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, labour 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 CFDA shall cease to exist, and the NMPA was established to undertake the duties of the former CFDA.

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》) (the "**Medical Device Regulations**") promulgated by the State Council and effective from 1 April 2000, and latest amended on 9 February 2021 and came into effect on 1 June 2021, the food and drug supervision and 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.

We distribute Class I medical devices and Class II medical devices (excluding *in vitro* diagnostic products) mainly in China, including medical imaging films, medical image printer, self-service film output printer.

Registration and Filings of Medical Device Products

According to the Measures for the Administration of Medical Devices Registration and Filing (醫療器械註冊與備案管理辦法) (the "**Measures for Medical Devices Registration and Filing**") promulgated by the SAMR on 26 August 2021 and became effective on 1 October 2021, Class I medical devices shall be subject to product filing-based administration. Class II and Class III medical devices shall be subject to product registration-based administration. For the filing of Class I medical devices in China, the applicant shall submit the filing materials to the municipal departments in charge of drug supervision and administration. Class II medical devices in China shall be examined by the provincial counterparts of NMPA and Class III medical devices in China shall be examined by NMPA, and after approval, a medical device registration certificate shall be issued. The registration and filing of medical devices shall comply with the relevant requirements of the classification rules and the Catalogue.

Pursuant to the Measures for Medical Devices Registration and Filing, for a Class II or Class III medical device which have already been registered, where there is a change to product name, model, specifications, structure and components, applicable scope, technical specifications for product and production address for imported medical device, the registrant shall apply to the relevant authority for the alteration. Where there is a change to the name and domicile of the registrant or its agent, the registrant shall apply to the relevant authority for the alteration. If there is a change in the manufacturing address of a domestic medical device, the registrant shall go through the formalities for the alteration after the corresponding change of production permits.

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.

We have the Class I medical devices filed with the food and drug supervision and administration departments of the local people's governments at the districted city level for the products we currently manufacture and sell in China. We also have the production licence of Class II medical devices issued by the food and drug supervision and administration departments of the local people's governments at the provincial level for the products (i.e. mobile X-ray system and high pressure injector) we will manufacture in the future.

Production Permit of Medical Devices

Pursuant to the Regulations of Medical Devices and the Administrative Measures on the Production of Medical Devices (《醫療器械生產監督管理辦法》) (the "**Production Measures**") promulgated by the CFDA on 30 July 2014, amended and coming into effect on 17 November 2017, a manufacturer of medical device shall satisfy all of the following conditions:

(i) possessing production sites, environmental conditions, production equipment and professional technicians that are suitable for such medical device produced;

(ii) possessing organisations or professional examination staff and examination equipment that carry out quality examination for such medical device produced;

(iii) formulating a management system which ensures the quality of such medical device;

(iv) having capability of after-sale services that is suitable for such medical device produced; and

(v) satisfying the requirements as prescribed in production R&D and production technique documents.

The enterprises engaging in the production of Class I medical devices shall make filings for such Class I medical devices with the food and drug supervision and administration departments of the local people's governments at the districted city level and submit proofing materials of qualification to engage in the production of such medical devices. The enterprises engaging in the production of Class II and Class III medical devices shall apply for production licences to the food and drug supervision and administration departments of the local people's governments of the provinces, autonomous regions or municipalities, and submit proofing materials of qualification to engage in the production of such medical devices and registration certificates for such medical devices produced.

A production permit for a medical device is valid for five years and the registrant shall apply to the original departments that issued such permit for renewal six months prior to its expiration date.

Medical device manufacturers shall be responsible for the quality of medical devices they manufacture. In the event of entrusted manufacture, the entrusting party shall be responsible for the quality of medical devices manufactured under entrustment. In the event of entrusted manufacture of medical devices, the entrusting party shall be the domestic registrant or record filing party of the medical devices manufactured under entrustment. In the event of entrusted manufacturing of the domestic medical devices which have been examined and approved according to the special examination and approval procedures applicable to innovative medical devices, the entrusting party shall obtain the licence for entrusted manufacture of medical devices or go through the formalities for record-filing of the manufacture of Class I medical devices. In the event of entrusted manufacture of medical devices, the entrusted party shall be a domestic manufacturing enterprise which has obtained the licence for entrusted manufacture of medical devices or gone through the formalities for record-filing of the manufacture of Class I medical devices. The entrusted party shall bear corresponding responsibility for the medical devices manufactured under entrustment. Furthermore, in order to further strengthen the supervision and management of medical devices production, standardise medical device production activities and ensure the safety and effectiveness of medical devices, the Measures for the Supervision and Administration of Medical Device Production (2022 Revised) (《醫療器械生產監督管理辦法(2022修訂)》) was promulgated by the NMPA on 10 March 2022, and will come into effect on 1 May 2022.

We have the Class I medical devices filed with the food and drug supervision and administration departments of the local people's governments at the districted city level for the products we currently manufacture and sell in China. We also have the production licence of Class II medical devices issued by the food and drug supervision and administration departments of the local people's governments at the provincial level for the products we will manufacture in the future.

Quality Management of Medical Devices

Medical device operation in the PRC is subject to the Good Supply Practise for Medical Devices (《醫療器械經營質量管理規範》) issued by the CFDA on 12 December 2014 and became effective on the same day, according to which enterprises engaging in medical device business shall carry out risk management based on the risk categories of medical devices operated by it, take corresponding quality management measures and keep relevant records or archives. The medical device business enterprises, unless otherwise provided therein, shall also have business premises and warehouses that match its business scope and scale, and the area of business premises and warehouses shall meet the business requirements. The storage operation area and auxiliary operation area of medical equipment shall be separated from office area and living area, or quarantine measures shall be taken for the storage operation area and auxiliary operation area. Also, medical device operation enterprises shall strengthen the management of return of goods to ensure the quality and safety of medical devices at the stage of return and prevent the mixing in of counterfeit and inferior medical devices.

Permit for Medical Device Operation

Pursuant to the Measures for the Supervision and Administration of Medical Devices Operation (《醫療器械經營監督管理辦法》) which was promulgated by CFDA on 30 July 2014 and became effective on 1 October 2014, and last amended on 17 November 2017, an enterprise engaging in the operation of medical devices shall have business premises and storage conditions suitable for the operation scale and scope, and shall have a quality control department or personnel suitable for the medical devices it operates. An enterprise engaged in the operation of Class II medical devices shall file with the municipal level food and drug supervision and administration department and provide proofing materials for satisfying the relevant conditions of engaging in the operation of medical devices, while an enterprise engaged in the operation of Class III medical devices shall apply for an operation permit to the municipal level food and drug supervision and administration department and provide proofing materials for satisfying the relevant conditions of engaging in the operation of such medical devices.

The food and drug supervision and administration department which receives operation permit application shall grant the operation permit if the enterprise meets the prescribed requirements. An operation permit is valid for five years and may be renewed pursuant to the relevant regulations. An enterprise engaging in medical devices operation shall not operate or use any medical device that has not been legally registered, without qualification certificate, expired, invalid or disqualified. Moreover, in order to further strengthen the operation supervision and management of medical devices, standardise the business activities of medical devices and ensure the safety and effectiveness of medical devices, the Measures for the Supervision and Administration of Medical Devices Operation (2022 Revised) (《醫療器械經營監督管理辦法(2022修訂)》) was promulgated by the NMPA on 10 March 2022, and will come into effect on 1 May 2022.

