PRC REGULATORY OVERVIEW

Our business operations are subject to the laws, regulations and policies of the PRC and extensive supervision by the Chinese government. The following descriptions set out the relevant PRC laws, regulations and policies we must comply with:

Regulation Relating To Medical Devices

Definition of Medical Devices

In accordance with Regulation on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), the term "medical devices" shall refer to the instruments, equipment, appliances, in vitro diagnostic reagents and calibrators, materials and other similar or relevant articles directly or indirectly used on the human body, including computer software needed.

As advised by our PRC Legal Advisor, the System has been characterized as a stand-alone medical device on the Class II medical device registration certificate issued by the Hunan MPA in 2018 and renewed in 2023. For details of our communications with the Hunan MPA, see "Business—Core Product: Brain Function Information Management Platform Software System—Material Communications with Competent Authorities."

Classification 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》), promulgated by the State Council on January 4, 2000, and effective from April 1, 2000, last amended on February 9, 2021 and came into effect on June 1, 2021, the NMPA shall be responsible for the supervision of medical devices within the territory of the PRC. All relevant departments of the State Council shall be responsible for the supervision of medical devices according to their respective mandate. The NMPA at the county level and above are responsible for the supervision of medical devices within their own administrative jurisdictions. The relevant departments of the local people's governments at the county level and above are responsible for supervising medical devices according to their respective mandates.

Medical devices in the PRC are categorized into three groups based on their degree of risk. Class I medical devices pose a low degree of risk and is safe for routine use while maintain their efficacy. Class II medical devices pose a moderate degree of risk and whose safety and efficacy should be ensured through strict control and administration. Class III medical devices pose a high degree of risk and must be ensured through strict control and administration by special measures to ensure safety and efficacy.

Classification of AI Medical Software Products

Pursuant to Guiding Principles for the Classification of AI-based Medical Software Products (《人工智能醫用軟件產品分類界定指導原則》, the "**Principles**") promulgated by the NMPA and came into effect on July 1, 2021, AI-based medical software refers to standalone software whose medical use is achieved based on the data of a medical device and using AI technologies. The Principles may apply mutatis mutandis to the classification and definition of medical devices containing components of AI software. AI-based medical software with well developed algorithms in medical applications (meaning software whose safety and efficacy has been fully validated) shall be categorized pursuant to the effective Medical Device Catalog (《醫療器械分類目錄》). While the currently effective Medical Device Catalog does not explicitly categorize DTx products as Class I, II or III, a vast majority of software medical devices (apart from a few types with mechanism of actions unrelated to DTx) are classified as either Class II or Class III medical devices. The key factor in judging whether a software product should be regulated as a medical device is its intended purpose. If the subject of software product is medical device data, and the product's core function is the processing, measurement, model calculation, analysis, etc. of medical device data, and the product is used for medical purposes, it falls within the definition of medical device under the Regulations on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), and shall be regulated as such. If the subject of the software product is non-medical device data (such as main complaint of patients or other information, examination and test reports and conclusions), or the product's core function is not to process, measure, perform model calculation or analyze medical device data, or the product is not used for medical purposes, such software product shall not be regulated as a medical device.

Registration and Record-Filing of Medical Devices

According to the Administrative Measures on the Registration and Record-filing of Medical Devices (《醫療器械註冊與備案管理辦法》), promulgated by the SAMR on August 26, 2021 and came into effect on October 1, 2021, the NMPA is responsible for the nationwide administration of medical device registration and record-filing.

In the PRC, record-filing is required for Class I medical devices and registration is required for Class II and Class III medical devices. Record-filing parties of domestic Class I medical devices shall submit record-filing materials to the drug regulatory authorities at cities with municipal districts. Domestic Class II medical devices shall be examined by the drug regulatory authorities of provinces which shall issue the medical device registration certificate upon approval. Domestic Class III medical devices shall be examined by the NMPA which shall issue the medical device registration certificate upon approval.

In accordance with Decree No. 47 of the State Administration for Market Regulation "Administrative Measures on the Registration and Record-filing of Medical Devices" (《醫療器械註冊與備案管理辦法》, "**Decree 47**"), for a Class II or III medical device that has been registered, in the event that there are material changes to the design, raw materials, production process, scope of application and method of use thereof, which might affect the safety and effectiveness of the medical device, the registrant of such medical device shall apply to the original registration authority for modification of registration; in the event of other changes, the registrant shall file the changes for record with the original registration authority within 30 days as of the date of change. According to our PRC Legal Advisor, as of the Latest Practicable Date, Decree 47 is still effective, and the competent authorities had not sought public comments on it according to public searches on Public Consultation System for Legislation.

For an application for modification of registration, the technical review agency under the NMPA shall mainly review the modified part and give review opinions on whether the modified product is safe, effective and of controllable quality. Document on modification of registration of a medical device shall be used together with the original medical device registration certificate, and its expiry date shall be the same as that of the original medical device registration certificate.

The Deep Learning Assisted Decision Making Medical Device Software Review Highlights (《深度學習輔助決策醫療器械軟件審評要點》), promulgated by the Center for Medical Device Evaluation of the NMPA on July 3, 2019, is applicable to the registration declaration of deep-learning assisted decision-making medical device software, including standalone software and software components. It employs a risk-based, full life-cycle management approach to address software technical review requirements. This encompasses aspects such as requirement analysis, data collection, algorithm design, validation and verification, software updates, including requirements for algorithm performance assessment, clinical evaluation, and network and data security.

