LAWS AND REGULATIONS RELATED TO OUR BUSINESS IN THE PRC

We are subject to a variety of PRC laws, rules and regulations affecting many aspects of our business. This section sets out a summary of the major relevant laws, regulations, rules and policies of PRC which may have material impacts on our business.

Laws and Regulations relating to Medical Devices

Regulations on the Supervision and Administration of Medical Devices

According to the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) (the "**2021 Medical Device Regulations**") which was issued by the State Council on January 4, 2000 and amended on February 9, 2021 and came into effect on June 1, 2021, the drug regulatory department under the State Council shall be responsible for the supervision and administration of medical devices nationwide. The relevant departments under the State Council shall be responsible for the supervision and administration relating to medical devices within the scope of their respective duties. We are now principally subject to the supervision of the National Medical Products Administration (國家藥品監督管理總局) and its local counterparts. The National Medical Products Administration was established in accordance with the Institutional Reform Program of the State Council (《國務院機構改革方案》) promulgated by the National People's Congress (the "**NPC**") on March 18, 2018, and the predecessor of the National Medical Products Administration is the China Food and Drug Administration (國家食品藥品監督管理總局) (the "**CFDA**," together with the National Medical Products Administration, hereinafter collectively, the "**NMPA**"). The NMPA is a newly established regulatory authority responsible for registration and supervision of pharmaceutical products, cosmetics and medical devices under the supervision of the State Administration for Market Regulation (國家市場監督管理總局) (the "**SAMR**"), a newly established institution for supervising and administrating the market in China. 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 their risk degree. Class I medical devices refer to those devices with low risks and whose safety and effectiveness can be ensured through routine administration. Class II medical devices refer to those devices with moderate risks and whose safety and effectiveness shall be strictly controlled and administered. Class III medical devices refer to those devices with relatively high risks and whose safety and effectiveness need to be strictly controlled and administered with special measures. The classification of specific medical devices is stipulated in the Medical Device Classification Catalog (《醫療器械分類目錄》), which was issued by the NMPA on August 31, 2017 and became executive on August 1, 2018.

The products we currently sell in China are Class I, Class II and Class III medical devices.

Regulations on Medical Device Products Import Registration

According to the 2021 Medical Device Regulations, if an overseas party seeks to export Class I medical devices into China, the domestic enterprise legal person designated by it shall have to prove that such medical devices are approved to be marketed by the competent authority of the country (region) where the record-filing party is located by filing the relevant materials and supporting materials to the drug regulatory department under the State Council for record-keeping purposes. And if an overseas registration applicant export Class II and Class III medical devices to China, the domestic enterprise legal person designated by it shall submit registration application materials and the supporting documents to the drug regulatory department under the State Council.

An exporter of Class I, Class II or Class III medical devices into China shall perform the following obligations and the domestic enterprise legal person designated by it shall assist in the following:

- establish a quality management system suitable for the products and maintain its effective operation;
- formulate a post-marketing research and risk control plan and ensure its effective implementation;
- carry out monitoring and re-evaluation of adverse events in accordance with the law;
- establish and implement a product traceability and recall system; and
- other obligations provided for by the drug regulatory department under the State Council.

Only medical devices which have been registered or filed for record in PRC can be imported into China. The imported medical devices shall be attached with instructions and labels in Chinese. The instructions and labels shall be in compliance with the relevant regulations and compulsory standards, and the instructions shall specify the origin of medical devices and the name, address and contact information of the domestic enterprise legal person designated by the overseas registrant or record-filing party of the medical devices. No medical devices may be imported in the absence of such instructions and labels in Chinese or if the instructions and labels are not in compliance with the 2021 Medical Device Regulations.

The Administrative Measures for the Registration and Filing of Medical Devices (《醫療器械註冊與備案管理辦法》) was promulgated by the SAMR on August 26, 2021 and came into effect on October 1, 2021. At the same time, the Administrative Measures for the Registration of Medical Devices (《醫療器械註冊管理辦法》) has been repealed. According to the Administrative Measures for the Registration and Filing of Medical Devices, the name and address of the overseas registrant and its designated domestic enterprise legal person are items subject to record-filing and change of the registration.

Where a domestic enterprise legal person designated by an overseas registrant or record-filing party of medical devices fails to perform the above obligations in the 2021 Medical Device Regulations, the drug regulatory department of the people's government of the province, autonomous region or municipality directly under the Central Government may impose rectification orders, issue a warning or impose a fine. In serious cases, the legal representative, principal, person directly in charge and other liable persons may be banned from engaging in the production of medical devices or similar business operations within five years. Where the overseas registrant or record-filing party of medical devices refuses to perform the decision on administrative penalty made in accordance with the 2021 Medical Device Regulations, it shall be banned from importing medical devices within ten years.

Regulations on the Registration of Domestic Medical Devices

According to the Administrative Measures for the Registration and Filing of Medical Devices, for the filings of Class I medical devices, the filing materials shall be submitted to the local branches at the city level of the NMPA. In case of any amendments made to matters stated in the filings, such amendments shall be filed with the original filing department. Class II and Class III medical devices must obtain their respective product registrations before they can be marketed and sold in China. Class II medical devices shall be examined by the provincial branches of the NMPA and Class III medical devices shall be examined by the NMPA, and a Medical Device Registration Certificate (醫療器械註冊證) for such medical device shall be issued upon approval. In case of any substantial changes of the designs, raw materials, production technologies, scopes of application and application methods, among other things, of the registered Class II or Class III medical devices, which may affect the safety and effectiveness of such medical devices, the registrants shall submit the application for change of registration with the original registration departments within 30 days. The Medical Device Registration Certificate is valid for five years and the registrant shall file for renewal with NMPA at least six months prior to its expiration date.

Clinical Evaluation and Clinical Trials of Medical Devices

According to the 2021 Medical Device Regulations and the Administrative Measures for the Registration and Filing of Medical Devices, clinical evaluation is required for the registration and filing of medical devices. Clinical evaluation of medical devices refers to activities in which clinical data are analyzed and evaluated by adopting scientific and reasonable methods to confirm the safety and effectiveness of medical devices within the scope of application. However, clinical evaluation may be exempted under any of the following circumstances:

- the medical device has clear and definite working mechanisms, finalized designs and mature manufacturing techniques, the marketed medical devices of the same category have been put into clinical application for years with no record of severe adverse event, and their general purposes remain unchanged;

- the safety and effectiveness of such medical devices can be proved through non-clinical evaluation.

Clinical evaluation of medical devices may be carried out through clinical trials or analysis and evaluation of clinical literature materials and clinical data of medical devices of the same kind to prove the safety and effectiveness of medical devices in light of product characteristics, clinical risks, existing clinical data and other circumstances. Pursuant to the Notice on Release of Catalogue of Medical Devices Exempted from Clinical Evaluation (《關於發佈免於臨床評價醫療器械目錄的通告》) (the "**Exemption Catalogue**") issued by the NMPA on September 16, 2021 and came into effect on October 1, 2021, for medical devices that are not included in the Exemption Catalogue, clinical evaluations shall be conducted before the registration or filing.

Clinical trials shall be conducted in accordance with the Good Clinical Practice for Medical Device Trials (《醫療器械臨床試驗質量管理規範》) (the "**Good Clinical Practice**"), which was issued by the NMPA and the NHC jointly on March 24, 2022 and came into effect on May 1, 2022. The Good Clinical Practice set forth the necessary procedures of clinical trials for medical devices, including, among others, the protocol design, conduct, monitoring, verification, inspection, and data collection, recording, analysis and conclusion and reporting procedure of a clinical trial. Prior to commencement of a clinical trial, the applicant must complete the pre-clinical research of the medical device, including product performance verification and confirmation, product inspection report based on the technical requirements, risk-benefit analysis, the results of which should support the clinical trial. Prior to the commencement of a clinical trial, approval by the ethics committees of the relevant clinical trial organization should be obtained and the applicant, the clinical trial organization and the principal investigators must enter into agreements in writing to arrange their rights and obligations during the trial.

Import of Urgently Needed Medical Devices in Boao Pilot Zone

The State Council issued the Decision on Suspension of Implementation Regulations on the Supervision and Administration of Medical Devices in Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province (《國務院關於在海南博鰲樂城國際醫療旅遊先行區暫停實施〈醫療器械監督管理條例〉有關規定的決定》) on April 2, 2018, according to which, for medical devices that are urgently needed in the Boao Lecheng International Medical Tourism Pilot Zone and have not been registered in China for the same type of medical devices, the State Council empowers the People's Government of Hainan Province (the "**Hainan Government**") to approve the import and use of the Urgently Needed Medical Devices in certain medical institutions.

The Hainan Government promulgated The Notice of Provisions on the Administration of Imported Medical Devices of Urgent Need in Boao Lecheng International Medical Tourism Pilot Zone of Hainan Province (《海南省人民政府關於印發〈海南自由貿易港博鰲樂城國際醫療旅遊先行區臨床急需進口醫療器械管理規定〉的通知》) on June 2, 2020, according to which, a qualified medical institution in the Boao Pilot Zone may apply for the import of certain Urgently Needed Medical Devices. Such application shall be subject to the evaluation and approval of Hainan Provincial Health Commission and the Medical Products Administration of Hainan Province, as well as the customs formalities with Haikou Customs.

Regulations on the Production and Quality Management of Medical Devices

The Measures on the Supervision and Administration of Medical Devices Production (《醫療器械生產監督管理辦法》) (the "**Measures on of Medical Devices Production**"), which was promulgated on March 10, 2022 and came into effect on May 1, 2022, stipulates that manufacturer of medical devices shall satisfy the following conditions:

- it has production sites, environmental conditions, production equipment and professional technicians that are suitable for such medical devices to be produced;
- it has organizations or professional examination staffs and examination equipment for carrying out quality examinations for such medical devices to be produced;
- it has formulated a management system that ensures the quality of the medical device;
- it has the capability of after-sale services that is suitable for such medical devices to be produced; and
- it satisfies the requirements as prescribed in R&D and production technique documents.

Medical device manufacturers shall be responsible for the quality of medical devices they manufacture. The enterprises engaging in the production of Class I medical devices shall make filings for such Class I medical devices with the local branches at the prefecture city level of the NMPA and submit materials to prove that it is qualified to engage in the production of such medical devices. The enterprises engaging in the production of Class II or Class III medical devices shall apply for a Manufacture License for Medical Devices (醫療器械生產許可證) with provincial branches of the NMPA, and submit materials proving it is qualified to engage in the production of such medical devices and a Medical Device Registration Certificate for the production of such medical devices. A Manufacture License for Medical Devices is valid for five years and the registrant shall file for renewal application with the original branch of the NMPA at least six months prior to its expiration date.