We currently have the Class II record-filing certificate for medical device business operations and the Class III medical device operation permits, which are within the validity term.

Two Invoice System

On 26 December 2016, the State Council together with seven other central government departments (including the NHFPC and the State Administration of Food and Drug) jointly issued the Notice on Opinions on the Implementation of the Two Invoice System in Drug Procurement by Public Medical Institutions (for Trial Implementation) (《關於在公立醫療機構藥品採購中推行兩票制的實施意見(試行)》) (the "**Notice**"). According to the Notice, the aim of the "Two Invoice System" is to only allow a maximum of two invoices to be issued in the value chain with the first invoice to be issued by manufacturers to distributors and the second one to be issued by distributors to hospitals and healthcare institutions.

On 5 March 2018, six government departments including the National Health Commission and MOF jointly issued the Notice on Consolidating the Achievements of Cancelling 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 centralised purchase of high value medical consumables, and that the "Two Invoice System" in relation to high-value medical consumables shall be gradually implemented.

On 19 July 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》), according to which, high-value medical consumables refer to the medical consumables that are directly used for human bodies, and are strictly required for safety, and are in great clinical demand and priced relatively high, and can impose heavy burdens on patients for affording them. Local governments are encouraged 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. The integrity operation and practise of enterprises of high-value medical consumables and their practitioners are included in the credit management system to enhance the recording, publication, and early warning of dishonest behaviour, and strengthen the management of performance.

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 23 July 2019, "Two Invoice System" for high-value consumables needs to be further discussed given the huge differences between the nature of high-value consumables and drugs, including the complexity of clinical use and after-sales service.

The following table sets out the regulatory development regarding the implementation of the "Two Invoice System" for each of the provinces in the PRC at the Latest Practicable Date, the specific implementation shall take into account the actual situation of the locality.

No.	Provinces	Scope of the implementation of the "Two Invoice System"
1.	Anhui	implements the "Two Invoice System" for the procurement of medical consumables in all public medical institutions above the second level. In practise, the "Two Invoice System" applies to high-value medical consumables and does not include low-value medical consumables. The medical imaging film products are not included.
2.	Beijing	there is no clear provision on the "Two Invoice System" for consumables.
3.	Chongqing	there is no clear provision on the "Two Invoice System" for consumables.
4.	Fujian	only strictly implements the "Two Invoice System" for the procurement of high-value medical consumables, and there is no clear provision for low-value medical consumables.
5.	Gansu	only encourages the implementation of the "Two Invoice System" for high-value medical consumables, and there is no clear provision for low-value medical consumables.
6.	Guangdong	has gradually implemented the "Two Invoice System" for the purchase and sale of high-value medical consumables, and there is no clear provision for low-value medical consumables.

No.	Provinces	Scope of the implementation of the "Two Invoice System"
7.	Guangxi	only encourages the implementation of the "Two Invoice System" for the purchase and sale of high-value medical consumables, and there is no clear provision for low-value medical consumables.
8.	Guizhou	has gradually implemented the "Two Invoice System" for the purchase and sale of high-value medical consumables, and there is no clear provision for low-value medical consumables.
9.	Hainan	all public medical institutions only implement the "Two Invoice System" for the purchase and sale of high-value medical consumables (the relevant provision was in the draft stage of soliciting public opinions), and there is no clear provision for low-value medical consumables.
10.	Hebei	implements the "Two Invoice System" for the purchase and sale of medical consumables (the relevant provision was in the draft stage of soliciting public opinions) and encourages the implementation of the "Two Invoice System" for the purchase and sale of high-value medical consumables, but there is no clear provision for low-value medical consumables.
11.	Heilongjiang	only has explicit provisions on the "Two Invoice System" for the purchase and sale of testing reagents, sterile and implantable medical devices.
12.	Henan	has not implemented the "Two Invoice System" for medical consumables either at the provincial level or in Zhengzhou, the provincial capital of Henan Province.
13.	Hubei	has gradually implemented the "Two Invoice System" for the classified centralised procurement of high-value medical consumables, and there is no clear provision for low-value medical consumables.
14.	Hunan	only explores how to implement the "Two Invoice System" for the purchase and sale of high-value medical consumables, and there is no clear provision for low-value medical consumables.
15.	Inner Mongolia	encourages qualified public medical institutions to implement the "Two Invoice System" for the purchase and sale of medical consumables and launches the pilot program of the "Two Invoice System" for high-value medical consumables, but there is no clear provision for low-value medical consumables.
16.	Jiangsu	has not implemented the "Two Invoice System" for medical consumables either at the provincial level or in Nanjing, the provincial capital of Jiangsu Province.

No.	Provinces	Scope of the implementation of the "Two Invoice System"
17.	Jiangxi	only encourages the implementation of the "Two Invoice System" for the purchase and sale of high-value medical consumables, and there is no clear provision for low-value medical consumables.
18.	Jilin	only encourages public hospitals to actively explore to implement the "Two Invoice System" for high-value medical consumables, and there is no clear provision for low-value medical consumables.
19.	Liaoning	implements the "Two Invoice System" for the distribution of medical consumables and testing reagents in all public medical and health institutions, but it does not clearly define whether it applies to high-value or low-value medical consumables.
20.	Ningxia	implements the "Two Invoice System" for the circulation and distribution of medical consumables and encourages the implementation of the "Two Invoice System" for the purchase and sale of high-value medical consumables, but there is no clear provision for low-value medical consumables.
21.	Qinghai	implements the "Two Invoice System" for the procurement of high-value consumables and general medical consumables in all public medical institutions, however, medical imaging film products do not fall within the scope of the definition of general medical consumables.
22.	Shaanxi	implements the "Two Invoice System" for all medical consumables in all public medical institutions, which indicates that medical imaging film products shall be included. In case of any difficulty, the "Two Invoice System" for high-value medical consumables may be implemented first.
23.	Shandong	only implements the "Two Invoice System" for drug procurement, and there is no clear provision on the "Two Invoice System" for consumables.
24.	Shanghai	there is no clear provision on the "Two Invoice System" for consumables.
25.	Shanxi	implements the "Two Invoice System" for the procurement of medical consumables, but it is not clearly defined whether it applies to high-value or low-value medical consumables.
26.	Sichuan	has gradually implemented the "Two Invoice System" for the purchase and sale of high-value medical consumables, and there is no clear provision for low-value medical consumables.
27.	Tianjin	encourages the implementation of the "Two Invoice System" for the purchase and sale of high-value medical consumables, and there is no clear provision for low-value medical consumables.

No.	Provinces	Scope of the implementation of the "Two Invoice System"
28.	Xinjiang	only encourages the implementation of the "Two Invoice System" for the purchase and sale of high-value medical consumables, and there is no clear provision for low-value medical consumables.
29.	Xizang	has formulated provisions on the "Two Invoice System" for the procurement of high-value medical consumables, but there is no clear provision for low-value medical consumables.
30.	Yunnan	there is no clear provision on the "Two Invoice System" for consumables.
31.	Zhejiang	has implemented the "Two Invoice System" for the procurement of medical consumables, but it does not clearly define whether it applies to high-value or low-value medical consumables.