Potential Reclassification of DTx Medical Devices from Class II to Class III

As of the Latest Practicable Date, there are three recommendations from Chinese regulatory authorities regarding the reclassification of DTx medical devices from Class II to Class III, none of which affects the System. According to the recommendation of the NMPA's First Medical Device Classification Summary of 2023 (《2023年第一次醫療器械產品分類界定結果匯總》, or the "**2023 First Summary**"), software for the assessment and treatment of cognitive impairment that acquires data through magnetic resonance imaging of the brain ("**Brain MRI**") as well as neurological and psychological assessment of patients was recommended for classification as a Class III medical device. In addition, based on the recommendation of the NMPA's Second Medical Device Classification Summary of 2023 (《2023年第二次醫療器械產品分類界定結果匯總》, or the "**2023 Second Summary**"), supplemental depression assessment software used in conjunction with functional near-infrared spectroscopy ("**fNIRS**") should be classified as a Class III medical device.

Lastly, according to the recommendation of the NMPA's Third Medical Device Classification Summary of 2023 (《2023年第三次醫療器械產品分類界定結果匯總》, or the "**2023 Third Summary**"), software that provides intervention measures such as cognitive behavioral therapy, mindfulness therapy and exercise therapy should be classified as a Class III medical device.

As advised by the PRC Legal Advisor, the 2023 First Summary, 2023 Second Summary and 2023 Third Summary represent advice from the relevant experts nationwide and are not the binding regulations on medical device classification, as of the Latest Practicable Date. As advised by our PRC Legal Advisor, as of the Latest Practicable Date, in accordance with applicable PRC laws and regulations and taking into account the recommendations of the 2023 First Summary, 2023 Second Summary and 2023 Third Summary, our Directors are of the view that, with the exception of the Depression Treatment Software, the likelihood our products, namely the System, the Basic Cognitive Ability Testing Software, Cognitive Ability Supplemental Screening and Assessment Software, Dyslexia Supplemental Screening and Assessment Software, Covid-19 Induced Cognitive Impairment Assessment and Recovery Training Software, Attention Deficit Hyperactivity Disorder Assessment and Treatment Software as well as Quantitative Cognitive Assessment Software for Depression, will be reclassified from Class II into Class III is relatively low. In contrast, our Depression Treatment Software has a relatively high possibility of being reclassified from Class II into Class III. We do not expect a significant change in market demand for the Depression Treatment Software as a result of such reclassification into Class III. However, such reclassification is expected to raise the entry barrier for the reclassified product because evidence-based clinical evaluation would be required to obtain regulatory approval as a Class III medical device. This leads to competitive advantages for us as we already possess the resources and experience to carry out evidence-based clinical evaluation for cognitive DTx products, which many competitors do not, according to Frost & Sullivan.

According to the Regulation on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), Class III medical devices are those devices that pose such a high degree of risk to users that the safety and effectiveness of the medical device can only be ensured through strict control and supervision of special measures. In line with this view, the Administrative Measures on the Registration and Record-filing of Medical Devices (《醫療器械註冊與備案管理辦法》) requires Class III medical devices to be examined by the NMPA, which shall issue the medical device registration certificate only after examination and approval. Similarly, according to the Measures for the Supervision and Administration of Medical Devices Manufacture (《醫療器械生產監督管理辦法》), those who intend to engage in the manufacture of Class III medical devices must first be approved by the drug regulatory authority of a province where they are located and obtain a medical device manufacturing permit in accordance with law.

Digital Health Guiding Principles System

On March 7, 2022, the Center for Medical Device Evaluation of NMPA issued Guiding Principles for the Technical Review of Medical Device Software Registration (《醫療器械軟件註冊審查指導原則》) (the "**Software Guiding Principles**"), Guiding Principles for the Technical Review of Medical Device Cybersecurity Registration (《醫療器械網路安全註冊審查指導原則》) (the "**Cybersecurity Guiding Principles**") and Guiding Principles for the Technical Review of AI Medical Device Registration (《人工智能醫療器械註冊審查指導原則》) (the "**AI Guiding Principles**"). The abovementioned three guiding principles are integral components of the digital health guiding principles system.

In terms of the interrelationships among the abovementioned guiding principles, (i) Software Guiding Principles is the foundational guiding principle of the digital health guiding principle system and also serves as the general guiding principle for medical device software, which aims to provide guidance to applicants for medical device software registration on the standardized life cycle processes and the preparation of registration application materials for medical device software; (ii) Cybersecurity Guiding Principles is the general guiding principle

for medical device cybersecurity, which aims to provide direction to applicants for the standardization of the life cycle processes of medical device cybersecurity and the preparation of registration application materials for medical device cybersecurity; (iii) and AI Guiding Principles is the general guiding principle for AI medical device, which aims to provide instruction to applicants in establishing the life cycle processes of AI-based medical devices and the preparation of registration application materials for such devices.

In accordance with the Software Guiding Principles, a standalone software shall comply with the requirements of medical device registration declaration documents and pay special attention to the following requirements: (i) the product name shall conform to the generic naming conventions for standalone software that disclose details related to input data, core functions and intended use; (ii) the registrant shall submit self-developed software research report, external software environment assessment report (if applicable), and GB/T 25000.51 self-testing report; (iii) the technical requirements for standalone software products shall clearly specify the software's name, model specifications, release version and version naming conventions; and (iv) the user manual for the medical device shall comply with relevant laws, regulatory documents, national standards and industry standards.