Regulations on the GMP Rules for Medical Devices

The Good Manufacturing Practice Rules for Medical Devices (《醫療器械生產質量管理規範》) (the "**GMP Rules for Medical Devices**") was promulgated on December 29, 2014 and came into effect on March 1, 2015. According to abovementioned rules, an enterprise engaging in the production of medical devices shall establish and effectively maintain a quality control system. The enterprise shall establish its procurement control procedure and assess its suppliers by establishing an examination system to ensure that 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 apply to risks associated with the related products.

Pursuant to The Notice of Four Guidelines including On-site Inspection Guidelines for the GMP Rules for 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〉等四個指導原則的通知》) which was promulgated by the NMPA 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 for the issuance of production permit (including the change and renewal of production permit), the inspection team shall, in accordance with the guidelines, issue recommended conclusions for on-site inspections, which include "passed", "failed" or "to be reassessed after rectification." During the supervision and inspection, if it is found that the requirements of the key items or ordinary items that may have a direct impact on product quality are not satisfied, the enterprise shall suspend production and be subject to rectification orders. If it is found that the requirements of the ordinary items that do not directly affect product quality are not satisfied, the enterprise shall rectify such issue in a prescribed time. The regulatory authorities shall examine and verify the recommended conclusions and on-site inspection materials submitted by the inspection group and issue the final inspection results.

Regulations on Supervision and Administration of Medical Devices Operation

According to the Measures for the Supervision and Administration of Medical Devices Operation (《醫療器械經營監督管理辦法》) promulgated by the SAMR on March 10, 2022 and came into effect on May 1, 2022, 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 quality control department or personnel suitable for the medical devices it operates. An enterprise engaged in the operation of Class I medical devices, the license or record is not required for business activities, while 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 materials to provide it satisfies the relevant conditions of engaging in the operation of medical devices, and an enterprise engaged in the operation of Class III medical devices shall apply for a Business Operation License of Medical Devices (醫療器械經營許可證) to the municipal level drug supervision and administration department and provide material to provide that it satisfies the relevant conditions of engaging in the operation of such medical devices.

The relevant local department of NMPA which receives operation permit application shall grant the Business Operation License of Medical Devices if the enterprise meets the prescribed requirements. A Business Operation License of Medical Devices is valid for five years and maybe 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 or filed, without qualification certificate, outdated, invalid, or disqualified.

A medical device operator shall establish a quality control system and quality control measures covering the entire process including purchase, acceptance inspection, storage, sales, transport and after-sales service, in accordance with laws, regulations and GSP requirement and keep relevant records to ensure continuous compliance in its business conditions and acts.

- A wholesaler of Class II and Class III medical devices and a retailor of Class III medical devices shall establish a system of sale records. Records of quality control and sale shall be authentic, accurate complete and traceable.

- A medical device operator shall purchase medical devices from legally qualified registrants, record-filing parties or operators of medical devices.

- A medical device operator shall take effective measures to ensure that devices are transported and stored as required in their instructions and labels, and keep records thereof so as to ensure quality and safety.

Tendering Processes for Medical Devices

The Chinese government has implemented measures to encourage centralized procurement of expensive medical consumables through tendering processes. On June 21, 2007, the National Health Commission of the PRC, formerly known by the names the Ministry of Health and National Health and Family Planning Commission (the "**NHC**") issued the Notice on Further Strengthening the Administration of Centralized Procurement of Medical Devices (《關於進一步加強醫療器械集中採購管理的通知》), which requires that all nonprofit medical institutions established by local governments, associations or state-owned enterprises participate in the centralized procurement. Public tendering will be the principal method for centralized procurement.

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. High-value medical devices usually refer to medical devices that directly use on the human body, have strict requirements on safety, have large consumption for clinical use and have relatively high prices.

According to the Administrative Norms on Centralized Procurement of High-Value Medical Consumables (《高值醫用耗材集中採購工作規範(試行)》) issued on December 17, 2012, the online centralized procurement (the "**Centralized Procurement**")* works of high-value medical consumables will be led by the 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 (《關於印發〈治理高值醫用耗材改革方案〉的通知》) (the "**Circular on High-Value Medical Consumables**"). According to the Circular on High-Value Medical Consumables, high-value medical consumables are defined as medical consumables directly used on the human body, with strict requirements on safety, in great demand clinically, relatively highly-priced, and that can pose heavy burdens on patients. The Circular on High-Value Medical Consumables releases several reform initiatives aiming at managing

* The online centralized procurement referred to the centralized volume-based procurement regime that is carried out through online portal, and the online centralized procurement is the same as centralized volume-based procurement regime in its substance.

high-value medical consumables, including: (i) 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 "**NHSA**"), the NMPA, and the NHC by the end of 2020; (ii) 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 Healthcare Security Administration and the Ministry of Finance (the "**MOF**") by the end of June 2020; (iii) for high-value medical consumables with large clinical consumption, high procurement amount and mature clinical use which are produced by multiple enterprises, centralized procurement by category shall be explored, medical institutions are encouraged to jointly carry out procurement through negotiation based on the quantity, and the procurement executed by cross-provincial alliance shall be actively explored. 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 by the end of 2019; and (iv) the medical insurance payment policy shall be formulated and implemented by the National Healthcare Security Administration, the MOF and the NHC. 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 on High-Value Medical Consumables.

Regulations on Centralized Volume-Based Procurement

On July 19, 2019, the General Office of the State Council released the Notice of the General Office of the State Council on Promulgation of the Reform Plan for the Control of High-value Medical Consumables (《國務院辦公廳關於印發〈治理高值醫用耗材改革方案〉的通知》), the State Council officially proposed to strengthen the standardized administration of high-value medical consumables. It was required to explore the classification of high-value medical consumables in accordance with the principles of volume-based procurement, volume-price linkage, and promotion of market competition, and conduct centralized procurement. On March 11, 2021, the NPC approved the Outline of the 14th Five-Year Plan for National Economic and Social Development of the People's Republic of China and the Vision for 2035 (《中華人民共和國國民經濟和社會發展第十四個五年規劃和2035年遠景目標綱要》), proposing to promote the reform of centralized and large-scale procurement and use of drugs and consumables organized by the State and develop high-end medical devices. The Guiding Opinions on National Organization of Centralized Volume-based Procurement and Use of High-Value Medical Consumables (《關於開展國家組織高值醫用耗材集中帶量採購和使用的指導意見》) which was issued by NHSA and other seven PRC authorities clearly stipulates that some high-value medical consumables with increased clinical usage, high purchase amount, mature clinical use, sufficient market competition, and high level of homogeneity will be included in the scope of volume-based procurement. On May 24, 2021, the General Office of the State Council released Notice of the General Office of the State Council on the Key Tasks of Deepening the Reform of the Medical and Health System in 2021 (《國務院辦公廳關於深化醫藥衛生體制改革2021年重點工作任務的通知》), the State Council stipulated to expand the scope of volume-based procurement of high-value medical consumables.

Pursuant to the Notice of the General Office of the State Council on Promulgation of the Reform Plan for the Control of High-value Medical Consumables (《國務院辦公廳關於印發〈治理高值醫用耗材改革方案〉的通知》) and other related regulations, the scope of volume-based procurement of high-value medical consumables is gradually expanding. The Key Control List of the First Batch of National High-value Medical Consumables (《第一批國家高值醫用耗材重點治理清單》) which was issued by the General Office of the National Health Commission on January 8, 2020, clarifies 18 types of high-value medical consumables for key control. Pursuant to the Notice on the Rapid Collection of the Second Batch of High-value Medical Consumables Centralized Procurement Data and Price Monitoring (《關於開展高值醫用耗材第二批集中採購數據快速採集與價格監測的通知》) which was issued by the NHSA on November 20, 2020, the list of the second batch of medical consumables mainly included six kinds of high-value disposables and supplemented the first batch of medical consumables including ophthalmic products.

Two-Invoice System

On December 26, 2016, eight government departments including the NMPA 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)的通知》), or the Notice. According to the Notice, the "Two-Invoice System" refers to issuing invoice at the time from a pharmaceutical manufacturer to a distributor, and issuing invoice again at the time from a circulating enterprise to a medical institution. The domestic general distributor could be treated as a pharmaceutical manufacturer in the "Two-Invoices System."

On March 5, 2018, six government departments including the NHC of the PRC 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 centralized purchase of high-value medical consumables, and that the "Two-Invoice System" in relation to high-value medical consumables shall be gradually implemented.

On July 19, 2019, the General Office of the State Council issued the Circular on High-value Medical Consumables, 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.

Regulations on Advertisements of Medical Devices

The State Administration for Market Regulation 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》) (the "**Examination Interim Measures**") on December 24, 2019, which came into effect on March 1, 2020. The Examination Interim Measures stipulates that the advertisements for medical devices shall not be released without being reviewed. The contents of a medical device advertisement shall be based on the contents of the registration certificate or filing certificate approved by the drug administrations, or the registered or filed product instructions. Where the medical device advertisement includes the name, scope of application, functional mechanism or structure or composition of the medical device, the information in such

advertisement must not exceed that as set out in the product registration certificate or filing certificate. The validity period of an advertisement for medical device shall not exceed that of its registration certificate or filing certificate or production license, whichever is shorter. If no valid period is prescribed in the product registration certificate, filing certificate or production license, the valid period of the advertisement shall be 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.

Regulations on Medical Device Recalls

Pursuant to the Administrative Measures for Medical Device Recalls (《醫療器械召回管理辦法》), which was promulgated on January 25, 2017 and came into effect on May 1, 2017, in terms of the severity of the case, medical device recalls are divided into three classes, namely: (i) Class I recall, where the circumstances leading to the recall may cause or have caused serious harm to health; (ii) Class II recall, where the circumstances leading to the recall may cause or have already caused temporary or reversible harm to health; or (iii) Class III recall, where the circumstances leading to the recall are not likely to cause any harm but a recall is necessary.

Medical device manufacturers shall determine the recall class based on the 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 website of the NMPA and major media. In terms of Class II and Class III recalls, the recall notice shall be published on the website of the provincial level of food and drug administrative authority.

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 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 16, 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 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.

The General Office of the State Council further released the Guidance On Further Deepening the Reform of the Payment Method of Basic Medical Insurance (《關於進一步深化基本醫療保險支付方式改革的指導意見》) in June 2017. The main objectives are to implement a diversified reimbursement mechanism including diagnosis related groups, per-capita caps, and per-bed-day caps. Local administration of healthcare security will introduce a total budget control for their jurisdictions and decide the amount of reimbursement to public hospitals based on hospitals' performance and the spending targets of individual basic medical insurance funds.