Pursuant to the Notice on Printing and Distributing the Reform Plan for the Management of High-value Medical Consumables, high-value medical consumables refer to the medical consumables that are directly used for human bodies, and are strictly required for safety, and are in great clinical demand and priced relatively high, and can impose heavy burdens on patients for affording them. The aim of the "Two Invoice System" is to only allow a maximum of two invoices to be issued in the value chain with the first invoice to be issued by manufacturers to distributors and the second one to be issued by distributors to hospitals and healthcare institutions. According to Centralised Procurement Catalogue of High-value Medical Consumables of Shandong Province (First Batch) (《山東省高值醫用耗材集中採購目錄(第一批)》) and Centralised Procurement Catalogue of High-value Medical Consumables of Shandong Province (Second Batch) (《山東省高值醫用耗材集中採購目錄(第二批)》) issued by Health and Family Planning Commission of Shandong Province, the consumables included in the centralised procurement scope of high-value medical consumables in Shandong Province mainly include vascular interventional, non-vascular interventional, orthopaedic implantation, neurosurgery, electrophysiology, pacemaker, extracorporeal circulation and blood purification, and ophthalmic materials. As of the Latest Practicable Date, our products are not classified as the high-value medical consumables which is defined in the Notice or Catalogue mentioned above.

On 30 September 2019, ten local government departments of Shandong Province including Health Committee issued the Notice on "Two Invoice System" Implementation Plan in Medicines Procurement by Public Medical Institutions in Shandong Province (《關於印發〈山東省公立醫療機構藥品採購推行"兩票制"實施方案〉的通知》), which stipulates that all public medical institutions in Shandong Province shall implement the "Two Invoice System" on the procurement of drugs from 30 October 2019. As of the Latest Practicable Date, Shandong Province has not yet implemented the "Two Invoice System" on the procurement of high-value or low-value medical consumables.

Advertisements of Medical Devices

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 (i) no approval document has been obtained. (ii) the authenticity of any approval document has not been verified, or (iii) the content of the advertisement is inconsistent with the approval documents, such medical device advertisement shall not be published.

The SAMR promulgated the Interim Measures for the Administration of the Examination and Administration of Drugs, Medical Devices, Health Foods, and Formula Foods for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》) on 24 December 2019, which came into effect from 1 March 2020 and replace the Regulations of Medical Devices and the Measures for the Examination of Medical Devices Advertisements.

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 (《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 14 December 1998, under which all employers in urban cities are required to enrol 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 16 January 2003, China launched the New Rural Cooperative Medical System to provide medical insurance for rural residents in selected areas which has spread to the whole nation thereafter. 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 10 July 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 3 January 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), which was issued on 30 June 1999 and became effective on the same day, prescribes the coverage of diagnostic and treatment devices and diagnostic tests where part of the fees are 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.

Medical Device Recalls

Pursuant to the Administrative Measures for Medical Device Recalls (《醫療器械召回管理辦法》) promulgated by the NMPA on 25 January 2017 and came into effect on 1 May 2017, in light of the severity of the defect, medical device recall is divided into: (i) Class I recall: the use of the medical device may cause or have caused serious health hazards; (ii) Class II recall: the use of the medical device may cause or have caused temporary or reversible health hazards; (iii) Class III recall: the use of the medical device is less likely to cause any harm but recall is still required.

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, and the recall notice published on such websites shall be linked to the NMPA website.

Procurement of Medical Devices by public hospital and healthcare institutions

According to the Law of the PRC on Government Procurement (《中華人民共和國政府採購法》) (the "**Procurement Law**") promulgated by the Standing Committee of the NPC on 29 June 2002 and was last amended and implemented on 31 August 2014, the government procurement methods includes public invitation, invited bidding, competitive negotiation, single-source procurement, inquiry about quotations, and other methods confirmed by the department for supervision over government procurement under the State Council. Pursuant to Article 71 of the Procurement Law, if public invitation shall be used as required by the law and yet other government procurement methods were used without authorisation, the purchaser and the procurement agency shall be ordered to make corrections, shall be warned and may be subject to a fine, and the person-in-charge or any other person who is directly responsible shall be punished pursuant to the law. Since we are not the purchaser nor the procurement agency, we are not subject to Article 71 of the Procurement Law and will not be fined.

However, pursuant to Article 73 of the Procurement Law, if any unlawful act pursuant to Article 71 is committed which has resulted in or may result in the provider winning the bid, the procurement contract shall be cancelled if it has not been performed.

According to the Law of the PRC on Tendering and Bidding (《中華人民共和國招標投標法》) promulgated by the Standing Committee of the NPC on 30 August 1999 and was lasted amended on 27 December 2017 and implemented on 28 December 2017, and the Regulations on the Implementation of the Law of the PRC on Tendering and Bidding (《中華人民共和國招標投標法實施條例》) promulgated by State Council on 20 December 2011 and was lasted amended and implemented on 2 March 2019, the procedures of procurement of medical devices by public bidding mainly includes the issuance of bidding announcement, making and publishing bidding documents, bidding for suppliers, bid opening and evaluating bid, determining bid-winning suppliers, issuing bid-winning notice, signing contracts and filing records etc. After the supplier is determined, the bidder shall conclude a written contract in accordance with the bidding documents and the bidding documents of the winning bidder. The bid inviter and the winning bidder shall not conclude any other agreement deviating from the substantive content of the contract.

As confirmed by our Directors, our Group is not aware of any material non-compliance with relevant PRC laws and regulations of our Group's end customers from the sales channel of direct sales to hospitals and/or healthcare institutions during the Track Record Period.

Further, based on the above and as far as the relevant work conducted by the PRC Legal Advisers (including reviewing relevant sales contracts, interviewing with relevant end customers and consulting with relevant government authorities), the PRC Legal Advisers, being the legal advisers of the PRC law of the Group (instead of the end customers), are not aware of any material non-compliance with relevant PRC laws and regulations of our Group's end customers from the sales channel of direct sales to hospitals and/or healthcare institutions during the Track Record Period.

On 25 November 2020, the NHSA issued the Response to Proposal No. 7777 of the Third Session of the Thirteenth National People's Congress (《國家醫療保障局對十三屆全國人大三次會議第7777號建議的答覆》), which illustrates that the country is currently promoting the establishment of an integrated provincial bidding and procurement platform for bidding, procurement, trading, settlement and supervision, and promoting the construction of regional and national alliance procurement mechanisms. At the same time, the NHSA is coordinating the construction of a subsystem of a unified national medical security information platform for drugs and medical devices procurement management, in order to achieve national linkage of drug and medical consumables procurement, distribution and supervision.

As of the Latest Practicable Date, the national alliance recruitment and procurement platform is yet to be implemented.

According to the Notice of the State Council on Issuing the "Made in China (2025)" (GuoFa [2015] No. 28) (國務院關於印發《中國製造2025》的通知》(國發[2015]28號)) promulgated by the State Council on 8 May 2015, it takes high-performance medical equipment as one of the ten key areas of development. China should organise and implement a number of special and major projects for innovation and industrialization, including high-end diagnosis and treatment equipment, and make it clear that by 2025, the market share of high-end equipment with independent intellectual property rights in relevant fields will increase significantly.

