant income derived in the PRC and the established institutions or premises set up by them, the enterprise income tax is, in that case, set at the rate of 10% for their income sourced from inside the PRC.

VALUE-ADDED TAX AND BUSINESS 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, and the VAT rate of cultural creativity industry, categorized in modern service industry, is 6%.

The Provisional Regulations of PRC Concerning Value-added Tax (中華人民共和國增值税暫行條例) (the "**VAT Regulations**") was promulgated by the State Council on December 13, 1993 and amended on November 10, 2008, February 6, 2016 and November 19, 2017. The Implementing Rules for the Interim Regulations of the PRC on Value-added Tax (中華人民共和國增值税暫行條例實施細則) (the "**Implementing Rules on VAT**") was promulgated by the Ministry of Finance on December 25, 1993, first amended on December 15, 2008 and came into effect on January 1, 2009, subsequently amended on October 28, 2011 and effective on November 1, 2011. Under the VAT Regulations and Implementing Rules on VAT, entities and individuals selling goods, providing labor services of processing, repairing or maintenance, or selling services, intangible assets or real property in China, or importing goods to China, shall be identified as taxpayers of value-added tax, and shall pay value-

added tax. Unless stated otherwise, for VAT payers who are selling or importing goods, and providing processing, repairs and replacement services in the PRC, the tax rate shall be 17%, in certain limited circumstances, 11%.

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 deduction rates of 17% and 11% applicable to the taxpayers 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 and 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 Arrangement between Mainland China and Hong Kong for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with respect to Taxes 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) effective from August 21, 2006, no more than 5% withholding tax rate applies to dividends paid by a PRC company to a Hong Kong resident, provided that the recipient is a company that holds at least 25% of the capital of the PRC company. The 10% withholding tax rate applies to dividends paid by a PRC company to a Hong Kong resident if the recipient is a company that holds less than 25% of the capital of the PRC company.

Furthermore, pursuant to the Circular of the State Administration of Taxation on Relevant Issues Concerning the Implementation of Dividend Clauses in Tax Treaties (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), which was promulgated on and effective from February 20, 2009, all of the following requirements should be satisfied where a fiscal resident of the other party to the tax agreement needs to be entitled to such tax agreement treatment as being taxed at a tax rate specified in the tax agreement for the dividends paid to it by a PRC resident company: (a) such a fiscal resident who obtains dividends should be a company as provided in the tax agreement; (b) owner's equity interests and voting shares of the PRC resident company directly owned by such a fiscal resident reaches a specified percentage; and (c) the equity interests of the PRC resident company directly owned by such a fiscal resident, at any time during the 12 months prior to the acquisition of the dividends, reaches a percentage specified in the tax agreement.

In addition, according to the Announcement of the State Administration of Taxation on Promulgation of the Administrative Measures on Non-residents 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), which was promulgated by the SAT on October 14, 2019 and became effective on January 1, 2020, non-resident taxpayers claiming treaty benefits shall be handled in accordance with the principles of "self-assessment, claiming benefits, retention of the relevant materials for future inspection". 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, simultaneously gather and retain the relevant materials pursuant to the provisions of these Measures for future inspection, and accept follow-up administration by the tax authorities.

EU REGULATORY OVERVIEW

Overview

As of the Latest Practicable Date, the EU had issued and implemented three medical device directives, including:

- Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) (1990). This directive applies to active implantable medical devices such as cardiac pacemakers and implantable insulin pumps. It came into effect on January 1, 1993.
- Council Directive 93/42/EEC on Medical Devices (MDD) (1993). This directive applies to medical devices and their accessories other than the active implantable devices covered by AIMDD. It took effect on January 1, 1995.
- Directive 98/79/EC of the European Parliament and of the Council on in vitro Diagnostic Medical Devices (IVDMD). This directive applies to *in vitro* diagnostic medical devices and their accessories such as blood cell counters and pregnancy detection devices. Member states of EU were required to adopt and publish the laws, regulations and administrative provisions necessary to comply with IVDMD not later than December 7, 1999 and apply these provisions with effect from June 7, 2000.

Classification of Medical Device

The EU classifies medical device products applicable in the MDD according to their nature, function, and intended purpose. Medical devices are divided into four categories: I, IIa, IIb, and III. Broadly speaking, low-risk medical devices belong to Class I, medium-risk medical devices belong to Class IIa and IIb, and high-risk medical devices belong to Class III. TAVI products are classified as Class III medical device in Europe.

Recent Developments in EU Medical Device Regulations

In 2017, the EU formally adopted and issued the new medical device ("**MDR**") regulation EU2017/745 and the in vitro diagnostic medical device ("**IVDR**") regulation EU2017/746. The MDR regulations incorporate the AIMDD, which is combined with the MDD. These two regulations have come into effect already. The MDR was initially expected to become applicable in May 2020 (which was postponed for one year due to the COVID-19 pandemic). The IVDR is expected to become applicable in 2022.

Key differences between the MDR and the MDD are set out as follows.

- ***Strengthen the compliance responsibilities of manufacturers and economic communities (including agents, distributors).*** Manufacturers need to appoint a person in charge of compliance, who will be primarily responsible for post-market supervision, accident reporting and to ensure all the products are properly inspected in accordance with the requirements of the quality management system before delivered, and that technical documents and compliance statements are updated in a timely manner.

- ***More pre-market review.*** For certain high-risk devices, the pre-market evaluation mechanism will be applied. The evaluation mechanism will be conducted by a panel of experts under the European Commission. This panel of experts will review the preliminary evaluations from the notified body.

- ***Transparency and traceability.*** The EU will adopt the Unique Device Identification ("**UDI**") system to identify and track devices. In addition, the new regulations will establish a revised and publicly-accessible database, which will keep device certification information and clinical research, vigilance, and post-marketing monitoring information. For implantable devices, such as TAVI product, manufacturers are required to summarize its main safety data, clinical performance and the outcome of clinical evaluation in a publicly available document.

- ***Strengthen the supervision of clinical evidence.*** The MDR imposed a higher requirement for the storage of clinical evidence.

The CE Mark registration for VitaFlow™ II will be governed by the newly-adopted MDR. The Company has taken into account the MDR updates with respect to the regulatory pathway of VitaFlow™ II in Europe before initiating the clinical trial in Europe. Accordingly, the MDR will not have a material impact on the registration of VitaFlow™ in Europe.

EMERGING MARKETS REGULATORY OVERVIEW

Currently, there are certain jurisdictions that recognize marketing approval for medical device in the United States, Europe or its country of origin and do not require additional local clinical trial. For example, in Thailand and Argentina, medical devices that have obtained the marketing approval and the certificate for medical device export are eligible for commercialization without undergoing additional clinical trial. In Russia, medical device companies may use clinical data obtained in its country of origin for product registration and do not need to conduct another clinical trial in Russia.