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 (《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》), which was issued on June 30, 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.

Regulations Relating To Importation And Exportation Of Goods

According to the Customs Law of the PRC (《中華人民共和國海關法》) which was promulgated by the Standing Committee of the National People's Congress (the "**SCNPC**") on January 22, 1987 and became effective on July 1, 1987, and latest amended and came into force on April 29, 2021, the import of goods throughout the period from the time of arrival in the territory of China to the time of customs clearance, the export of goods throughout the period from the time of declaration to the customs to the time of departure from the territory of China, and the transit, transshipment and through-shipment goods throughout the period from the time of arrival in the territory of China to the time of departure from the territory of China shall be subject to customs control.

According to the Foreign Trade Law of the PRC (《中華人民共和國對外貿易法》) which was promulgated by the SCNPC on May 12, 1994 and became effective on July 1, 1994, and latest amended and came into force on November 7, 2016, any foreign trade business operator that is engaged in the import and export of goods or technology shall be registered for archival purposes with the administrative authority of foreign trade of the State Council or the institution entrusted thereby, unless it is otherwise provided for by any law, administrative regulation or the foreign trade department of the State Council. Where any foreign trade business operator that fails to file for archival registration according to relevant provisions, the customs may not handle the procedures of customs declarations and release of the import or export goods.

According to the Administrative Provisions on the Filling of Customs Declaration Entities of the PRC (《中華人民共和國海關報關單位備案管理規定》), promulgated by the General Administration of Customs of the PRC on November 19, 2021 and came into effect on January 1, 2022. Consignors or consignees of imported or exported goods or customs declaration enterprises that apply for filing shall obtain market entity qualifications. Also, consignors or consignees of imported or exported goods that apply for filing shall also complete the record-filing formalities for foreign trade business operators.

Pursuant to the Regulations on the Administration of Export Sales Certificates of Medical Devices (《醫療器械產品出口銷售證明管理規定》) promulgated by the NMPA on June 1, 2015 and coming into effect on September 1, 2015, if the registration certificate for a medical device and production permit for a medical device has been obtained in China, or the medical device registration and production recordation have been completed, the food and drug supervision and administration department may issue a Medical Device Product Export Sales Certificate (醫療器械產品出口銷售證明) to the relevant manufacturing enterprise. The validity term of the Medical Device Product Export Sales Certificate should not exceed the earliest deadline for the various documents submitted by the enterprise in the application materials, and the maximum validity term shall also not exceed two years.

Production Safety and Liability

Production Safety Law of the PRC

Pursuant to the Production Safety Law of the PRC (《中華人民共和國安全生產法》) amended on June 10, 2021 and coming into effect on September 1, 2021, an enterprise shall (i) provide production safety conditions as stipulated in this law and other relevant laws, administrative regulations, national and industry standards, (ii) establish a comprehensive production safety accountability system and production safety rules, and (iii) develop production safety standards to ensure production safety. Any entity that fails to provide required production safety conditions is prohibited from engaging in production activities.

The person-in-charge of an enterprise shall be fully responsible for the safety of production of the enterprise. An enterprise having more than 100 employees shall establish a department or engage in personnel managing production safety specifically. Personnel who is responsible for managing production safety shall inspect the safety of production regularly based on the characteristics of production of the enterprise and shall deal with any safety issue identified during the inspection in a timely manner. Any unsolved issue shall be reported to the person-in-charge in a timely manner and the person-in-charge shall solve such issue immediately. The inspection and measures taken shall be duly recorded. Enterprises and institutions shall provide their employees with training on production safety and shall truthfully inform their employees of any potential risks in relation to the workplace and duties, preventive measures and emergency measures. In addition, an enterprise shall provide its employees with protective equipment that meets the national or industry standards and supervise and train them to use such equipment.

Product Quality Law of the PRC

Pursuant to the Product Quality Law of the PRC (《中華人民共和國產品質量法》) was promulgated by the SCNPC on February 22, 1993, and amended 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 it is not allowed to pass off sub-standard products 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 people 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 people and the safety of lives and property. It shall be prohibited to produce or sell industrial products that do not meet 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.

Tort Law of the PRC

Pursuant to the Tort Law of the PRC (《中華人民共和國侵權責任法》) promulgated on December 26, 2009 and coming into effect on July 1, 2010, in the event of product defects which have caused others to suffer damages, the manufacturer shall bear tort liability. In the event of product defects as a result of the seller's negligence which has caused others to suffer damages, the seller shall bear tort liability. Where the seller is unable to specify the manufacturer and the distributor of the defective products, the seller shall bear tort liability. In case of damages caused by product defects, the infringed party may seek compensation from the manufacturer of the products or the seller of the products. Where the product defects are caused by the manufacturer, the seller shall have the right to seek recourse against the manufacturer after the seller has made compensation. In the event of product defects as a result of the seller's negligence, the manufacturer shall have the right to seek recourse against the seller after the manufacturer has made compensation. On May 28, 2020, the Civil Code of the PRC (《中華人民共和國民法典》) was adopted by the third session of the 13th NPC, which came into effect on January 1, 2021 and simultaneously replaced the current effective Tort Law of the PRC. The Civil Code of the PRC does not make material changes on the substance of the aforementioned provisions of the Tort Law of the PRC.

Regulations Relating to Environmental Protection

Pursuant 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 became effective on the same day, latest amended on April 24, 2014 and became effective on January 1, 2015, the waste discharge licensing system has been implemented in the PRC and entities that discharge wastes shall obtain a Waste Discharge License (排污許可證). Furthermore, facilities for the prevention and control of pollution at a construction project shall be designed, constructed and put into operation simultaneously with the major construction works of the construction project.

Pursuant to the Environmental Impact Assessment Law of the PRC (《中華人民共和國環境影響評價法》) promulgated on October 28, 2002, became effective on September 1, 2003 and latest amended on December 29, 2018, the State implements administration by classification on the environmental impact of construction projects according to the level of impact on the environment. The construction unit shall prepare an environmental impact report or an environmental impact form or complete an environmental impact registration form (the "**Environmental Impact Assessment Documents**") for reporting and filing purposes. If the Environmental Impact Assessment Documents of a construction project have not been reviewed by the approving authority in accordance with the law or have not been granted approval after the review, the construction unit is prohibited from commencing construction works.

Pursuant to Interim Measures on Administration of Environmental Protection for Acceptance Examination Upon Completion of Construction Projects (《建設項目竣工環境保護驗收暫行辦法》) which was promulgated on November 20, 2017 and came into effect on the same day, the construction unit is the responsible party for the acceptance of the environmental protection facilities for the completion of the construction project, and shall, in accordance with the procedures and standards stipulated in relevant regulations, organize the acceptance of the environmental protection facilities, prepare the acceptance report, disclose the relevant information, accept social supervision, ensure that the environmental protection facilities to be constructed for the construction project are put into operation or used at the same time as the main project, and be responsible for the content, conclusion and public information of the acceptance. The construction unit shall be responsible for the truthfulness, accuracy and completeness of the acceptance content, conclusions and information disclosed, and shall not falsify the acceptance process. The major construction works of the construction project cannot be put into operation until the supporting facilities for environmental protection pass the inspection.

Pursuant to Law of the PRC on Prevention and Control of Environmental Pollution Caused by Solid Wastes (《中華人民共和國固體廢物污染環境防治法》) which was promulgated on October 30, 1995 and latest amended on April 29, 2020 and came into effect on September 1, 2020, the construction of projects which discharge solid waste and the construction of projects for storage, use and treatment of solid waste shall be carried out upon the appraisal regarding their effects on the environment and comply with the relevant state regulations concerning the management of environmental protection in respect of construction projects. The necessary supporting facilities for the prevention and control of environmental pollution caused by solid wastes as specified in the environmental impact assessment documents of the construction project shall be designed, constructed and put into operation simultaneously with the major construction works of the construction project.

Pursuant to the Law of the PRC on Prevention and Treatment of Water Pollution (《中華人民共和國水污染防治法》) which was promulgated on May 11, 1984, latest amended on June 27, 2017, and came into effect on January 1, 2018, the environmental impact assessment shall be conducted on new construction, reconstruction and construction expansion projects or other installations on water which directly or indirectly discharge pollutants into the water according to law. The water pollution prevention and treatment facilities of a construction project must be designed constructed and put into operation simultaneously with the major construction works of the construction project. The water pollution prevention and treatment facilities shall comply with the requirements of approved or filed environmental impact assessment documents.

The Administrative Measures on Licensing of Urban Drainage (《城鎮污水排入排水管網許可管理辦法》), which was promulgated by the Ministry of Housing and Urban-rural Development on January 22, 2015 and came into effect on March 1, 2015, provides that enterprises, institutions and individual industrial and commercial households engaging in industry, construction, catering industry, medical industry and discharging sewage into the urban drainage network must apply for and obtain a License for Urban Drainage (《排水許可證》).

Regulations on Foreign Investment

Regulations on Foreign Investment

Investment activities in the PRC by foreign investors were principally governed by the Special Administrative Measures (Negative List) for 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)》), or the 2021 Negative List, and the Catalogue of Industries for Encouraging Foreign Investment (《鼓勵外商投資產業目錄(2020年版)》), or the Encouraging List. The Negative List, which came into effect on January 1, 2022, sets out special administrative measures (restricted or prohibited) in respect of the access of foreign investments in a centralized manner, and the Encouraging List which came into effect on January 27, 2021, sets out the encouraged industries for foreign investment.

Foreign-Invested Enterprises

On December 29, 1993, the SCNPC issued the PRC Company Law (《中華人民共和國公司法》), or the Company Law, which was lasted amended on October 26, 2018. The Company Law regulates the establishment, operation and management of corporate entities in China and classifies companies into limited liability companies and limited companies by shares. According to the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》) promulgated by the SCNPC on March 15, 2019 and came into effect on January 1, 2020, the state shall implement the management systems of pre-establishment national treatment and negative list for foreign investment, and shall give national treatment to foreign investment beyond the negative list. Simultaneously, Sino-foreign Equity Joint Ventures of the PRC (《中華人民共和國中外合資經營企業法》), the Wholly Foreign-owned Enterprises Law of the PRC (《中華人民共和國外資企業法》) and Sino-foreign Cooperative Joint Ventures of the PRC (《中華人民共和國中外合作經營企業法》) have been repealed since January 1, 2020.

On December 26, 2019, the State Council promulgated 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. After the Regulations on Implementing the Foreign Investment Law of the PRC came into effect, the Regulations on Implementing the Sino-Foreign Equity Joint Venture 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 (《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 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 of the PRC (《中華人民共和國中外合作經營企業法實施細則》) have been repealed simultaneously.