In accordance with Cybersecurity Guiding Principles, the registration declaration materials shall comply with the requirements of medical device registration declaration documents, Software Guiding Principles and additionally pay special attention to requirements of (i) separately submitting a research report on the network security of the self-developed software; and (ii) include within the manual network security instructions and usage guidelines.

In accordance with AI Guiding Principles, the registration declaration materials shall comply with the requirements of medical device registration declaration documents, Software Guiding Principles, Cybersecurity Guiding Principles and also pay special attention to the following requirements: (i) AI standalone software shall conform to generic naming conventions that disclose details such as input data, target diseases and intended use; (ii) for novel products with medium or high levels of software security, the software research materials and algorithm-based reports for each AI algorithm or algorithm combination shall be submitted; (iii) for products with a high level of software security and intended for use by patients or in primary healthcare institutions, a separate user training plan shall be provided in principle; (iv) if the product's technical requirements include performance metrics based on evaluation database testing, the basic information of the evaluation database must be specified; (v) for decision-support products, the user manual must provide a clear summary of the algorithm performance evaluation for the AI algorithm.

The Guidelines for the Naming of Common Names for Medical Software (《醫用軟件通用名稱命名指導原則》), promulgated by the NMPA on July 12, 2021, directs the formulation of generic names for medical software products. It is applicable to standalone medical software medical devices, excluding software components (non-independent software).

The Medical Device Software — Software Life Cycle Processes (《醫療器械軟件–軟件生存周期過程》), promulgated by the NMPA on September 27, 2020 and came into effect on September 1, 2021, is applicable to the development and maintenance of medical device software, encompassing software that is a medical device itself or that constitutes embedded or integral parts of the final medical devices. It provides the expected processes for software that can be executed on a processor or run through other software (such as interpreters) operating on a processor.

The AI Medical Devices — Quality Requirements and Evaluation (《人工智能醫療器械–質量要求和評價》), promulgated by the NMPA on July 1, 2022 and came into effect on July 1, 2023, includes provisions on (i) terminology for the quality assessment of artificial intelligence medical devices; (ii) proposing general quality requirements and evaluation methods for datasets; (iii) introducing quality requirements and evaluation methods for data annotation processes; (iv) proposing general requirements and evaluation methods for the traceability of AI medical devices; (v) standardizing safety requirements and evaluation methods for AI algorithms used in medical devices; (vi) specifying environmental conditions for the operation of AI medical devices; (vii) strengthening the ability to protect subjects' privacy; and (viii) achieving ethical requirements for AI at a technical level, and safeguard human rights.

Good Clinical Trial Practice for Medical Devices

The Good Clinical Trial Practice for Medical Device (《醫療器械臨床試驗質量管理規范》), which was promulgated jointly by the NMPA and the NHC on March 24, 2022 and came into effect on May 1, 2022, governs the entire medical device clinical trial process, including protocol design, implementation, monitoring, auditing and inspection, as well as data collection, recording, storage, analysis, summary and reporting. Clinical trials of medical devices shall be carried out in clinical trial institutions and only for medical devices that meet the corresponding conditions and have gone through requisite record-filing processes. Clinical trials of medical devices are required to be approved by an ethics committee. For Class III medical devices, the approval of the NMPA is also required, and the clinical trial shall be carried out in a qualified Class III Grade A medical institution.

The sponsor of a medical device clinical trial shall establish a quality management system covering the whole process of the clinical trial of medical device to ensure the clinical trial complies with relevant laws and regulations and protect the rights and interests and safety of subjects.

Research and Clinical Evaluation of Medical Devices

In accordance with Regulation on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) and Administrative Measures on the Registration and Record-filing of Medical Devices (《醫療器械註冊與備案管理辦法》),the research and development and experiments of medical devices shall be in compliance with the relevant laws, regulations and mandatory standards of China.

According to the Administrative Measures on the Registration and Record-filing of Medical Devices (《醫療器械註冊與備案管理辦法》), promulgated by the SAMR on August 26, 2021 and came into effect on October 1, 2021, clinical evaluation shall be conducted for the registration or record-filing of medical devices, and clinical evaluation materials shall be submitted when applying for the registration of medical devices. 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. Clinical trials shall be carried out for medical devices for which the existing clinical literature materials and clinical data are insufficient to confirm their safety and effectiveness in the clinical evaluation of medical devices. Clinical trials for medical devices shall be conducted in clinical trial institutions for medical devices that meet the corresponding conditions and have been filed for record as required by the good clinical practice (GCP) for medical devices.

However, clinical evaluation of a medical device may be exempted when: (1) the medical device has a clear mechanism of action, a finalized design and a mature production process, and the medical devices of the same type have been used in clinical use for years without record of serious adverse events, and the new medical device does not deviate from the general purpose of the medical device with an established clinical record; or (2) if the safety and efficacy of the medical device can be proved through non-clinical evaluation. Where clinical evaluation is exempted, a submission of clinical evaluation materials is not required. The catalogue of medical devices exempted from clinical evaluation shall be formulated, adjusted and published by the NMPA.