Pursuant on the Outline of the Program for Health China 2030 (《"健康中國2030"規劃綱要》) promulgated by the Communist Party of China Central Committee and the State Council on 25 October 2016, it specifies that China needs to strengthen the construction of innovation capacity such as high-end medical devices, accelerate the transformation and upgrading of medical devices, improve the international competitiveness of medical diagnosis and treatment equipment and medical materials with independent intellectual property rights, and put forward the goal of fully integrating the quality standards of medical devices with international standards by 2030.

According to the Notice on Implementing Relevant Policies on Equal Treatment of Domestic and Foreign-funded Enterprises in Government Procurement Activities (Caiku [2021] No.35) (關於在政府採購活動中落實平等對待內外資企業有關政策的通知(財庫[2021]35號)) promulgated by MOF on 13 October 2021, for government procurement activities, except for procurement projects involving national security and state secrets, products produced in China by domestic and foreign-funded enterprises shall not be treated differently. Products produced in China, whether their suppliers are domestic or foreign-funded enterprises, shall be guaranteed the equal right to participate in government procurement activities according to law.

REGULATIONS ON INFORMATION SECURITY AND DATA PRIVACY

On 28 May 2020, the NPC approved the Civil Code of the PRC (《中華人民共和國民法典》) (the "**Civil Code**"), which came into effect on 1 January 2021. Pursuant to the Civil Code, the personal information of a natural person shall be protected by the law. Any organization or individual that needs to obtain personal information of others shall obtain such information legally and ensure the safety of such information, and shall not illegally collect, use, process or transmit personal information of others, or illegally purchase or sell, provide or make public personal information of others.

The Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), or the Personal Information Protection Law, released by the SCNPC on 20 August 2021 and became effective from 1 November 2021, stipulates the scope of personal information and establishes rules for processing personal information onshore and offshore. The Personal Information Protection Law sets forth certain specific personal information protection requirements, including but not limited to more specific inform and consent requirements in various contexts, strengthened and classified obligations of personal information processors, and more limitations and rules on process of personal information.

On 10 June 2021, the SCNPC promulgated the Data Security Law of People's Republic of China (《中華人民共和國數據安全法》) (the "**PRC Data Security Law**"), which became effective on 1 September 2021. Pursuant to the PRC Data Security Law, data refers to any record of information in electronic or any other form and data processing includes but is not limited to the collection, storage, use, processing, transmission, provision, and public disclosure of data. Industrial sector, telecommunications, transportation, finance, natural resources, health, education, science and technology, and other departments shall undertake the duty to supervise data security in their respective industries and fields. The PRC Data Security Law stipulates that each organization or individual collecting data shall adopt legal and proper methods, and shall not steal or obtain data by other illegal methods, and the data processing activities shall comply with laws and regulations, respect social mores and ethics, comply with commercial ethics and professional ethics, be honest and trustworthy, perform obligations to protect data security, and undertake social responsibility; it shall not endanger national security, the public interest, or individuals' and organizations' lawful rights and interests.

On 28 December 2021, the Cyberspace Administration of China, or the CAC, together with other PRC governmental authorities, promulgated the revised Measures for Cybersecurity Review (《網絡安全審查辦法》), or the Cybersecurity Measures. Pursuant to the Cybersecurity Measures, (i) the purchase of network products and services of a critical information infrastructure operator and data processing activities of an online platform operator that affect or may affect national security shall be subject to the cybersecurity review, (ii) particularly, if a critical information infrastructure operator purchase network products and services that affect or may affect national security, or an online platform operator possessing personal information of over one million users and pursues a foreign listing (國外上市), such operator must apply for cybersecurity review, and (iii) relevant governmental authorities in the PRC may initiate cybersecurity review if such governmental authorities determine any network products and services, and data processing activities affect or may affect national security. On 14 November 2021, the CAC published the Regulations on the Administration of Cyber Data Security (Draft for Comments) (《網絡數據安全管理條例(徵求意見稿)》), or the Draft Cyber Data Regulations. The Draft Cyber Data Regulations provides that data processors conducting the following activities shall apply for cybersecurity review: (i) merger, reorganization, or division of internet platform operators that have acquired a large number of data resources related to national security, economic development, or public interests, which affects or may affect national security; (ii) a foreign listing by a data processor processing personal information of over one million users; (iii) a listing in Hong Kong which affects or may affect national security; or (iv) other data processing activities that affect or may affect national security.

On 7 July 2022, CAC promulgated Measures for the Security Assessment of Outbound Data Transfers (《數據出境安全評估辦法》), which became effective on 1 September 2022 and provide that a data processor is required to apply for security assessment for cross-border data transfer in any of the following circumstances: (i) where a data processor provides critical data to offshore entities and individuals; (ii) where a CIIO or a data processor which processes personal information of more than one million individuals provides personal information to offshore entities and individuals; (iii) where a data processor has provided personal information in the aggregate of more than 100,000 individuals or sensitive personal information of more than 10,000 individuals in total to offshore entities and individuals since January 1 of the previous year; or (iv) other circumstances prescribed by the CAC for which declaration for security assessment for cross-board transfer of data is required.

LAWS AND REGULATIONS RELATING TO ANTI-BRIBERY

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

Medical Big Data

On 21 June 2016, the General Office of the State Council promulgated the Guiding Opinions of the General Office of the State Council on Promoting and Regulating the Application and Development of Health and Medical Big Data (Guo Ban Fa [2016] No. 47) (《國務院辦公廳關於促進和規範健康醫療大數據應用發展的指導意見》(國辦發[2016]47號)), which stipulates that the health and medical big data are important basic strategic resources of the State. The State will promote the sharing and opening of health and medical big data resources, encourage various medical and health institutions to promote the collection and storage of health and medical big data, enhance application support and technical support for operation and maintenance, and open up data resource sharing channels, speed up the construction and improvement of basic databases with electronic health records, electronic medical records and electronic prescriptions of residents as the core, and comprehensively deepen the application of health and medical big data.

On 25 April 2018, the General Office of the State Council promulgated the Opinions of the General Office of the State Council on Promoting the Development of "Internet + Medical Health" (Guo Ban Fa [2018] No. 26) (《國務院辦公廳關於促進「互聯網+醫療健康」發展的意見》(國辦發[2018]26號)), which provides that it is necessary to accelerate the realisation of exchange and sharing of medical and health information:

- All regions and relevant departments shall coordinate to promote the construction of a unified, authoritative, interconnected national health information platform, gradually realise the connection with the national data sharing and exchange platform, and enhance data collection in relation to population, public health, medical services, medical insurance, drug supply and comprehensive management, smooth data sharing channels among departments, regions and industries, and promote the sharing and application of national health information;

- The State speeds up the construction of a basic resource information database, and improves the database in relation to the entire population, electronic health records and electronic medical records;

- The state improves the tiered diagnosis and treatment information system based on the Internet and big data technology, and promotes the gradual consumption of the sharing of electronic health records, electronic medical records and inspection results in all tiers and types of hospitals, and the authorised use among different levels of medical and health institutions.

On 3 December 2018, the National Health Commission of the PRC promulgated the Administrative Measures for the Classification and Evaluation of the Application Level of the Electronic Medical Record System (Trial) and the Classification and Evaluation Standards for the Application Level of the Electronic Medical Record System (Trial) (《關於印發電子病歷系統應用水準分級評估管理辦法(試行)及評估標準(試行)的通知》) to promote informatization construction of medical institutions with electronic medical records as the core. The aforesaid administrative measures and evaluation standards stipulate the departmental institutions, principles, procedures and standards for the classification and evaluation of the application level of the electronic medical record system in medical institutions.