On December 30, 2019, the Ministry of Commerce of the PRC (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 January 1, 2020 and replaced the Interim Measures for the Recordation Administration 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》), for carrying out investment activities directly or indirectly in PRC, the foreign investors or foreign-invested enterprises shall submit investment information to the commerce authorities pursuant to these measures.

Regulations on Overseas Investment

Pursuant to the Measures for the Administration of Overseas Investment (《境外投資管理辦法》) which was issued by the MOFCOM on September 6, 2014 and became effective on October 6, 2014, the MOFCOM and the commerce departments at provincial levels shall subject the overseas investment of enterprises to recordation or confirmation management, depending on the actual circumstances of investment. Overseas investment involving any sensitive country or region, or any sensitive industry shall be subject to confirmation management. Overseas investment under other circumstances shall be subject to recordation management.

Pursuant to the Measures for the Administration of Overseas Investment of Enterprises (《企業境外投資管理辦法》) which was issued by the NDRC on December 26, 2017 and became effective on March 1, 2018, an enterprise in the territory of the PRC (the "**Investor**") shall, in overseas investment, undergo the formalities for the confirmation or recordation, among others, of an overseas investment project (the "**Project**"), report the relevant information, and cooperate in supervisory inspection. Sensitive projects conducted by investors directly or through overseas enterprises controlled by them shall be subject to approval management. Non-sensitive Projects directly conducted by Investors, namely, non-sensitive Projects involving Investors' direct contribution of assets or rights and interests or provision of financing or security, shall be subject to recordation management. The aforementioned sensitive Project means a Project involving a sensitive country or region or a sensitive industry. The NDRC promulgated the Catalogue of Sensitive Sectors for Outbound Investment (2018 Edition) (《境外投資敏感行業目錄(2018年版)》), effective on March 1, 2018, to list the sensitive industries in detail.

Laws and Regulations Related to Overseas Listing

On December 24, 2021, the CSRC released the Administrative Provisions of the State Council on the Overseas Offering and Listing of Securities by Domestic Companies (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(草案徵求意見稿)) and the Administrative Measures for the Overseas Offering and Listing of Securities Record-filings 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)) (collectively the "**Draft Regulations on Listing**") for public comments. Pursuant to the Draft Regulations on Listing, PRC domestic companies (including (i) any PRC company limited by shares, and (ii) any offshore company that conducts its business operations primarily in China and contemplates to offer or list its securities in an overseas market based on its onshore equities, assets or similar interests) that directly or indirectly offer or list their securities in an overseas market are required to file with the CSRC within three business days after submitting their listing application documents to the relevant regulator in the place of intended listing. Overseas offerings and listings (i) that are prohibited by specific laws and regulations, (ii) that constitute threat to or endanger national security as reviewed and determined by competent authorities, (iii) that involve material ownership disputes, (iv) where the PRC domestic companies, their controlling shareholder or actual controller are convicted of investigated for certain criminal offences, or directors, supervisors and senior management of the issuer involved in certain criminal offences or severe administrative penalties (together the "**Forbidden Circumstances**"), among other circumstances, are explicitly forbidden.

To our best knowledge, none of the Forbidden Circumstances applies to us, and our PRC Legal Adviser also confirms to us that as of the Latest Practicable Date, there are no specific clauses or relevant provisions in PRC laws and regulations that explicitly prohibited us from [**REDACTED**] overseas. In addition, based on the results of public searches conducted by our PRC Legal Adviser against our PRC-incorporated subsidiaries, Gao Tieta (our Controlling Shareholder and Chairman), as well as our other directors and senior management, there is no evidence revealing any of them having been convicted of any criminal offences or severe administrative penalties that would prohibit us from conducting overseas [**REDACTED**] and [**REDACTED**] under the Draft Regulations on Listing, nor did any of our PRC-incorporated subsidiaries are involved in material ownership disputes. Moreover, as of the Latest Practicable Date, we have not received any notifications from the competent authority that our [**REDACTED**] and [**REDACTED**] threatens or endangers national security. Based on the foregoing, our PRC Legal Adviser does not find that we fall within the Forbidden Circumstances as provided under the Draft Regulations on Listing. Therefore, if the Draft Regulations on Listing become effective in their current form before the proposed [**REDACTED**] is completed, subject to the specific filing procedures expected to be detailed in implementation rules subsequently, the Draft Regulations on Listing can be complied with, as our Directors do not foresee and our PRC Legal Adviser is not aware of any legal impediment for us to comply with the Draft Regulations on Listing in any material aspects.

Regulations on Data Security

On December 28, 2021, thirteen government departments including the Cyberspace Administration of China (國家互聯網信息辦公室, the "**CAC**") jointly issued the Cybersecurity Review Measures (《網絡安全審查辦法》) which became effective on February 15, 2022. The Cybersecurity Review Measures provide that, to ensure the security of the supply chain of critical information infrastructure, security of network and data and safeguard national security, a

cybersecurity review is required when national security has been or may be affected where critical information infrastructure operators (關鍵信息基礎設施運營者) purchase network product or service and network platform operators (網絡平台運營者) process data. When a network platform operator in possession of personal information of over one million users apply for a listing overseas (國外), it must apply to CAC for a cybersecurity review. We believe that the said cybersecurity review is not applicable to us, primarily because we are not critical information infrastructure operators and we are seeking to [**REDACTED**] on the Main Board of the Stock Exchange instead of [**REDACTED**] in foreign countries.

On November 14, 2021, the CAC released the Network Data Security Management Regulations (Draft for Comment) (the "**Draft Data Security Regulations**") (《網絡數據安全管理條例(徵求意見稿)》), data processors seeking a public listing in Hong Kong that influence or may influence national security must apply to the CAC for a cybersecurity review. However, the Draft Regulations provides no further explanation or interpretation of "influence or may influence national security". As advised by our PRC Legal Adviser, according to the National Security Law (國家安全法), national security refers to the condition in which the state power, sovereignty, unity and territorial integrity, people's welfare, sustainable economic and social development and other vital interests of the State shall relatively face no danger or encounter no internal and external threats, as well as the capability to safeguard sustainable safety condition. The specific scope of what situations would be considered "influence or may influence national security" will be subject to the identification and interpretation of the PRC government authorities. At present, the Draft Data Security Regulations had been released for consultation purposes, as such, there still remain uncertainties as to its final content, anticipated adoption or effective date, final interpretation and implementation, and other aspects.

Based on the literal interpretation of the Draft Data Security Regulations, our PRC Legal Adviser is of the view that, given that (i) our customers are corporate customers and we do not access any data owned or held by our customers before or during the sale of products; (ii) for after-sale technical services, we resolve technical issues of the medical devices, and not in any way participating or assisting the corporate customers with data processing activities; (iii) we do not purchase in any other way any personal information, or carry out any other form of cooperation in respect of exchange, cleaning and processing of personal information, and neither do we process any important data based on the definition under the Draft Data Security Regulations, our business operations do not have a bearing on national security and would not likely to render the vital interests of the State with danger or encounter internal or external threats and hence, if the Draft Data Security Regulations are implemented in the current form, it may be unlikely that we would be required to undergo a cybersecurity review for the proposed [**REDACTED**].

Given the proposed [**REDACTED**] is [**REDACTED**] in Hong Kong and considering the nature of our business, our PRC Legal Adviser is of the view that the Company was not required to notify the CAC of the proposed [**REDACTED**] under PRC laws as of the Latest Practicable Date. As of the Latest Practicable Date, we had not been notified by any authorities of being classified as a data processor carrying out data processing activities that influence or may influence national security, neither had we been subject to any cybersecurity review, enquiry, investigation or notice by the CAC or any other authorities in connection with the proposed [**REDACTED**]. Based on the foregoing as well as the confirmation of our PRC Legal Adviser, our Directors currently do not expect the Cybersecurity Review Measures and the Draft Data Security Regulation will have a material adverse impact on our business, results of operations, or the proposed [**REDACTED**].

Our Directors believe that we are compliant with the regulations and policies in effect issued by the CAC to date. Nevertheless, there remain uncertainties with respect to any future development of the relevant regulatory regime. There can be no assurance that the relevant authorities will not take a view that is contrary to or otherwise different from that of our Directors and our PRC Legal Adviser above, and it is also possible that the PRC government authorities may require us to apply for the cybersecurity review for other reasons. We will continue to closely monitor the rule-making process and will assess and determine whether we are required to apply for the cybersecurity review when and once the Draft Data Security Regulation is formally promulgated.

Regulations on Employment and Social Security

Regulations on Employment

The major PRC laws and regulations that govern employment relationship are the Labor Law of the PRC (《中華人民共和國勞動法》), or the Labor Law (issued by the SCNPC on July 5, 1994, came into effect on January 1, 1995 and latest revised on December 29, 2018), the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》) or the Labor Contract Law (promulgated by the SCNPC on June 29, 2007 and became effective on January 1, 2008, and then amended on December 28, 2012 and became effective on July 1, 2013) and the Implementation Rules of the Labor Contract Law of the PRC (《中華人民共和國勞動合同法實施條例》), or the Implementation Rules of the Labor Contract Law (issued by the State Council on September 18, 2008 and came into effect on the same day). According to the aforementioned laws and regulations, labor relationships between employers and employees must be executed in written form. The laws and regulations above impose stringent requirements on the employers in relation to entering into fixed-term employment contracts, hiring of temporary employees and dismissal of employees. As prescribed under the laws and regulations, employers shall ensure their employees have the right to rest and the right to receive wages no lower than the local minimum wages. Employers must establish a system for labor safety and sanitation that strictly abides by state standards and provide relevant education to its employees. Violations of the Labor Contract Law and the Labor Law may result in the imposition of fines and other administrative liabilities and/or incur criminal liabilities in the case of serious violations.

Regulations on Social Insurance

According to the Social Insurance Law of PRC (《中華人民共和國社會保險法》), which was issued by the SCNPC on October 28, 2010 and revised on December 29, 2018, enterprises and institutions in the PRC shall provide their employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, occupational injury insurance, medical insurance and other welfare plans. The employer shall apply to the local social insurance agency for social insurance registration within 30 days from the date of its formation. And it shall, within 30 days from the date of employment, apply to the social insurance agency for social insurance registration for the employee. Any employer who violates the regulations above shall be ordered to make correction within a prescribed time limit; if the employer fails to rectify within the time limit, the employer and its directly liable person will be fined. Meanwhile, the Interim Regulation on the Collection and Payment of Social Insurance Premiums (《社會保險費徵繳暫行條例》) prescribes the details concerning the social insurance.