The Guidelines for the Clinical Evaluation Techniques for Medical Devices (《醫療器械臨床評價技術指導原則》), promulgated by the NMPA on September 18, 2021, primarily introduces the concepts of clinical assessment and clinical evidence, elucidating the relationships among clinical trials, clinical data, clinical assessment, and clinical evidence. It guides applicants on how to conduct clinical evaluations, compile associated documentation, and incorporate them as integral components of the conformity assessment, as well as aims to instruct regulatory authorities on how to assess the clinical evidence submitted by applicants.

The Hunan MPA, being the relevant authority that reviewed and approved the medical device registration applications of the System, further clarified the requirements for adding new indications under development to existing medical device registration certificates in a July 2023 consultation (the "**2023 Consultation**") and stated that where clinical literature materials and clinical data of medical devices of the same kind are not available to evaluate the safety and efficacy of a medical device for certain indications, the applicant must complete clinical trials on those indications before applying for modification of the medical device registration certificate to include such indications.

Production 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》) and the Measures on the Supervision and Administration of Medical Devices Production (《醫療器械生產監督管理辦法》), which was promulgated by the SAMR on and effective from July 20, 2004, latest amended on March 10, 2022 and came into effect on May 1, 2022, in order to engage in the production of medical devices, an entity shall meet the following conditions: (1) having the production site, environmental conditions, production equipment and professional technicians that meet the needs of the medical devices to be produced; (2) having the facility or full-time personnel and testing equipment capable of testing the quality of the medical devices to be produced; (3) having a system of internal control that can ensure the quality of medical devices; (4) having the after-sale service capabilities that meet the needs of the medical devices to be produced; and (5) having the capability to meet the requirements as prescribed in the documents on product research and development and production techniques.

To engage in the production of Class II and Class III medical devices, an entity shall apply for a manufacturing licensing to the drug regulatory department of the people's government of the province where it is located and submit the relevant materials and the registration certificate of the medical devices to be produced. The manufacturing permit for medical devices is valid for five years. When it is necessary to renew the permit upon its expiration, the formalities for renewal shall be completed in accordance with the relevant laws on administrative licensing.

In accordance with Appendix to Good Manufacturing Practices for Standalone Software as Medical Devices (《醫療器械生產質量管理規範附錄-獨立軟件》, the "**Appendix**") the manufacturing quality management system for standalone software as medical devices shall meet the requirements, including but not limited to personnel, equipment, design development, procurement, manufacturing management, quality control, sales and after-sales service, of the Good Manufacturing Practice for Medical Devices (《醫療器械生產質量管理規範》) and the Appendix.

The Medical Devices — Application of Usability Engineering to Medical Device (《醫療器械可用性工程對醫療器械的應用》), promulgated by the NMPA on January 26, 2016 and came into effect on January 1, 2017, delineates the manufacturer's procedural framework for the analysis, determination, design, validation, and confirmation of usability that has a direct bearing on the safety of medical devices. The usability engineering process is deployed to assess and mitigate risks associated with normal usage, encompassing both correct and incorrect utilization. It serves the purpose of identifying, though not actively addressing, risks related to abnormal usage.

The Medical Devices — Application of Risk Management to Medical Device (《醫療器械–風險管理對醫療器械的應用》), promulgated by the SAMR on October 12, 2022 and came into effect on November 1, 2023, prescribes the terminology, principles, and procedures governing the risk management of medical devices, encompassing both medical device

software and *in vitro* diagnostic medical devices. The delineated processes within this document are structured to aid manufacturers of medical devices in the identification of hazards associated with such devices, the estimation and assessment of pertinent risks, the implementation of risk controls, and the ongoing monitoring of the efficacy of these controls.

Operation 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》) and 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 July 30, 2014 and effective from October 1, 2014, latest amended on March 10, 2022 and came into effect on May 1, 2022, a business operator shall file for record with the drug regulatory department of the government for the business operation of Class II medical devices and apply for operation licensing for the business operation of Class III medical devices. Furthermore, no business operator or using entity of medical devices may operate or use medical devices that have not been registered or filed for record in accordance with the law, or medical devices without conformity certificates, or expired, invalidated or obsolete. The valid period of the operating permit for medical devices is five years. Where it is necessary to renew the permit upon its expiration, the formalities for renewal shall be observed in accordance with the provisions of relevant laws on administrative licensing.

Post-marketing Responsibility about Medical Devices

In accordance with Regulation on the Supervision and Administration of Medical Devices (《醫療器械監督管理條例》), a registrant or record-filing party of medical devices shall establish a monitoring system for adverse events of medical devices (醫療器械不良事件監測體系), be equipped with a monitoring body and personnel for adverse events suitable for its products, take the initiative to monitor adverse events of its products, and report the information on investigation, analysis, evaluation and product risk control to the technical monitoring agency for adverse events of medical devices in accordance with the provisions of the drug regulatory department under the State Council. The manufacturers or business operators and using entities of medical devices shall assist the registrant or record-filing party of medical devices in monitoring adverse events of the medical devices produced, operated or used by them; if any adverse event of medical devices or suspicious adverse event is found, it shall be reported to the technical monitoring agency for adverse events of medical devices in accordance with the provisions of the drug regulatory department under the State Council.

In accordance with Administrative Measures on the Registration and Record-filing of Medical Devices (《醫療器械註冊與備案管理辦法》), a registrant of medical devices shall take the initiative to carry out post-marketing research, further confirm the safety, effectiveness and quality controllability of the medical devices and strengthen the continuous management of the medical devices on the market.