LAWS AND REGULATIONS RELATING TO FOREIGN INVESTMENT

On 29 December 1993, the Standing Committee of the NPC issued the PRC Company Law (《中華人民共和國公司法》), or the Company Law, which was lasted amended on 26 October 2018. Pursuant to the PRC Company Law, limited liability companies and joint stock limited companies established in the PRC have the status of legal persons. The liability of shareholders of a limited liability company and a joint stock limited company is limited to the amount of registered capital they have contributed or shares they have subscribed for. The PRC Company Law shall also apply to foreign-invested companies. Where laws on foreign investment have other stipulations, such stipulations shall apply.

Pursuant to the Special Management Measures (Negative List) for the Access of Foreign Investment (2021 version) (《外商投資准入特別管理措施(負面清單) (2021年版)》) promulgated by the NDRC and MOFCOM on 27 December 2021, and came into effect on 1 January 2022, limitations were stipulated for foreign investments in different industries in the PRC and foreign investments shall be classified into two categories, namely "Catalogue of Encouraged Industries for Foreign Investment" and "Special Management Measures (Negative List) for the Access of Foreign Investment". The "Special Management Measures (Negative List) for the Access of Foreign Investment" is further classified into "Catalogue of Industries Limited for Foreign Investment" and "Catalogue of Industries Prohibited for Foreign Investment". Industries which do not fall within the "Special Management Measures (Negative List) for the Access of Foreign Investment" are industries permitted for foreign investment. According to the PRC Legal Advisers, the business we engaged in is not classified under "Special Management Measures (Negative List) for the Access of Foreign Investment".

On 30 December 2019, the MOFCOM and the SAMR 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 1 January 2020 and replaced the Interim Administrative Measures. Since 1 January 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 authorities pursuant to these measures.

The Foreign Investment Law of the PRC (《中華人民共和國外商投資法》), (the "**Foreign Investment Law**"), was formally adopted by the 2nd session of the Thirteenth NPC on 15 March 2019 and became effective on 1 January 2020. The Foreign Investment Law is formulated to further expand opening-up, vigorously promote foreign investment and protect the legitimate rights and interests of foreign investors. According to the Foreign Investment Law, foreign investments are entitled to pre-entry national treatment and are subject to negative list management system. The pre-entry national treatment means that the treatment given to foreign investors and their investments at the stage of investment access is not lower than that of domestic investors and their investments. The negative list management system means that the state implements special management measures for the access of foreign investment in specific fields. Foreign investors shall not invest in any forbidden fields stipulated in the negative list and shall meet the conditions stipulated in the negative list before investing in any restricted fields.

Foreign investors' investment, earnings and other legitimate rights and interests within the territory of the PRC shall be protected in accordance with the law, and all national policies on supporting the development of enterprises shall equally apply to foreign-invested enterprises. The State guarantees that foreign-invested enterprises participate in the formulation of standards in an equal manner. The State guarantees that foreign-invested enterprises participate in government procurement activities through fair competition in accordance with the law. The State shall not expropriate any foreign investment except under special circumstances. In special circumstances, the State may levy or expropriate the investment of foreign investors in accordance with the law for the needs of the public interest. The expropriation and requisition shall be conducted in accordance with legal procedures and timely and reasonable compensation shall be given. In carrying out business activities, foreign-invested enterprises shall comply with relevant provisions on labour protection, social insurance, tax, accounting, foreign exchange and other matters stipulated in the PRC laws and regulation.

Upon taking effect on 1 January 2020, the Foreign Investment Law replaced the Sino-Foreign Equity Joint Venture Enterprise Law (《中華人民共和國中外合資經營企業法》), the Sino-Foreign Cooperative Joint Venture Enterprise Law (《中華人民共和國中外合作經營企業法》) and the Wholly Foreign-Owned Enterprises Law (《中華人民共和國外資企業法》) to become the legal foundation for foreign investment in the PRC.

On 26 December 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 1 January 2020 and replaced the Regulations on Implementing the Sino-Foreign Equity Joint Venture Enterprise Law (《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 (《中外合資經營企業合營期限暫行規定》), the Regulations on Implementing the Wholly Foreign-Owned Enterprise Law (《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 (《中華人民共和國中外合作經營企業法實施細則》).

Foreign Exchange Regulation

The principal regulations governing foreign currency exchange in China are the Regulations on Foreign Exchange Administration of the PRC (《中華人民共和國外匯管理條例》) promulgated by the State Council on 29 January 1996 and most recently amended on 5 August 2008. Under the PRC foreign exchange regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, may be made in foreign currencies without prior approval from SAFE by complying with certain procedural requirements. By contrast, approval from or registration with appropriate government authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency denominated loans or foreign currency is to be remitted into China under the capital account, such as a capital increase or foreign currency loans to our PRC subsidiary.

In November 2012, SAFE promulgated the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on 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》), as amended, which substantially amends and simplifies the foreign exchange procedure. Pursuant to this circular, the opening of various special purpose foreign exchange accounts, such as pre-establishment expenses accounts, foreign exchange capital accounts and guarantee accounts, the reinvestment of RMB proceeds by foreign investors in the PRC, and remittance of foreign exchange profits and dividends by a foreign-invested enterprise to its foreign shareholders no longer require the approval or verification of SAFE, and multiple capital accounts for the same entity may be opened in different provinces, which was not possible previously. In addition, SAFE promulgated the Circular on Printing and Distributing the Provisions on Foreign Exchange Administration over Domestic Direct Investment by Foreign Investors and the Supporting Documents (《關於印發<外國投資者境內直接投資外匯管理規定>及配套文件的通知》) in May 2013, as amended, which specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC shall be conducted by way of registration and banks shall process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches. In February 2015, SAFE promulgated the Circular of Further Simplifying and Improving the Policies of Foreign Exchange Administration Applicable to Direct Investment (《關於進一步簡化和改進直接投資外匯管理政策的通知》), or SAFE Circular 13, which became effective on 1 June 2015. Under SAFE Circular 13, the foreign exchange procedures are further simplified, and foreign exchange registrations of direct investment will be handled by the banks designated by the foreign exchange authority instead of SAFE and its branches. However, the foreign invested enterprises were still prohibited by SAFE Circular 13 to use the RMB converted from foreign currency-registered capital to extend entrustment loans, repay bank loans or inter-company loans.

On 9 June 2016, SAFE issued the Circular on Reforming and Regulating Policies on the Control over Foreign Exchange Settlement of Capital Accounts (《關於改革和規範資本項目結匯管理政策的通知》), or Circular 16, which took effect on the same day. Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt offering proceeds and remitted foreign listing proceeds, and the corresponding Renminbi obtained from foreign exchange settlement are not restricted from extending loans to related parties or repaying the inter-company loans (including advances by third parties).