Apart from the general provisions about social insurance, specific provisions on various types of insurance are set out in the Regulation on Work-Related Injury Insurance (《工傷保險條例》) which was issued by the State Council on April 27, 2003, came into effect on January 1, 2004 and revised on December 20, 2010, the Regulations on Unemployment Insurance (《失業保險條例》) which was issued by the State Council on January 22, 1999 and came into effect on the same day, the Trial Measures on Employee Maternity Insurance of Enterprises (《企業職工生育保險試行辦法》), which was issued by the Ministry of Labor on December 14, 1994 and came into effect on January 1, 1995. Enterprises subject to these regulations shall provide their employees with the corresponding insurance.

Regulations on Housing Provident Fund

According to the Regulation Concerning the Administration of Housing Provident Fund (《住房公積金管理條例》), which was implemented on April 3, 1999 and latest amended on March 24, 2019, any newly established entity shall make deposit registration at the housing accumulation fund management center within 30 days as of its establishment. After that, the entity shall open a housing accumulation fund account for its employees in an entrusted bank. Within 30 days as of the date an employee is recruited, the entity shall make deposit registration at the housing accumulation fund management center and seal up the employee's housing accumulation fund account in the bank mentioned above within 30 days from termination of the employment relationship.

Any entity that fails to make deposit registration of the housing accumulation fund or fails to open a housing accumulation fund account for its employees shall be ordered to complete the relevant procedures within a prescribed time limit. Any entity failing to complete the relevant procedure within the time limit will be fined RMB10,000 to RMB50,000. Any entity that fails to make payment of housing provident fund within the time limit or has a shortfall in payment of housing provident fund will be ordered to make the payment or make up the shortfall within the prescribed time limit, otherwise, the housing provident management center is entitled to apply for compulsory enforcement with the People's Court.

Regulations on Intellectual Property

Regulations on Trademarks

Pursuant to the Trademark Law of the PRC (《中華人民共和國商標法》) which was promulgated on August 23, 1982 and latest amended on April 23, 2019 and came into effect on November 1, 2019, the Implementation Regulations of the Trademark Law of PRC (《中華人民共和國商標法實施條例》) which was issued on August 3, 2002 and amended on April 29, 2014, the Trademark Office under the State Administration for Industry and Commerce of the PRC (the "**Trademark Office**") shall handle trademark registrations and grant a term of ten years to registered trademarks, which may be renewed for additional ten year period upon request from the trademark owner. The Trademark Law of the PRC has adopted a "first-to-file" principle with respect to trademark registration. Where an application for trademark for which application for registration has been made is identical or similar to another trademark which has already been registered or is under 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 of 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. A trademark registrant may, by entering into a trademark licensing contract, license another party to use its registered trademark. Where another party is licensed to use a registered trademark, the licenser shall report the license to the Trademark Office for recordation, and the Trademark Office shall publish it. An unrecorded license may not be used as a defense against a third party in good faith.

Regulations on Patents

According to the Patent Law of the PRC (《中華人民共和國專利法》), promulgated by the SCNPC on March 12, 1984 and latest amended on October 17, 2020 which became effective on June 1, 2021 and the Implementing Rules of the Patent Law of the PRC (《中華人民共和國專利法實施細則》), promulgated by the China Patent Bureau Council on January 19, 1985, and last amended on January 9, 2010 and effective from February 1, 2010, there are three types of patents in the PRC invention patents, utility model patents and design patents. The protection period of a patent right for invention patents shall be 20 years, the protection period of a patent right for utility model patents shall be 10 years, and the protection period of design patent right is 15 years, both commencing from the filing date.

On October 17, 2020, the SCNPC issued the Patent Law of the PRC (Revised in 2020) (《中華人民共和國專利法(2020年修正)》) (the "**2020 Patent Law**"), which came into effect on June 1, 2021. Compared with the Patent Law of the PRC (Revised in 2008), changes in the 2020 Patent Law mainly include: (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) strengthening the joint liability of internet service providers for network patent infringement; (v) improving the distribution of the burden of proof in patent infringement cases; (vi) increasing the compensation for patent infringement; and (vii) patent term adjustment to compensate delays of the NIPA in the review of patent applications.

Pursuant to the Measures for the Filling of Patent Licensing Contracts (《專利實施許可合同備案辦法》) promulgated by the State Intellectual Property Office on June 27, 2011 and became effective on August 1, 2011, the State Intellectual Property Office shall be responsible for recordation of patent licensing contracts nationwide and the parties concerned shall complete recordation formalities within three months from the effective date of a patent licensing contract.

Regulations on Domain Names

According to the Administrative Measures for Internet Domain Names (《互聯網域名管理辦法》), which was promulgated by the Ministry of Industry and Information Technology (the "**MIIT**") on August 24, 2017 and became effective on November 1, 2017, the MIIT is responsible for supervision and administration of domain name services in the PRC. Communication administrative bureaus at provincial levels shall conduct supervision and administration of the domain name services within their respective administrative jurisdictions. Domain name registration services shall, in principle, be subject to the principle of "first apply, first register." A domain name registrar shall, in the process of providing domain name registration services, ask the applicant for which the registration is made to provide authentic, accurate and complete identity information on the holder of the domain name and other domain name registration related information.

Regulations Relating to Foreign Exchange and Overseas Investment

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the PRC (《中華人民共和國外匯管理條例》) which became effective on April 1, 1996 and latest amended on August 5, 2008. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

On November 19, 2012, the State Administration of Foreign Exchange (the "**SAFE**") issued the Circular of Further Improving and Adjusting Foreign Exchange Administration Policies on Foreign Direct Investment (《國家外匯管理局關於進一步改進和調整直接投資外匯管理政策的通知》), (the "**SAFE Circular 59**"), which came into effect on December 17, 2012 and latest amended on December 30, 2019. The SAFE Circular 59 aims to simplify the foreign exchange procedure and promote the facilitation of investment and trade. According to the SAFE Circular 59, 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 derived 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, as well multiple capital accounts for the same entity may be opened in different provinces. Later, the SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies in Respect of 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》) on February 13, 2015, which was partially abolished on December 30, 2019 and prescribed that the bank instead of SAFE can directly handle the foreign exchange registration and approval under foreign direct investment while SAFE and its branches indirectly supervise the foreign exchange registration and approval under foreign direct investment through the bank.

On May 10, 2013, the SAFE issued the Administrative Provisions on Foreign Exchange in Domestic Direct Investment by Foreign Investors (《外國投資者境內直接投資外匯管理規定》) (the "**SAFE Circular 21**"), which became effective on May 13, 2013 and latest amended on December 30, 2019. The SAFE Circular 21 specifies that the administration by SAFE or its local branches over direct investment by foreign investors in the PRC must be conducted by way of registration and banks must process foreign exchange business relating to the direct investment in the PRC based on the registration information provided by SAFE and its branches.

According to the Notice on Relevant Issue Concerning the Administration of Foreign Exchange for Overseas Listing (《關於境外上市外匯管理有關問題的通知》) issued by the SAFE on December 26, 2014, the domestic companies shall register the overseas listing with the foreign exchange control bureau located at its registered address in 15 working days after completion of the overseas listing and issuance. The funds raised by the domestic companies through overseas listing may be repatriated to China or deposited overseas, provided that the intended use of the fund shall be consistent with the contents of the document and other public disclosure documents.

According to the Notice of the State Administration of Foreign Exchange on Reforming the Management Mode of Foreign Exchange Capital Settlement of Foreign Investment Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》) (the **"SAFE Circular 19**") promulgated on March 30, 2015, coming effective on June 1, 2015 and partially abolished on December 30, 2019, foreign-invested enterprises could settle their foreign exchange capital on a discretionary basis according to the actual needs of their business operations. Whilst, foreign-invested enterprises are prohibited to use the foreign exchange capital settled in RMB (a) for any expenditures beyond the business scope of the foreign-invested enterprises or forbidden by laws and regulations; (b) for direct or indirect securities investment; (c) to provide entrusted loans (unless permitted in the business scope), repay loans between enterprises (including advances by third parties) or repay RMB bank loans that have been on-lent to a third party; and (d) to purchase real estates not for self-use purposes (save for real estate enterprises).

On June 9, 2016, SAFE issued the Notice of the State Administration of Foreign Exchange on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《國家外匯管理局關於改革和規範資本項目結匯管理政策的通知》) (the "**SAFE Circular 16**"), which came into effect on the same day. The SAFE Circular 16 provides that discretionary foreign exchange settlement applies to foreign exchange capital, foreign debt [**REDACTED**] and remitted foreign [**REDACTED**], and the corresponding RMB capital converted from foreign exchange may be used to extend loans to related parties or repay inter-company loans (including advances by third parties). However, there remain substantial uncertainties with respect to SAFE Circular 16's interpretation and implementation in practice.

On October 23, 2019, SAFE promulgated the Notice on Further Facilitating Cross-Board Trade and Investment (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), which became effective on the same date (except for Article 8.2, which became effective on January 1, 2020). The notice canceled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. In addition, restrictions on the use of funds for foreign exchange settlement of domestic accounts for the realization of assets have been removed and restrictions on the use and foreign exchange settlement of foreign investors' security deposits have been relaxed. Eligible enterprises in the pilot area are also allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing revenues for domestic payments without providing materials to the bank in advance for authenticity verification on an item by item basis, while the use of funds should be true, in compliance with applicable rules and conforming to the current capital revenue management regulations.

Regulations Relating to Taxation

Enterprise Income Tax ("EIT")

Pursuant to the Enterprise Income Tax Law (《中華人民共和國企業所得税法》) amended by the SCNPC and coming into effect on December 29, 2018 and the Implementation Rules of the EIT Law (《中華人民共和國企業所得税法實施條例》) amended by the State Council and coming into effect on April 23, 2019, a domestic enterprise which is established within the PRC in accordance with the laws or established in accordance with any laws of foreign countries (regions) but with an actual management entity within the PRC shall be regarded as a resident enterprise. A resident enterprise shall be subject to an EIT of 25% of any income generated within or outside the PRC. A preferential EIT rate shall be applicable to any key industry or project which is supported or

encouraged by the State. High and new technology enterprises which are supported by the State may enjoy a reduced EIT rate of 15%.

The PRC and the government of Hong Kong entered into the Arrangement between the Mainland of the PRC and 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稅避免雙重徵稅和防止偷漏稅的安排》) (the "**Arrangement**") on August 21, 2006 and came into effect on December 8, 2006. According to the Arrangement, if a Hong Kong resident company owns at least 25% equity interests in a PRC company and is the beneficial owner of the dividends paid by the PRC company, the PRC withholding tax on the dividends shall not exceed 5% of the gross amount of the dividends.