Price Controls

Pursuant to the Notice of Issuing the 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》), which was jointly promulgated by the National Development and Reform Commission (the "**NDRC**"), the Ministry of Health of the PRC and the Ministry of Human Resources and Social Security of the PRC and came into effect 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, more reasonable pricing can be achieved by measures such as limiting price differentiation of the product in circulation and publishing market price information.

Advertisements of Medical Devices

Pursuant to the Interim Administrative Measures for the Review of Advertisements for Drugs, Medical Devices, Health Food and Formula Food for Special Medical Purposes (《藥品、醫療器械、保健食品、特殊醫學用途配方食品廣告審查管理暫行辦法》), which was promulgated by the SAMR on December 24, 2019 and came into effect on March 1, 2020, advertisements for medical devices shall not be released without being reviewed by the relevant administration for market regulation and drug administration of a province or other authorized administrative authorities. In addition, advertisers shall be responsible for the veracity and legitimacy of the contents of advertisements for medical devices.

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 involves the name, scope of application, functional mechanism or structure or composition, etc. of the medical device, the scopes of the registration certificate or filing certificate, or registered or filed product instruction shall not be exceeded.

All advertisements for medical devices recommended for personal use must prominently display a disclaimer stating, "Please read the product instructions carefully or purchase and use the product as directed by a health care professional." If the product registration certificate of the medical device stipulates any contraindications or precautions, the advertisement shall include a disclaimer in a prominent position stating, "for contraindications and precautions, please refer to the instructions for details."

Regulation Relating to Cybersecurity and Artificial Intelligence

AI Algorithms and Deep Synthesis Technology

According to the "Recommended Algorithm Management Provisions for Internet Information Services" (《互聯網信息服務算法推薦管理規定》) and "Guiding Opinions on Strengthening the Comprehensive Governance of Algorithms in Internet Information Services" (《關於加強互聯網信息服務算法綜合治理的指導意見》), algorithm-based recommendation

service providers are responsible for the security of their algorithms. They must have a management system that includes measures for auditing, ethical review, fraud prevention, security assessment and data security emergency response. They must also have dedicated personnel and technical measures. Service providers should regularly review and evaluate their algorithmic mechanisms, models, data and results, and notify users when an algorithm-based recommendation service is active and provide effective channels for user complaints and reports. Service providers should also label content generated or edited by deep synthesis technology in accordance with the Administrative Provisions on Deep Synthesis in Internet Information Services (《互聯網信息服務深度合成管理規定》).

Data Collection

According to the Data Security Law (《數據安全法》), data processors must collect data in a legal and lawful manner and use it only for the purposes and within the limits established by law or agreed with the user. They may not obtain data by illegal means. The Personal Data Protection Law (《個人信息保護法》) outlines the lawful means and basis for processing personal data, which include obtaining the individual's consent, fulfilling a contract, complying with a legal obligation, responding to public health emergencies, conducting news reporting for the public interest, and protecting the life, health or property safety of individuals under emergency circumstances. Before collecting personal information, processors must inform individuals of various matters, such as the name and contact information of the processor, the purpose and method of processing the information, and individuals' rights under the Personal Information Protection Act. This must be done through a stand-alone notice in clear and easily understandable language. Individuals must be notified of any changes to this notice.

Data Integrity and Accuracy

According to the Cybersecurity Law (《網絡安全法》), a person who constructs, operates, or provides services through a network must take technical and other necessary measures to ensure cybersecurity and operational stability, effectively respond to cybersecurity incidents, prevent cybercrimes and unlawful activities, and maintain the integrity, confidentiality, and usability of online data, in accordance with the provisions of laws, administrative regulations, and mandatory requirements of national standards.

Furthermore, according to the Personal Information Protection Law, handling of personal information must ensure the quality of personal information and avoid adverse effects on the rights and interests of individuals due to inaccurate and incomplete personal information.

Entrusted Data Processing

The Personal Information Protection Law provides that a trustee entrusted with the processing of personal information shall, in accordance with relevant laws and administrative regulations, take necessary measures to ensure the security of personal information and assist the personal information processor in fulfilling its obligations under the law.

When a personal information processor entrusts personal information to another party for processing, they must agree on the purpose, time period, processing method, type of personal information, protection measures, and the rights and obligations of both parties. The personal information processor must also supervise the other party's activities in processing personal information.

Co-processing of Personal Information

According to the Personal Information Protection Law, when two or more personal information processors jointly handle personal information, they must agree on their respective rights and obligations. However, this agreement does not affect an individual's right to demand the exercise of his or her rights under the Personal Information Protection Law. If a personal information processor jointly handles personal information and violates an individual's rights, they shall be jointly and severally liable according to law.

Provision of Information to Other Processors

In accordance with the Personal Information Protection Law, when a personal information processor provides personal information to other processors, it shall inform the individual of the name and contact information of the recipient, purposes and methods of processing, and categories of personal information, and obtain the individual's separate consent or have other lawful grounds.

Monetization of Public and User-derived Data

Pursuant to the Provisions on the Administration of Medical Records of Medical Institutions (2013 Edition) (《醫療機構病歷管理規定(2013年版)》), which was jointly promulgated by the National Health and Family Planning Commission (the "**NHFPC**") and the National Administration of Traditional Chinese Medicine (the "**NATCM**") and came into effect on January 1, 2014, medical institutions and their staff shall strictly protect the privacy of patients and are prohibited from disclosing any of the patient's medical records for purposes other than medical treatment, teaching or research.