On 26 January 2017, SAFE promulgated the Circular on Further Improving Reform of Foreign Exchange Administration and Optimising 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》), or Circular 3, which took effect on the same day. Circular 3 sets out various measures, including the following:

- relaxing the policy restriction on foreign exchange inflow to further enhance trade and investment facilitation, including:
  - expanding the scope of foreign exchange settlement for domestic foreign exchange loans,
  - allowing the capital repatriation for offshore financing against domestic guarantee,
  - facilitating the centralised management of foreign exchange funds of multinational companies, and
  - allowing offshore institutions within pilot free trade zones to settle foreign exchange in domestic foreign exchange accounts; and
- continuing to implement and improve the management policy for the remittance of foreign exchange profits from direct investment including:
  - improving the statistics of current account foreign currency earnings deposited offshore, and
  - requiring banks to verify board resolutions, tax filing form, and audited financial statements before wiring foreign invested enterprises' foreign exchange distribution above US$50,000;
- strengthening genuineness and compliance verification of foreign direct investments, and
- implementing full scale management of offshore loans in Renminbi and foreign currencies by requiring the total amount of offshore loans be no higher than 30% of the onshore lender's equity shown on its audited financial statements of the last year.

On 23 October 2019, SAFE issued Circular on Further Facilitating Cross-border Trade and Investment (《關於進一步促進跨境貿易投資便利化的通知》), or Circular 28, which took effect on the same day. Circular 28 allows non-investment foreign-invested enterprises to use their capital funds to make equity investments in China, provided that such investments do not violate the negative list and the target investment projects are genuine and in compliance with laws. Since Circular 28 was issued only recently, its interpretation and implementation in practise are still subject to substantial uncertainties.

To use our offshore foreign currency to fund our PRC operations, we will apply to obtain the relevant approvals of SAFE and other PRC government authorities as necessary. Our PRC subsidiary's distributions to their offshore parents and our cross-border foreign exchange activities are required to comply with the various requirements under the relevant foreign exchange rules.

SAFE Circular 37

SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles (《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》), or SAFE Circular 37, on 4 July 2014, which replaced the former circular commonly known as "SAFE Circular 75" (《關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》) promulgated by SAFE on 21 October 2005. SAFE Circular 37 requires PRC residents to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, for the purpose of overseas investment and financing, with their legally owned assets or equity interests in domestic enterprises or offshore assets or interests, referred to in SAFE Circular 37 as a "special purpose vehicle". SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle, such as increase or decrease of capital contributed by PRC individuals, share transfer or exchange, merger, division or other material event. In the event that a PRC shareholder holding interests in a special purpose vehicle fails to fulfil the required SAFE registration, the PRC subsidiary of that special purpose vehicle may be prohibited from making profit distributions 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. Furthermore, failure to comply with the various SAFE registration requirements described above could result in liability under PRC law for evasion of foreign exchange controls. On 13 February 2015, SAFE released SAFE Circular 13, under which qualified local banks will examine and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration, from 1 June 2015. There exist substantial uncertainties with respect to its interpretation and implementation by governmental authorities and banks.

Regulation of Dividend Distribution

Under our current corporate structure, our Cayman Islands holding company may rely on dividend payments from our PRC subsidiary, which is a wholly foreign-owned enterprise incorporated in the PRC, to fund any cash and financing requirements we may have. The principal laws, rules and regulations governing dividend distribution by wholly foreign-owned enterprise in the PRC are the PRC Company Law, as amended, and the 2019 PRC Foreign Investment Law. Under these laws, rules and regulations, wholly foreign-owned enterprises may pay dividends only out of their accumulated profit, if any, as determined in accordance with PRC accounting standards and regulations. A wholly foreign-owned enterprise is required to set aside as general reserves at least 10% of their after-tax profit, until the cumulative amount of their reserves reaches 50% of their registered capital. A PRC company is not permitted to distribute any profits until any losses from prior fiscal years have been offset. Profits retained from prior fiscal years may be distributed together with distributable profits from the current fiscal year.

Regulations Relating to Merger and Acquisition of Domestic Enterprises by Foreign Investors and Overseas Listing

According to 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) ("**M&A Rules**") which were jointly adopted by the MOFCOM, the SAFE and other four ministries on 8 August 2006, took effect on 8 September 2006 and amended on 22 June 2009, "mergers and acquisitions of domestic enterprises by foreign investors" refers to: (a) a foreign investor converts a non-foreign invested enterprise (domestic company) to a foreign invested enterprise by purchasing the equity interest from the shareholder of such domestic company or the increased capital of the domestic company ("**Equity Merger and Acquisition**"); or (b) a foreign investor establishes a foreign invested enterprise to purchase the assets from a domestic enterprise by agreement and operates the assets therefrom; or (c) a foreign investor purchases the assets from a domestic enterprise by agreement and uses these assets to establish a foreign invested enterprise for the purpose of operation of such assets ("**Assets Merger and Acquisition**").

M&A Rules provides that mergers and acquisitions of domestic enterprises by foreign investors shall be subject to the approval of the MOFCOM or its delegates at provincial level. In the event that any domestic company, enterprise or natural person merges or acquires a domestic company that has affiliated relationship with it through an overseas company legally established or controlled by such domestic company, enterprise or natural person, the merger and acquisition applications shall be submitted to the MOFCOM for approval. Any circumvention on the requirement including domestic re-investment of a foreign invested enterprise is not allowed.

On 24 December 2021, the CSRC published the Administrative Provisions of the State Council on the Overseas Issuance and Listing of Securities by Domestic Enterprises (Draft for Comments) (《國務院關於境內企業境外發行證券和上市的管理規定(草稿徵求意見稿)》)(the "**Draft Administrative Provisions**"), and the Administrative Measures for Record-filings of the Overseas Issuance and Listing of Securities by Domestic Companies (Draft for Comments) (《境內企業境外發行證券和上市備案管理辦法(徵求意見稿)》) (the "**Draft Measures for Record-filing**", together with the Draft Administrative Provisions, the "**Drafts relating to Overseas Listings**"), which are open for public comments until 23 January 2022.

The Draft Administrative Provisions, if adopted in its current form, will comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies' securities, and will regulate both direct and indirect overseas offering and listing of PRC domestic companies' securities by adopting a filing-based regulatory regime. According to the Draft Administrative Provisions, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to fulfil the filing procedure with the CSRC and report relevant information. Overseas offerings and listings that are prohibited by specific laws and regulations, constitute threat to or endanger national security, involve material ownership disputes, the PRC domestic companies, their controlling shareholder or actual controller involving in certain criminal offence, or directors, supervisors and senior management of the issuer involving in certain criminal offence or administrative penalties, among other circumstances, are explicitly forbidden.

As implementation rules, the Draft Measures for Record-filing specifies the filing requirement and procedures. The Draft Measures for Record-filing provides that if the issuer meets the following criteria, the overseas securities offering and listing conducted by such issuer will be deemed as indirect overseas offering by PRC domestic companies: (i) any of the revenue, net profit, total assets or net assets of the domestic companies accounted for more than 50% of the respective audited revenue, net profit, total assets or net assets of the issuer within the latest fiscal year; (ii) a majority of the officers responsible for management of the issuer are PRC citizens or have their usual place of residence located in mainland China, the issuer's main place of operation is within mainland China. It is unclear based on the Draft Measures for Record-filing whether either or both of the above criteria need to be satisfied. Where an issuer makes an application for initial public offering to competent overseas regulators, the issuer must submit to the CSRC filing documents within three working days after such application is submitted. The Draft Measures for Record-filing also requires subsequent report to the CSRC on material events, such as material change in principal business and change of control.