Pursuant to the Circular of the State Administration of Taxation on Relevant Issues relating to the Implementation of Dividend Clauses in Tax Agreements (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》) (Guo Shui Han [2009] No. 81) which was promulgated by the State Administration of Taxation (the "**SAT**") and became effective on February 20, 2009, all of the following requirements shall be satisfied before a fiscal resident of the other party to a tax agreement can 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: (i) such a fiscal resident who obtains dividends should be a company as provided in the tax agreement; (ii) the equity interests and voting shares of the PRC resident company directly owned by such a fiscal resident reaches a specified percentage; and (iii) the equity interests of the PRC resident company directly owned by such a fiscal resident, at any time during the twelve months prior to receipt of the dividends, reach a percentage specified in the tax agreement.

According to the Announcement on Several Issues concerning the Enterprise Income Tax on Income from the Indirect Transfer of Assets by Non-Resident Enterprises (《關於非居民企業間接轉讓財產企業所得稅若干問題的公告》) (the SAT Public Notice [2015] No. 7) which was promulgated by the SAT on February 3, 2015 and came into effect on the same day), where a non-resident enterprise indirectly transfers equities and other assets of a PRC resident enterprise to avoid the EIT payment obligation by making an arrangement with no reasonable business purpose, such indirect transfer shall be redefined and recognized as a direct transfer in accordance with the provisions of the EIT Law. Where the EIT on the income from the indirect transfer of real estate or equities shall be paid in accordance with the provisions of this Announcement, the entity or individual that directly assumes the obligation to make relevant payments to the transfer or according to the provisions of the relevant laws or as agreed upon in the contract shall be the withholding agent.

Value-Added Tax

The major PRC law and regulation governing value-added tax are the Interim Regulations on Value-added Tax of the PRC (《中華人民共和國增值稅暫行條例》) (issued on December 13, 1993 by the State Council, came into effect on January 1, 1994, and latest amended on November 19, 2017), as well as the Implementation Rules for the Interim Regulations on Value-Added Tax of the PRC (《中華人民共和國增值稅暫行條例實施細則》) (issued on December 25, 1993 by the MOF, came into effect on the same day and latest amended on October 28, 2011), any entities and individuals engaged in the sale of goods, supply of processing, repair and replacement services, and import of goods within the territory of the PRC are taxpayers of VAT and shall pay the VAT in

accordance with the law and regulation. The rate of Value-added tax (the "**VAT**") for sale of goods is 17% unless otherwise specified, such as the rate of VAT for sale of transportation is 11%. With the VAT reforms in the PRC, the rate of VAT has been changed several times. The MOF and the SAT issued the Notice of on Adjusting VAT Rates (《關於調整增值税税率的通知》) on April 4, 2018 to adjust the tax rates of 17% and 11% applicable to any taxpayer's VAT taxable sale or import of goods to 16% and 10%, respectively, this adjustment became effect on May 1, 2018. Subsequently, the MOF, the SAT and the General Administration of Customs jointly issued the Announcement on Relevant Policies for Deepening the VAT Reform (《關於深化增值税改革有關政策的公告》) on March 20, 2019 to make a further adjustment, which came into effect on April 1, 2019. The tax rate of 16% applicable to the VAT taxable sale or import of goods shall be adjusted to 13%, and the tax rate of 10% applicable thereto shall be adjusted to 9%.

LAWS AND REGULATIONS RELATED TO OUR BUSINESS IN THE EU

Regulation of Medical Devices

Under European medical devices law, medical devices are assigned to regulatory classes based on their intended purpose and inherent risk which determine the level of control deemed necessary to assure their safety and effectiveness. Medical devices are classified as: class I (low risk), class IIa or IIb (medium risk), or class III (high risk).

The regulatory framework concerning the commercialization of medical devices is harmonized by EU Regulation 2017/745 (Medical Devices Regulation, "**MDR**") as well as local implementing or supplementary laws in the countries in which the MDR applies (the "Union," which currently comprises of the EU member states, EEA member states that are not EU member states and Turkey). Non-Union countries in Europe, such as the UK and Switzerland, apply their own national medical devices legislation, which may be more or less convergent with the MDR.

Certain medical devices CE marked before May 26, 2021 may also continue to comply with the essential requirements set out in Annex I of EC Directive 93/42/EEC (Medical Devices Directive, "**MDD**") under the transitional regime provided under article 120 MDR. However, also for these products important elements of the MDR apply already. The MDR applies directly in all Union Member States with the intention to provide more legal certainty for market stakeholders as compared to Union Member States having to transpose EU Directives into national law.

This regulatory framework aims at protecting the health and safety of patients and users of medical devices and govern, among other things, the following product-related activities in which medical device manufacturers, their contract manufacturers and suppliers, as well as their importers and distributors, are involved, in particular development, manufacturing, labelling, safety, market access, advertising and promotion, import and export, sales and distribution.

In order to commercialize medical devices, medical devices are required to comply with the general safety and performance requirements and quality system requirements of the applicable regulatory framework. Compliance with its requirements entitles medical device providers to affix the CE conformity marking to their medical devices, without which the products cannot be commercialized in the Union. The European Standard setting bodies, mainly the European Committee for Standardization (CEN/CENELEC), have adopted numerous harmonized standards covering a wide range of essential requirements and general safety and performance requirements

for medical devices and accessories. Compliance with the relevant harmonized standards applicable to a given essential or general safety and performance requirement for a medical device or accessory provides presumption of conformity with the requirements concerned. The Medical Devices Coordination Group ("**MDCG**") has adopted various guidelines, consensus statements and interpretative documents aimed at ensuring the uniform application of the provisions of the applicable regulatory framework under the MDR. MEDDEV guidelines issued under the MDD may still be relevant for devices covered by the essential requirements of the MDD as provided in the transitional regime set out in article 120 (3) MDR.

In order to demonstrate compliance with the essential or general and safety performance requirements and obtain the right to affix the CE conformity marking to a device, medical device manufacturers must perform a so-called conformity assessment procedure, which varies according to the category of medical device and its classification. Except for low-risk medical devices in class I, where the manufacturer can normally issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential or general safety and performance requirements of the applicable regulatory framework, a conformity assessment procedure requires the intervention of an independent and neutral institution accredited by a Member State of the Union (a "**Notified Body**") to conduct the conformity assessment. For higher risk classes than class I and in certain other specific cases (e.g. sterile devices or devices with a measuring function) a Notified Body will evaluate the conformity assessment application and follow an evaluation procedure depending on the classification of the product, after which it confirms separately if the device and quality system are sufficiently supported in the application to complete the conformity assessment. If the conformity assessment by the Notified Body is completed, a CE Certificate is issued as a prerequisite for the manufacturer to draft and issue an EU Declaration of Conformity for the respective product, which allows the manufacturer to affix the CE marking to the products in scope of the CE certificate.

The lawful affixing of the CE marking authorizes the manufacturer to commercialize its products anywhere within the Union and in certain non-Union countries that recognize the CE mark. Additional national requirements of the respective Member States, such as language requirements for the instructions for use, may also apply.

Failure to comply with the applicable laws and regulations could result in, among other things, delays in obtaining market access, competent authority enforcement, product recalls, product seizures, interruptions of production, operating restrictions, suspension or withdrawal of product market access, injunctions, and civil or criminal sanctions.

Since May 26, 2021, the MDR sets the applicable regulatory framework for medical devices in the Union. Devices with a valid CE certificate under the MDD may still be placed on the market in the Union under certain conditions until the latest of either the date on which the CE certificate for the device expires or until May 26, 2024. Latest by May 26, 2024, all medical devices must have obtained CE-certification under the MDR.

The MDR, compared to the MDD, stipulates additional requirements, including e.g.:

- Renewed conformity assessment of products by the manufacturer regarding their intended purpose and risk class, leading for certain product types to up-classification and, consequently, increased involvement of Notified Bodies and higher regulatory standards to be met.

- Extension of retention period to ten year (or fifteen years in case of implantable devices) for related documents.

- Technical Documentation to contain more detailed information, supporting clinical data and requirements to provide information in the languages of the EU Member States targeted for sales will be widened.

- Additional regulatory responsibilities will be extended to importers, distributors, authorised representatives and persons responsible for regulatory compliance.

- A database (Eudamed) for product registrations, the Unique Device Identification (UDI), and for the identification of certain economic operators with regulatory responsibilities will be established.

- Content on labelling artifacts and promotional materials needs to be reviewed under partially new and more precise rules, e.g., regarding specifics to be set out in Instructions for Use (IFU).

- The rules for systems and procedure packs have been amended with additional requirements, e.g., registration of the party that produces them and UDI for systems and procedure packs.

- Post Market Surveillance Plans and Post Market Clinical Follow-Up (as part of the products' technical documentation and to be implemented in quality system processes) need to be established for the entire life cycle of a product in order to actively collect post-market data from the supply chain, users and patients about the device's performance and safety.

- In addition, Post Market Surveillance Reports and Periodic Safety Update Reports are to be implemented. A maximum 15 day reporting timeline for serious incidents (formerly 30 days) needs to be followed, but depending on the risk associated with the serious incident timelines may be as short as two days.

- Broadened requirements on clinical evaluation.

Finally, the European guidelines for the interpretation of the MDR (MDCG Guidelines), which have been adopted by the MDCG are of high practical relevance.

To safeguard continued access to the Union market and other markets that depend on CE marking compliance needs be established with the MDR.

The applicable regulatory framework requires that confirmation of conformity with relevant MDR general safety and performance requirements under the normal conditions of the intended use of the device shall be provided by means of clinical evaluation ("**Clinical Evaluation**"), an evaluation procedure based on clinical data providing sufficient clinical evidence, unless, in exceptional cases with adequate justification reason, other data are sufficient.

Regulations on Advertising, Promotion and Healthcare Compliance

Apart from new specific advertising and promotion requirements in the MDR the advertising and promotion of medical devices is subject to additional horizontal EU Directives concerning misleading and comparative advertising and unfair commercial practices, as well as local Member State legislation or self-regulatory rules governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of medical devices to professional users as well as to the general public. In addition, local rules may impose limitations on medical device manufacturers' interaction with healthcare professionals ("**HCPs**"), e.g. as regards consultancy fees paid to HCPs, and may require the manufacturer to make local submissions of monetary interactions or other transfers of value to HCPs to local transparency registers.

Reimbursement

The rules for reimbursement of medical devices by health insurance schemes are not harmonized within the Union but vary greatly from Member State to Member State.