In addition, pursuant to the Administrative Measures for Population Health Information (for Trial Implementation) (《人口健康信息管理辦法(試行)》) promulgated by the NHFPC on and effective from 5 May 2014, Population Health Information shall be used for the purpose of improving the quality of medical research, scientific decision-making and public services. Any confidential information and personal privacy information shall not be provided to other processors.

Furthermore, pursuant to the Personal Information Protection Law (《個人信息保護法》) which came into effect on November 1, 2021, individuals shall be informed if their personal information is used for direct or indirect monetization (such as improving products and services, researching and developing new products and providing personal information to other processors). In addition, the provision of personal information to other processors requires the individuals' separate consent.

According to our data security consultant, as of October 17, 2023, we are not involved in the unauthorized disclosure of patient data for any purpose other than medical, educational, or research purposes, nor are we involved in the sale or trade of patient data. We have informed our users and obtained their consent through our privacy policy when we use DTx data to improve our products and services and to develop new products. We therefore comply with the relevant regulatory requirements described above.

Proposed Draft Cybersecurity Regulations

On September 24, 2024, the State Council promulgated the Cyber Data Security Administrative Regulations （《網絡數據安全管理條例》） (the "Cyber Data Security Regulation"), which will take effect on January 1, 2025.

The Cyber Data Security Regulation covers a wide range of cybersecurity issues. Most of the regulatory details under it have already been embodied in the Cybersecurity Law of the PRC (《中華人民共和國網絡安全法》), the Data Security Law of the PRC (《中華人民共和國數據安全法》) and the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》). New requirements proposed by the Cyber Data Security Regulation primarily deal with filing and security assessment.

On June 10, 2021, the SCNPC promulgated the Data Security Law of the PRC (《中華人民共和國數據安全法》), which took effect on September 1, 2021. The Data Security Law sets forth the regulatory framework, the responsibilities of relevant governmental authorities in regulating data security and the duties of data processors. On August 20, 2021, the SCNPC promulgated the Personal Information Protection Law of the PRC (《中華人民共和國個人信息保護法》), which took effect on November 1, 2021 and aims to protect personal information rights and interests, regulate the processing of personal information, ensure the orderly and free flow of personal information and promote reasonable use of personal information.

According to our data security consultant, we have adopted comprehensive data compliance measures covering multiple aspects and processes of our business and services in accordance with the relevant requirements of cybersecurity and data compliance laws and regulations within the PRC. As of the Latest Practicable Date, we are in compliance with all material aspects of the proposed requirements under the Cyber Data Security Regulation. Therefore, subject to material changes in the Cyber Data Security Regulation, the implementation of the Cyber Data Security Regulation upon its final promulgation is unlikely to have a material adverse impact on our business operations or the proposed [**REDACTED**].

On 28 December 2021, the CAC promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the "**Cybersecurity Review Measures**"), which came into effect on February 15, 2022. According to the Cybersecurity Review Measures, there are two mechanisms to trigger cybersecurity review:

(a) Voluntary declarations by enterprises: any (i) critical information infrastructure operators that intend to purchase network products and services; and (ii) a network platform operator possessing the personal information of more than one million people and intends to be listed overseas, may submit for voluntary cybersecurity review.

(b) Regulatory authority initiated review: If the relevant regulatory authority set up under the Cybersecurity Review Measures believes that any network product or service or data processing activity affects or is likely to affect national security, the Office of Cybersecurity Review shall report such circumstance to the Office of the Central Cyberspace Affairs Commission for approval, and conduct a review upon approval. With respect to the review of voluntary declarations by enterprises, we have consulted with the China Cybersecurity Review Technology and Certification Center (the "**CCRC**"), the organization commissioned by the Office of Cybersecurity Review of CAC to undertake specific cybersecurity reviews, regarding its proposed [**REDACTED**], which confirmed that we do not need to take the initiative to report to the regulatory authorities for cybersecurity review.

Whether a cybersecurity review will be initiated by the regulatory authorities depends on the interpretation of Article 2 of the Cybersecurity Review Measures, specifically the impact or potential impact of the data processing activities of network platform operators on national security. National security is defined as the condition in which the state power, sovereignty, unity, territorial integrity, people's welfare, sustainable economic and social development and other vital state interests are not threatened internally or externally. The Cybersecurity Review Measures also outline various national security risk factors in the area of cybersecurity, including:

(i) The risk that the use of products and services could result in the unlawful control of, disruption to, or destruction of critical information infrastructure ("**CII**");

(ii) The harm to the business continuity of CII due to disruptions in the delivery of products and services;

(iii) The security, openness, transparency, and diversity of sources of products and services, the reliability of supply channels and the risk of supply disruptions due to political, diplomatic and trade factors;

(iv) Product and service providers' compliance with laws, administrative regulations and departmental rules of the PRC;

(v) The risk that core data, important data or large amounts of personal information will be stolen, leaked, corrupted or illegally used or illegally exported;

(vi) The risk that CII, core data, important data or large amounts of personal information will be influenced, controlled or maliciously used by foreign governments as a result of the listing; and

(vii) Other factors that may affect the security of CII, cybersecurity and data security.

As of the Latest Practicable Date, we had not received any notice from any competent authority within the industry or any regulatory department requiring us to perform a cybersecurity review.