At the press conference held for Drafts relating to Overseas Listings, officials from the CSRC clarified that implementation of the Drafts relating to Overseas Listings will follow the non-retroactive principle, which means only the initial public offerings by PRC domestic companies and financing by existing overseas listed PRC domestic companies to be conducted after the foregoing regulations become effective will be required to complete the filing process. In addition, the new regulations and rules will grant a proper transition period for existing overseas-listed companies that do not have subsequent financing activities to comply with the filing requirement. As advised by our PRC Legal Advisers, the Drafts relating to Overseas Listings apply to overseas offerings and listings of PRC domestic companies, while do not raise new compliance requirements for business operations of PRC domestic companies. Therefore, we and our PRC Legal Advisers do not foresee the Drafts relating to Overseas Listings, if become effective in their current form, would have a material adverse impact on our business operations and our proposed Listing. We will closely monitor relevant regulatory developments. As of the Latest Practicable Date, we had not received any inquiry, notice, warning, or sanctions regarding this listing or our corporate structure from the CSRC or any other PRC government authorities with respect to the filing requirement under the new regulatory regime. Our PRC Legal Advisers have also conducted public searches against our PRC-incorporated subsidiaries, our controlling shareholders and actual controllers, as well as our directors and senior management, and did not find any of them having been involved in relevant criminal offences or administrative penalties that would prohibit us from conducting overseas listing or listing under the Drafts relating to Overseas Listings. Based on the foregoing and our PRC Legal Advisers' due inquiry, nothing has come to the attention of our PRC Legal Advisers that we will fall within any of the circumstances which would prohibit PRC domestic companies from conducting overseas listing and listing as provided under the Drafts relating to Overseas Listings. Therefore, if the Drafts relating to Overseas Listings become effective in their current form before the listing is completed, other than uncertainties of the filing procedures which may be further clarified in the final version of the Drafts relating to Overseas Listings and/or their implementation rules, we do not foresee any impediment for us to comply with the Drafts relating to Overseas Listings in any material respect.

OTHER LAWS AND REGULATIONS

Labour and Social Protection

Pursuant to the Labour Law of the PRC (《中華人民共和國勞動法》) promulgated by the Standing Committee of the NPC on 5 July 1994 and last amended and coming into effect on 29 December 2018, the Labour Contract Law of the PRC (《中華人民共和國勞動合同法》) amended by the Standing Committee of the NPC on 28 December 2012 and coming into effect on 1 July 2013 and the Implementation Rules of the Labour Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》) promulgated by the State Council and coming into effect on 18 September 2008, an employer shall strictly comply with the national standards, provide trainings to its employees, protect their labour rights and perform its labour obligations. An employer shall enter into a written labour contract with its employees. Labour contracts shall be categorised into labour contracts with fixed term, labour contracts without fixed term and labour contracts to be expired upon completion of certain tasks. The remuneration payable by an employer to its employees shall not be less than local minimum wage.

Pursuant to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) promulgated by the Standing Committee of the NPC on 28 October 2010, amended and coming into effect on 29 December 2018, the Administrative Regulations on Housing Provident Fund of the PRC (《中華人民共和國住房公積金管理條例》) amended by the State Council and coming into effect on 24 March 2019 and the Provisional Regulations on Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) amended by the State Council and coming into effect on 24 March 2019, a domestic enterprise shall pay premium for basic pension insurance, unemployment insurance, maternity insurance, work injury insurance, basic medical insurance and housing provident fund for its employees at the applicable rates based on the amounts stipulated by the laws. If it fails to pay required amount of premium to local administrative authorities on time or in full, it may be required to settle the overdue amount or subject to fine.

Intellectual Properties

Trademark

The Trademark Law of the PRC (《中華人民共和國商標法》) which took effect in 1 March 1983 and was most recently amended by the Standing Committee of the NPC on 23 April 2019 and coming into effect on 1 November 2019 and the Implementation Rules of the Trademark Law of the PRC (《中華人民共和國商標法實施條例》) amended by the State Council on 29 April 2014 and coming into effect on 1 May 2014, stipulate the application, examination and approval, renewal, alternation, transfer, use and invalidation of trademark registration, and protect the trademark rights entitled to trademark registrants. According to the aforesaid laws and regulations, the registration of a trademark shall be valid for ten years from the date of approval. Upon the expiry of the trademark registration, a renewal shall be made in accordance with requirements within 12 months if necessary. If the renewal is not made within the stipulated period, the valid period may be extended for a further period of six months. Each renewal of registration of trademark shall be valid for ten years from the date of the expiry of the previous trademark registration. A trademark registrant may licence others the right to use his/her trademark by entering into a trademark licence agreement.

Copyright

Copyright in the PRC, including copyrighted software, is principally protected under the Copyright Law of the PRC (《中華人民共和國著作權法》) which took effect in 1991 and was most recently amended on 11 November 2020 and took effect on 1 June 2021 and related rules and regulations. Under the Copyright Law of the PRC, the term of protection for copyrighted software is 50 years. The New Copyright Law increased the cost of infringement violations and expanded the protection coverage of Copyright Law. The Regulation on the Protection of the Right to Communicate Works to the Public over Information Networks (《信息網絡傳播權保護條例》), which was most recently amended on 30 January 2013 and took effect on 1 March 2013, provides specific rules on fair use, statutory licence, and a safe harbour for use of copyrights and copyright management technology and specifies the liabilities of various entities for violations, including copyright holders, libraries and Internet service providers. In order to further implement the Regulations for the Protection of Computer Software (《計算機軟件保護條例》) promulgated by the State Council on 20 December 2001 and lastly amended on 30 January 2013 and taking effect on 1 March 2013, the State Copyright Bureau issued the Registration of Computer Software Copyright Procedures (《計算機軟件著作權登記辦法》) on 20 February 2002, which applies to software copyright registration, licence contract registration and transfer contract registration with respect to software copyright.

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 24 August 2017 and coming into effect on 1 November 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 27 November 2017 and coming into effect on 1 January 2018 specifies the obligation of anti-terrorism and maintaining network security of internet information service providers.

REGULATIONS RELATING TO TAXATION

EIT Law

According to the EIT Law of the PRC (《中華人民共和國企業所得税法》), which was promulgated by the NPC on 16 March 2007 and came into effect on 1 January 2008 and was amended on 24 February 2017 and 29 December 2018, and the Implementation Regulations on the EIT Law (《中華人民共和國企業所得税法實施條例》) which was issued by the State Council on 6 December 2007, came into effect on 1 January 2008, and was amended on 23 April 2019, the tax rate of 25% will be applied to the income related to all PRC enterprises, foreign-invested enterprises and foreign enterprises which have established production and operation facilities in the PRC. These enterprises are classified into as either resident enterprises or non-resident enterprises. Enterprises which are established in accordance with the law of the foreign country or region, but whose actual management institutions (referring to the institutions conducting substantive and all-around management and control over the enterprises production, operation, personnel, accounting matters, finance, etc.) are in PRC, are deemed as resident enterprise. Thus, the tax rate of 25% applies to their income originating from both inside and outside the PRC.