Regulations on data protection

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

In addition to the GDPR, the Federal Data Protection Act (Bundesdatenschutzgesetz, BDSG) applies in Germany. Under the BDSG, companies in Germany with at least 20 employees regularly dealing with personal data have an obligation to formally appoint a data protection officer, which can be an employee or external service provider. The data protection officer is in charge of ensuring and monitoring data protection compliance and reports directly to the management of the entity.

The GDPR and BDSG require entities to process personal data in compliance with a set of general principles that are reflected in specific compliance requirements stipulated by them, for instance:

- Before processing personal data, an entity must ensure that the processing will comply with the general principles set out in the GDPR. These general principles are mainly related to the principle of lawfulness, transparency, purpose limitation, data minimization, accuracy, storage limitation, data security and accountability.

- Once the entity has assessed the specific intended processing activity, a legal basis for processing the personal data must be identified. The bases are stipulated in the GDPR and BDSG.

- The GDPR confers data subjects a number of rights with respect to the entity that is processing their personal data and, at the same time, imposes corresponding obligations on the entity. For example, the entity must be transparent about the processing of personal data and proactively give information to those persons whose personal data are intended to be processed. The data subjects also have a set of rights, such as the right to have their personal data deleted under certain circumstances, the right to have inaccurate data corrected and the right to access the personal data the entity processes about them.

- The GDPR requires an entity to maintain a record of its processing activities under its responsibility. This record must contain a list of information, such as the purposes of the processing, categories of personal data, categories of recipients etc.

- The GDPR also imposes a requirement to have data processing agreements with companies to whom processing of personal data is outsourced (the "**data processor**"). The purpose of the data processing agreement is to ensure that the data processor is contractually bound to implement appropriate technical and organizational measures that ensure compliance with the requirements in the GDPR and protect the rights of the data subjects.

- The GDPR imposes specific rules and requirements for the transfer of personal data to countries outside the European Union.

- The GDPR allows Member States to maintain or introduce further conditions, including limitations, with regard to the processing of genetic data, biometric data or data concerning health.

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

Complementing the GDPR and the BDSG, the (16) German Federal States have each adopted Health Data Protection Acts or Hospital Acts that foremost apply to hospitals (and which might have to be taken into account by a hospital's vendor), which may include specific definitions of patient data, specific regulations on the processing of patient data and the permissibility of outsourcing activities by hospitals.

EU Product Liability Directive

Companies may be subject to German or Dutch product liability law if the use of their medical products causes personal injury or property damage to patients, users or other persons after placement of the products on the market in Germany or in the Netherlands. For both of these EU Member States no-fault product liability is (partially) harmonized under EU Directive 85/374 on product liability ("**EU Product Liability Directive**"), while Member States remain able to maintain fault-based liability rules.

LAWS AND REGULATIONS RELATED TO OUR BUSINESS IN THE NETHERLANDS

Regulation of Medical Devices

The Act on Medical Devices (*Wet Medische Hulpmiddelen*) and its implementing decrees and ordinances supplement the direct effect of the MDR for elements of market surveillance and policy choices allowed to Union Member States under the MDR, such as local language requirements, administrative fees and enforcement by Dutch authorities. This Act and ordinances apply to products still placed on the market under a valid MDD certificate under the MDR transitional regime as well as for products CE marked under the MDR. Thus, the applicable Dutch rules for medical devices, in addition to the Act on Medical Devices:

- Decree on Medical Devices (*Besluit Medische Hulpmiddelen*)
- Ordinance on Medical Devices (*Regeling Medische Hulpmiddelen*)

The Act on Medical Devices, the Decree on Medical Devices and the Ordinance on Medical Devices refer back to the MDR in many of their provisions.

Fraud and Abuse

The Dutch Criminal Code (*Wetboek van Strafrecht*), applicable industry codes and the Act on Medical Devices prohibit both companies and healthcare professionals to engage in interactions promising, granting, receiving or offering any payment or other advantage to healthcare professionals in exchange for influence on the purchase decision, prescription or supply of medical devices. In addition, the Act on Medical Devices and the industry codes set limits to consultancy fees that may be paid to healthcare professionals.

The potential legal consequences of an infringement of these regulations are manifold: the person acting can be subject to criminal liability (imprisonment or fines), the agreement itself can be nullified and the companies or physicians may face administrative enforcement by the Healthcare Inspectorate or may be subject to a complaint at the self-regulatory Medical Devices Code Commission (*GMH Code Commissie*). Furthermore, the offering or receipt of payments or other incentives may be subject to criminal sanctions.

Regulations on the Advertising and Promotion

In the Netherlands, the advertising and promotion of medical devices is regulated under article 7 MDR, the prohibition on misleading business-to-business advertising in the Civil Code (*Burgerlijk Wetboek*), the requirements for comparative advertising in the Civil Code and the prohibition on unfair business-to-consumer commercial practices, which include numerous prohibitions and restrictions. Inter alia, it prohibits misleading advertising of medical devices and imposes specific requirements to comparative advertising. The self-regulatory Netherlands Advertising Code (*Nederlandse Reclame Code*) and the Code for the Advertising of Medicinal Products to the General Public (*Code Publieksreclame Geneesmiddelen*) contain further restrictions for advertisements addressing the general public in advertisements for medical devices. Infringements of the Civil Code provisions on advertising may be enforced against as an unfair commercial practice constituting an administrative offense or may be subject to civil

litigation by competitors or consumer organizations; this may result in injunctive relief and public rectifications. Infringement of the self-regulatory Netherlands Advertising Code (*Nederlandse Reclame Code*) and the Code for the Advertising of Medicinal Products to the General Public (*Code Publieksreclame Geneesmiddelen*) may lead to complaints by consumers or competitors that can lead to recommendations by the self-regulatory body, which, in case not followed by the advertiser, may be communicated to the Healthcare Inspectorate that may enforce against the advertiser based on the Act on Medical Devices in case the advertisement constitutes an infringement of the Medical Devices Act, Decree on Medical Devices or Ordinance on Medical Devices.

Reimbursement

In the Netherlands, the conditions for reimbursement differ according to whether the patient is insured through the basic coverage ("*basispakket*") of statutory health insurance funds based on the Act on Medical Care Insurance (the "*Zorgverzekeringswet*") or is additionally privately insured. Medical devices used in intramural cure and care are covered in the reimbursement of medical treatment under the Zorgverzekeringswet. Assistive medical devices are reimbursed by municipalities under several other government acts, such as the Long Term Care Act ("*Wet langdurige zorg*") and the Act on Societal Support ("*Wet maatschappelijke ondersteuning*").

Product Liability

Under Dutch product liability law, the producer of defective goods may be liable for damages under the product liability regime in the Dutch Civil Code ("**DCC**") as well as under general tort law under the DCC.

No fault liability

Product liability is laid down in article 6:185 and following of the DCC. This implements the EU Product Liability Directive in Dutch law. It provides for pure strict liability for defective products, i.e. it does not require the producer to be at fault. The producer is liable for (i) construction errors that inevitably affect an entire series, (ii) manufacturing errors that occur during production only on individual pieces, and (iii) instructional errors that consist in inadequate instructions for use or insufficient warning of possible dangers of the product. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including (a) the presentation of the product; (b) the use to which it could reasonably be expected that the product would be put; and (c) the time when the product was put into circulation.

The injured party must prove the damage, the defect and the causal relationship between the defect and the damage. The producer's liability is reduced or eliminated having regard to all the circumstances if the damage was caused both by a defect in the product and by the fault of the injured party or a person for whom the injured party is responsible.

In the case of damage to property, the product liability under the DCC is only applicable if an object is damaged which is normally intended for private use or consumption and was mainly used for this purpose by the injured person.

Liability in tort

Instead of the product liability under the DCC or also in addition to it, the liability in tort according to DCC may be relevant. This is a fault-based liability. In contrast to product liability under the DCC, it covers not only product defects in the narrower sense, but also breaches of a general duty of care in relation to the product, provided that this breach is attributable to the producer.

LAWS AND REGULATIONS RELATED TO OUR BUSINESS IN GERMANY

Regulation of Medical Devices

The German Medical Devices Act (*Medizinproduktegesetz*) implements the MDD into German law for as long as the MDD framework is applicable (until expiry of MDR grace periods). Thus, for products still certified under the MDD, the prerequisites for the lawful commercialization of medical devices are primarily regulated by the German Medical Devices Act (and the ordinances passed thereunder (*Rechtsverordnungen*)), including but not limited to:

- Ordinance on Medical Devices (*Verordnung über Medizinprodukte*);
- Ordinance on the Provision of Medical Devices (*Verordnung zur Regelung der Abgabe von Medizinprodukten*);
- Ordinance on Clinical Trials with Medical Devices (*Verordnung über klinische Prüfungen von Medizinprodukten*);
- Ordinance on the Installation, Operation and Use of Medical Devices (*Verordnung über das Errichten, Betreiben und Anwenden von Medizinprodukten*);
- Ordinance on the Identifying, Analysing and Counteractive Measures (*Verordnung über die Erfassung, Bewertung, und Abwehr von Risiken bei Medizinprodukten*);
- Ordinance on the Database-Supported Information System of the German Institute for Medical Documentation and Information for Medical Devices (*Verordnung über das datenbankgestützte Informationssystem über Medizinprodukte des Deutschen Instituts für Medizinische Dokumentation und Information*); and
- Ordinance on the Fees linked to the Medical Devices Act and the Ordinances passed thereunder (*Gebührenverordnung zum Medizinproduktegesetz und den zu seiner Ausführung ergangenen Rechtsverordnungen*).

Both the German Medical Devices Act, and the ordinances, however, refer back to the MDD in many parts.

In addition, the MDR applies or will apply directly to medical devices once CE-certified under the MDR, as will the local German supplementary act for the MDR (*Medizinprodukterecht-Durchführungsgesetz — MPDG*).

Fraud and Abuse

The German Criminal Code, the German Fifth Social Security Code (the "**SGB V**"), applicable industry codes and the state rules for professional conduct of physicians prohibit promising, granting, receiving or offering any payment or other advantage for the recommendations of physicians as well as the prescription or supply of medical aids or devices. Any circumvention of the regulation is prohibited as well.

The potential legal consequences of an infringement of these regulations are manifold: the person acting can be subject to criminal liability (imprisonment or fines), the agreement itself can be nullified, the physicians may face professional sanctions, and a hospital may be excluded from the hospital plan. In addition, violations can also be deemed to constitute an infringement of the German Unfair Competition Act, which prohibits unfair business practices. The violation of the Unfair Competitions Act, in turn, may *inter alia* result in injunctive relief and liability for damages. Furthermore, the offering or receipt of payments or other incentives may be subject to criminal sanctions.