According to our data security consultant, although the possibility that our data processing activities have an impact on national security cannot be completely ruled out, it is unlikely for the regulatory authorities to initiate a cybersecurity review against us given the type, nature, purpose, scale and other characteristics of our business operations. Therefore the Cybersecurity Review Measures is unlikely to have a material adverse impact on our business operations or the proposed [**REDACTED**].

Laws and Regulations on Bribery and Corruption

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

In accordance with the Criminal Law (《中華人民共和國刑法》), whoever gives any property to a staff member of a company, enterprise or other entity for any improper benefit, if the amount is relatively huge, shall be sentenced to fixed-term imprisonment of not more than 3 years or criminal detention and shall be fined; if the amount is huge, he shall be sentenced to fixed-term imprisonment from 3 to 10 years and shall be fined. Where any entity commits a crime as provided for in the preceding paragraph, it shall be fined, and its person directly in charge and other directly liable persons shall be penalized according to the provision of the above. In accordance with the Regulations on the Establishment of Adverse Records with Respect to Commercial Briberies in the Medicine Purchase and Sales Industry (《關於建立醫藥購銷領域商業賄賂不良記錄的規定》), where a manufacturer of drugs, medical devices and medical disposables, an enterprise, an agency or an individual offers staff of a medical institution any items of value or other benefits, the enterprise should be listed in the adverse records with respect to commercial bribery if relevant circumstances exist.

In accordance with the Notice on Promulgation of the Key Points for the Work of Correcting Malpractice in the Medicine Purchase and Sales Field and Medical Services in 2023 (《關於印發2023年糾正醫藥購銷領域和醫療服務中不正之風工作要點的通知》), it demands (i) rectifying the problems of malpractice in industrial organizations, especially the disguised apportionment in the name of donation, academic activities, holding or participation in conferences, etc., providing platforms for illegal tunneling, and illegal receipt of donations and funding; (ii) rectifying the malpractice in the purchase and sales of medical products, especially giving rebates to the practitioners of medical institutions, and tunneling to relevant institutions in the guise of various forms.

REGULATION RELATING TO PRODUCT QUALITY AND PRODUCTION SAFETY

Product Quality

The Product Quality Law of the PRC (《中華人民共和國產品質量法》), as amended by the Standing Committee of the National People's Congress (the "**SCNPC**") and effective as of December 29, 2018, applies to all production and sale activities in the PRC. Pursuant to the Product Quality Law of the PRC, products offered for sale must satisfy relevant quality and safety standards. Violations of state or industrial standards for health and safety and any other related violations may result in civil liabilities and administrative penalties, such as compensation for damages, fines, suspension or shutdown of business, as well as confiscation of products illegally produced and sold and the proceeds from such sales. Severe violations may subject the responsible individual or enterprise to criminal liabilities. Where a defective product causes physical injury to a person or damage to another person's property, the victim may claim compensation from the manufacturer or the seller of the product. Where the responsibility for product defects lies with the manufacturer, the seller, after compensating the victim, is entitled to recover such compensation from the manufacturer, and vice versa.

Pursuant to the PRC Civil Code (Part VII Liability for Tort) (《中華人民共和國民法典》(第七編侵權責任)) which was promulgated by the National People's Congress (the "**NPC**") on May 28, 2020 and came into effect on January 1, 2021, a patient may make claims against a medical institution or manufacturer of medical devices for any damage arising from a medical device defect. For any claim made by a patient, the medical institution is entitled to make claims against the manufacturer of medical devices after the settlement of the compensation payable to the patient.

Production Safety

Pursuant to the Production Safety Law of the PRC (《中華人民共和國安全生產法》), promulgated by the SCNPC on June 29, 2002, latest amended by on June 10, 2021 and came into effect on September 1, 2021, the market entities shall (1) comply with this law and other laws and regulations on safety production, strengthen the management of safety production, enhance accountability for safe production for all employees and strengthen rule-makings on safety production; (2) increase the investment and guarantee of safety production funds, materials, technologies, and personnel, improve safety production conditions, and boost safety

production standardization and informatization; (3) establish a dual prevention mechanism for safety risk classification and control, and for the investigation and treatment of hidden dangers, and improve the risk prevention and resolution mechanism to improve production safety standards and ensure production safety. Any entity that fails to provide required production safety conditions is prohibited from engaging in production activities.

Regulation Relating To Foreign Investment

The establishment, operation and management of corporate entities in the PRC are governed by the Company Law of PRC (《中華人民共和國公司法》), or the Company Law, which was promulgated by the SCNPC on December 29, 1993, latest amended on December 29, 2023 and became effective on July 1, 2024. A foreign-invested company is also subject to the Company Law unless otherwise provided by the foreign investment laws.

On March 15, 2019, the NPC promulgated the Foreign Investment Law of the PRC (《中華人民共和國外商投資法》), or the Foreign Investment Law, which became effective on January 1, 2020 and replaced the major former laws and regulations governing foreign investment in the PRC. Pursuant to the Foreign Investment Law, "foreign investments" refer to investment activities conducted by foreign investors directly or indirectly in the PRC.