According to the EIT Law, certain high-tech enterprises are entitled to a reduced EIT rate of 15%. The Administrative Measures for Certification of High and New Technology Enterprises (《高新技術企業認定管理辦法》) which was amended on 29 January 2016 and became effective on 1 January 2016, provides that, an enterprise legally certificated as a High and New Technology Enterprise is entitled to apply for preferential income tax policies according to EIT law and relevant regulations. A qualified enterprise will be issued the High and New Technology Enterprise Certificate (高新技術企業證書) and the qualification of a certificated enterprise shall be valid for a term of three years from the issuance date of the certificate.

The Notice of the State Administration of Taxation on Issues Related to the Implementation of Preferential Income Tax Policies for New and High Technology Enterprises (《國家税務總局關於實施高新技術企業所得税優惠政策有關問題的公告》) was promulgated by the SAT on 19 June 2017, which took effect on the date of promulgation. According to the Notice, after the qualification of high and new technology enterprise is received, an enterprise shall apply for tax concession from the year of issue printed on the certificate of high and new technology enterprise, and shall carry out filings with the administrative tax authority according to regulatory requirements.

According to the EIT Law and the Implementing Regulations of the EIT Law, for dividends payable to investors who are non-resident enterprises (who do not have institutions or places of business in the PRC, or that have institutions and places of business in PRC but to whom the relevant income tax is not effectively connected), 10% of the PRC withholding tax shall be paid, unless there are any applicable tax treaties are reached between the jurisdictions of non-resident enterprises and the PRC which may reduce or provide exemption to the relevant tax. Similarly, any gain derived from the transfer of shares by such investor, if such gain is regarded as income derived from sources within the PRC, shall be subject to 10% PRC income tax rate or a lower tax treaty rate (if applicable).

The PRC Government and the government of Hong Kong entered into the Arrangement between the Mainland of China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and the 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》) (the "**Arrangement**") on 21 August 2006 and implemented the Arrangement since 8 December 2006. According to the Arrangement, if the beneficiary of the dividends is a Hong Kong resident enterprise, which directly holds no less than 25% equity interests in a PRC company, the tax levied shall be 5% of the distributed dividends. The 10% withholding tax rate applies to dividends paid by a PRC company to a Hong Kong resident if such Hong Kong resident holds less than 25% of the equity interests in the PRC company.

In accordance with the Measures for Administration of Non-Resident Taxpayers' Enjoyment of the Treatment under Tax Treaties (《非居民納税人享受協定待遇管理辦法》) which was promulgated by the SAT on 14 October 2019, and came into effect on 1 January 2020, if non-resident taxpayers consider they are eligible for treatments under the tax treaties through self-assessment, they may, at the time of filing tax returns or making withholding tax filings through withholding agents, enjoy the treatments under the tax treaties, and shall concurrently collect and retain the relevant documents for inspection according to relevant regulations, and accept tax authorities' post-filing administration.

Value-added Tax

According to the Temporary Regulations of the PRC on Value-Added Tax (《中華人民共和國增值税暫行條例》), which was promulgated on 13 December 1993 by the State Council, came into effect on 1 January 1994 and was amended on 10 November 2008 and 6 February 2016 and 19 November 2017, and the Detailed Rules for the Implementation of the Provisional Regulations of the PRC on Value Added Tax (《中華人民共和國增值税暫行條例實施細則》), which was promulgated by the MOF on 25 December 1993, became effective on the same day and was amended on 15 December 2008 and 28 October 2011 (collectively, the "**VAT Law**"), taxpayers who engaged in the sale of goods, the provision of processing, repairing and replacement services, leasing service of tangible movable property or import goods within the territory of the PRC shall pay value-added tax. Except as otherwise provided in the VAT law, tax rate for selling services or intangible assets is 6%.

Furthermore, in accordance with the Measures for Implementing the Pilot Program of Replacing Business Tax with Value-Added Tax in an All-round Manner (《營業税改徵增值税試點實施辦法》), promulgated by the MOF and the SAT on 23 March 2016 and taking effect on 1 May 2016, entities and individuals engaging in sale of services, intangible assets or immovables in the PRC are taxpayers of VAT and shall not pay business tax. Unless stipulated otherwise, the general tax rate for the sales of services and intangible assets shall be 6%.

PRODUCT LIABILITY AND PROTECTION OF CONSUMERS' RIGHTS

Pursuant to the Product Quality Law (《中華人民共和國產品質量法》) promulgated on 22 February 1993 and latest amended on 29 December 2018 by the Standing Committee of the NPC, the seller shall be responsible for the repair, replacement or return of the product sold if (i) the product sold does not possess the properties for use that it should possess, and no prior and clear indication is given of such a situation; (ii) the product sold does not conform to the applied product standard as carried on the product or its packaging; or (iii) the product sold does not conform to the quality indicated by such means as a product description or physical sample. If a consumer incurs losses as a result of the purchased product, the seller shall compensate for such losses.

On 28 May 2020, the Civil Code adopted by the third session of the Thirteenth NPC of the PRC, which became effective on 1 January 2021, according to which a manufacturer or a commercial seller is subject to liability for harm to persons or property caused by the product defects. The injured patient may seek compensation from the manufacturer or the commercial seller. Where the patient seeks compensation from the commercial seller, the commercial seller have the right to make a claim against the liable manufacturer after it has made compensation.

The Law of the PRC on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated on 31 October 1993 and was amended on 27 August 2009 and 25 October 2013 to protect consumers' rights when they purchase or use goods and accept services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. Under the amendments made on 25 October 2013, all business operators must pay high attention to protecting customers' privacy and must strictly keep confidential any consumer information they obtain during their business operations. In addition, in extreme situations, medical product manufacturers and operators may be subject to criminal liability if their goods or services lead to the death or injuries of customers or other third parties.

REGULATIONS RELATING TO ENVIRONMENTAL PROTECTION

The Environmental Protection Law of the PRC (《中華人民共和國環境保護法》), or the Environmental Protection Law, which was promulgated by the Standing Committee of the NPC on 26 December 1989, came into effect on the same day and last amended on 24 April 2014 and came into force on 1 January 2015, outlines the authorities and duties of various environmental protection regulatory agencies. The Ministry of Environmental Protection is authorised to issue national standards for environmental quality and emissions, and to monitor the environmental protection scheme of the PRC. Meanwhile, local environment protection authorities may formulate local standards which are more rigorous than the national standards, in which case, the concerned enterprises must comply with both the national standards and the local standards.

Pursuant to the Administration Rules on Environmental Protection of Construction Projects (《建設項目環境保護管理條例》), which was promulgated by the State Council on 29 November 1998, amended on 16 July 2017 and became effective on 1 October 2017, depending on the impact of the construction project on the environment, an construction employer shall submit an environmental impact report or an environmental impact statement, or file a registration form. As to a construction project, for which an environmental impact report or the environmental impact statement is required, the construction employer shall, before the commencement of construction, submit the environmental impact report or the environmental impact statement to the relevant authority at the environmental protection administrative department for approval. If the environmental impact assessment documents of the construction project have not been examined or approved upon examination by the approval authority in accordance with the law, the construction employer shall not commence the construction.

Pursuant to the Environmental Impact Appraisal Law of PRC (《中華人民共和國環境影響評價法》), or the Environmental Impact Appraisal Law, which was promulgated by the Standing Committee of the NPC on 28 October 2002, amended on 2 July 2016 and 29 December 2018, for any construction projects that have an impact on the environment, an entity is required to produce either a report, or a statement, or a registration form of such environmental impacts depending on the seriousness of effect that may be exerted on the environment.