Regulations on the Advertising and Promotion

In Germany, the advertising and promotion of medical devices is primarily regulated by the Medical Product Advertisement Act (*Heilmittelwerbegesetz*), which includes numerous prohibitions and restrictions. Inter alia, it prohibits misleading advertising of medical devices and restricts the offer and granting of gifts or other advantages in connection with promotional activities. The Medical Product Advertisement Act contains further restrictions for advertisements addressing persons other than healthcare professionals. Infringements of the Medical Product Advertisement Act may be punished as an administrative offense; violations of the prohibition of misleading advertisement may even result in one year of imprisonment. Further, infringements may constitute an infringement of the Unfair Competition Act. This may result in injunctive relief and liability for damages.

Reimbursement

In Germany, the conditions for reimbursement differ according to whether the patient is insured through the statutory health insurance funds (the "**SHIF**") or is privately insured. About 85-90% of the German population is covered by the SHIF.

Product Liability

Companies may be subject to German product liability law if the use of their medical products causes personal injury or property damage to customers after placement of the products on the market in Germany.

Under German product liability law, the producer of defective goods may be liable for damages under the German Product Liability Act (ProdHaftG) as well as under tort law claims under the German Civil Code (BGB). Product liability under the ProdHaftG is more specific than the product liability under the BGB. In contrast to the latter, it is a pure strict liability, i.e. it does not require the producer to be at fault. The producer is liable for (i) construction errors that inevitably affect an entire series, (ii) manufacturing errors that occur during production only on individual pieces, and (iii) instructional errors that consist in inadequate instructions for use or

insufficient warning of possible dangers of the product. In the case of damage to property, the product liability under the ProdHaftG is only applicable if an object is damaged which is normally intended for private use or consumption and was mainly used for this purpose by the injured person. The ProdHaftG provides for a maximum liability amount for personal injury. If personal injury has been caused by a product or identical products with the same defect, the liable party is only liable up to a maximum amount of 85 million euros. Instead of the product liability under ProdHaftG or also in addition to it, the liability in tort according to BGB may be relevant. This is a fault-based liability. In contrast to product liability under the ProdHaftG, it covers not only product defects in the narrower sense, but also breaches of duty in product monitoring. The product monitoring obligation requires the manufacturer to keep an eye on the fate of the product even after it has been placed on the market and to react appropriately to damage reports, for example by recalling the product.

Other differences are that the product liability under the BGB also covers damage to property intended for commercial use and that no maximum liability limits are set.

LAWS AND REGULATIONS RELATING TO TRANSFER PRICING IN HONG KONG

Under the Inland Revenue Ordinance (Chapter 112 of the Laws of Hong Kong) (the "**IRO**"), for a company carrying on a trade, profession or business in Hong Kong, its assessable profits arising in or derived from Hong Kong shall be chargeable to profits tax.

The Inland Revenue Department (the "**IRD**") may make transfer pricing adjustments by disallowing expenses incurred by Hong Kong residents under sections 16(1), 17(1)(b) and 17(1)(c) of the IRO and challenging the entire arrangement under general anti-avoidance provisions such as sections 61 and 61A of the IRO if the IRD considers that the related party transactions are not conducted on an arm's length basis.

In April 2009, the IRD issued Departmental Interpretation and Practice Notes No. 45 ("**DIPN 45**"). DIPN 45 provides that where double taxation arises as a result of transfer pricing adjustments made by the tax authorities of another country, a Hong Kong taxpayer may potentially claim relief under the treaty between Hong Kong and that country (countries that entered into tax arrangements with Hong Kong include the PRC).

In December 2009, the IRD issued Departmental Interpretation and Practice Notes No. 46 ("**DIPN 46**"). DIPN 46 provides clarifications and guidance on the IRD's views on transfer pricing and how it intends to apply the existing provisions of the IRO to establish whether related parties are transacting at arm's length prices. In general, the practices followed by the IRD are based on the transfer pricing methodologies recommended by the Organisation for Economic Co-operation and Development (OECD) OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations.

Furthermore, the Inland Revenue (Amendment) (No. 6) Ordinance 2018 (the "**Amendment Ordinance**") was gazetted on July 13, 2018. The main objectives of the Amendment Ordinance are to codify the transfer pricing principles and implement certain measures under the Base Erosion and Profit Shifting ("**BEPS**") package promulgated by the OECD, such as the transfer pricing documentation requirements. The BEPS package seeks to counter the exploitation of gaps and mismatches in tax rules by multinational enterprises to artificially shift profit to low or no-tax locations where there is little or no economic activity.

Section 50AAF of the IRO now codifies the arm's length principle and allows for an adjustment of a taxpayer's profit upwards/losses downwards if the taxpayer has entered into transaction(s) with an associated person, and the pricing of such transaction(s) differs from that between independent persons and has created a Hong Kong tax advantage. Section 82A of the IRO stipulates that a person is liable to be assessed to additional tax of the amount of tax undercharged resulting from transfer pricing adjustments, unless it is proved that reasonable efforts have been made to determine the arm's length price for the transaction(s).

LAWS AND REGULATIONS RELATING TO TRANSFER PRICING IN GERMANY

Overview of the German transfer pricing regulations

Under German tax law, there is not one consolidated set of statutory rules on transfer pricing, but several provisions in different legislative acts. The rules on constructive dividends and Section 1 of the Foreign Tax Act (FTA) are the most relevant legal base for transfer pricing which are interpreted and supplemented by various legislative regulations and administrative circulars (including the Administrative Principles on the Transfer of Functions as of 12 August 2008, the Administrative Principles on the Allocation of Profits to Permanent Establishments as of 22 December 2016, the Administrative Principles on Transfer Pricing as of 14 July 2021 and the Administrative Principles 2020 as of 3 December 2020).

German transfer pricing rules and principles cover all sorts of business transactions concluded between German taxpayers and related parties abroad. All related-party transactions, not based on the statutes of association between (direct and indirect) shareholder (or partner) and company (or partnership), are subject to the arm's-length standard, regardless of whether the transactions are income or capital transactions. Examples are the license of intangible such as trademarks, the provision of services and the transfer of assets. In addition, all transactions undertaken between employees at the head office and at a permanent establishment (PE) of the same corporate entity (dealings) are covered.

The definition of a related party includes group companies with direct or indirect shareholdings of at least 25 per cent, family members and relatives as well as any party that is in a position to exert influence on a taxpayer or that has a special interest in the income generated by the taxpayer going beyond a regular business interest.

A peculiarity of the German tax law is that it considers the internationally accepted arm's-length principle where empirical data is available to determine arm's-length prices (the fact-based arm's-length test) and the concept of the prudent and diligent businessman to determine an arm's-length transfer price for intercompany transactions where empirical data is not available (the hypothetical arm's-length test).

Transfer Pricing Documentation Requirements

Resident and non-resident taxpayers, subject to the German transfer pricing regulations, must prepare the following transfer pricing documentation reports: a local file on the taxpayer's intercompany transactions with other related parties and, unless the enterprise's annual revenue has been less than €100 million in the preceding financial year, a master file containing specific group information. Transfer pricing documentation for ordinary business transactions must be submitted within 30 days upon request by the German Tax Authority, typically in the course of a tax audit. Contemporaneous preparation of transfer pricing documentation is not required unless the related party is resident of a country which is on the European Union (EU) blacklist of non-cooperative jurisdictions for tax purposes.

An exception is that extraordinary business transactions (e.g., transfer of assets, conclusion and amendment of long-term contracts) have to be documented, at the latest, within six months after the end of the business year in which the transaction took place; the documentation report has to be submitted within 30 days upon the request.

The documentation requirements also cover permanent establishments which in addition have to prepare an 'auxiliary and ancillary statement' covering its dealings and allocated assets.

Where consolidated group sales revenues amount to €750m or higher, annual country-by-country reporting (CbCR) is required.

Enterprises with intercompany sales of goods of no more than €6m (paid or received) per annum or intercompany provisions of services of no more than €600,000 per annum (paid or received) are exempt from the documentation requirements (de-minimis rule).

Mandatory transfer price adjustment, penalties and late interest

The following penalties and mandatory transfer pricing adjustments apply where a taxpayer fails to comply with the German transfer pricing documentation requirements:

- If the transfer pricing documentation report is not submitted or is 'essentially unusable', German regulations establish the rebuttable presumption that the income of the German entity has been under-reported lowering the burden of proof for tax authorities and requesting by law a mandatory transfer price adjustment at the upper end of the arm's-length range. Further, penalties of at least 5 per cent but not more than 10 per cent of the income adjustment are imposed (minimum amount of €5,000).

- If the transfer pricing documentation report is essentially usable but submitted late, tax authorities may impose late fees or penalties of up to €1m with a minimum penalty of €100 for each late day after the due date. Penalties may be waived if the taxpayer is not responsible (or has only limited responsibility) for the lack of appropriate documentation.

- Separate penalties may be imposed if the taxpayer fails to submit the CbCR at all or on time, or in the event the CbCR is deemed insufficient. Penalties may amount to up to €10,000.

In any case where income adjustments result in an increased tax burden, non-deductible interest will be assessed at a rate of 6 per cent per annum for the period commencing 15 months after the end of the calendar year in which the tax liability arose. The interest rate of 6 per cent per annum has been rendered unconstitutional by the German Constitutional Court with the mandate for the legislator to introduce market rates starting FY 2019; for years before 1 January 2019, the 6 per cent interest rate remains in force. As of July 2022, the interest rate has been reduced retroactively from 1 January 2019 to 0.15% per month (i.e., 1.8% p.a.).

LAWS AND REGULATIONS RELATING TO TRANSFER PRICING IN NETHERLANDS

Transactions between associated enterprises are subject to transfer pricing rules in the Netherlands, which generally follow the OECD Transfer Pricing Guidelines. In relevant part, those rules are included in Article 8b of the Corporate Income Tax Act (which also requires transfer pricing documentation for NL purposes under 8b(3)). A Documentation MasterFile report disclosing transfer pricing documentation for the whole group may be required if the group entities have a consolidated turnover of 50,000,000 (article 29f).

In case the Group has a consolidated turnover of 750,000,000 Euro, and the parent company is located in NL a country by country report as described under article 29(c) is required (article 29(e)).

Furthermore, the Transfer Pricing Decree of 22 April 2018, nr. 2018-6865 provides detailed guidance on several specific intercompany transactions. It should also be noted that the EU has implemented rules (referenced as "DAC6") in the Directive on Administrative Cooperation that apply to all EU Member States, and require mandatory disclosure of certain cross border transactions that involve so-called hard to value intangibles, which are defined in the (OECD) Transfer Pricing Guidelines.