The Foreign Investment Law of the PRC and its implementing rules created a system of pre-entry national treatment and a negative list with respect to foreign investment administration. The pre-entry national treatment refers to granting to foreign investors and their investments, in the stage of investment access, the treatment no less favorable than that granted to domestic investors and their investments. The negative list refers to special administrative measures for access of foreign investment in specific fields as stipulated by the State. Foreign investors shall not invest in the prohibited industries, and must satisfy certain conditions stipulated in the negative list for investment in the restricted industries. The current industry entry clearance requirements governing investment activities in the PRC by foreign investors are set out mainly in the Special Administrative Measures (Negative List) for Foreign Investment Access (2021 version) (《外商投資准入特別管理措施(負面清單)(2021年版)》) and the Encouraged Industry Catalog for Foreign Investment (2022 version) (《鼓勵外商投資產業目錄(2022年版)》). Industries not listed in these two categories are generally deemed "permitted" for foreign investment unless otherwise restricted by other PRC laws.

On December 30, 2019, the MOFCOM and the SAMR jointly promulgated the Measures for Information Reporting on Foreign Investment (《外商投資信息報告辦法》), effective on January 1, 2020, pursuant to which, where a foreign investor directly or indirectly carries out investment activities in China, the foreign investor or the foreign-invested enterprise shall submit the investment related information to the competent commerce authority through the enterprise registration system and the national enterprise credit information publicity system for further handling.

Regulations Relating To The Merger And Acquisition Of Domestic Enterprises By Foreign Investors And Overseas Listings

According to the Provisions on Merger and Acquisition of Domestic Enterprises by Foreign Investors (《關於外國投資者併購境內企業的規定》) (the "**M&A Rules**") which were jointly promulgated by the MOFCOM, the State Administration of Foreign Exchange (the "**SAFE**") and four other ministries on August 8, 2006, took effect on September 8, 2006 and amended on June 22, 2009, "mergers and acquisitions of domestic enterprises by foreign investors" refers to: (1) a foreign investor converting a non-foreign invested enterprise (domestic company) to a foreign invested enterprise by purchasing the equity interest from the shareholder of such domestic company or subscribing for the increased capital of the domestic company (the "**Equity Merger and Acquisition**"); or (2) a foreign investor establishing a foreign invested enterprise to purchase the assets from a domestic enterprise by agreement and operates the assets therefrom; or (3) a foreign investor purchasing the assets of a domestic enterprise by agreement and uses these assets to establish a foreign invested enterprise for the purpose of operating such assets ((2) and (3) collectively as the "**Assets Merger and Acquisition**").

The M&A Rules provides that mergers and acquisitions of domestic enterprises by foreign investors shall be subject to the approval of the MOFCOM or its delegates at provincial level. For instance, the approval from MOFCOM shall be obtained in circumstances where overseas companies established or controlled by PRC enterprises or residents acquire affiliated domestic companies. Any circumvention of the rules including through the domestic re-investment of a foreign invested enterprise is not allowed.

Regulation Relating To Overseas Listing

The CSRC promulgated Trial Administrative Measures of the Overseas Securities Offering and Listing by Domestic Companies (《境內企業境外發行證券和上市管理試行辦法》) (the "**Overseas Listing Trial Measure**s") and five relevant guidelines on February 17, 2023, which has become effective on March 31, 2023. The Overseas Listing Trial Measures regulates both direct and indirect overseas offering and listing by PRC domestic companies' by adopting a filing-based regulatory regime.

According to the Overseas Listing Trial Measures, PRC domestic companies that seek to offer and list securities in overseas markets, either in direct or indirect means, are required to complete the filing procedure with the CSRC and report relevant information. The Overseas Listing Trial Measures provides that no overseas offering and listing shall be made when: (1) such securities offering and listing is explicitly prohibited by provisions in the laws, administrative regulations and relevant state rules; (2) the intended securities offering and listing may endanger national security as reviewed and determined by competent authorities under the State Council in accordance with the laws; (3) the domestic company intending to make the securities offering and listing, its controlling shareholder or its actual controller, have committed relevant crimes such as corruption, bribery, embezzlement, misappropriation of property or undermining the order of the socialist market economy during the past three years;

(4) the domestic company intending to make the securities offering and listing is currently under investigation for suspected criminal offenses or alleged serious violations of laws and regulations, and no conclusion has yet been made thereof; or (5) there are material ownership disputes over equity held by the domestic company's controlling shareholder and/or by other shareholder controlled by the controlling shareholder and/or the actual controller.

The Overseas Listing Trial Measures also provides that if the issuer meets both of the following criteria, the overseas securities offering and listing conducted by such issuer will be deemed as indirect overseas offering subject to the filing procedure set forth under the Overseas Listing Trial Measures: (1) 50% or more of the issuer's operating revenue, total profit, total assets or net assets as documented in its audited consolidated financial statements for the most recent fiscal year is accounted for by domestic companies; and (2) the issuer conducts a substantial part of its business activities within Mainland China, or its principal place of business are located in Mainland China, or the senior managers in charge of its business operations and management are mostly Chinese citizens or domiciled in Mainland China. Where an issuer applies for an initial public offering with the competent overseas regulators, such issuer must file with the CSRC within three business days after such application is submitted to relevant overseas authorities. The Overseas Listing Trial Measures also requires subsequent reports to be filed with the CSRC on material events, such as change of control or voluntary or forced delisting of issuer who have completed overseas offerings and listings.

Regulation Relating To Intellectual Property Rights

Patent

The Patent Law of the PRC (《中華人民共和國專利法》) (the "**Patent Law**") has been further amended by the SCNPC on October 17, 2020 and came into effect on June 1, 2021. According to the current Patent Law, when the invention or utility model patent is granted, unless otherwise stipulated in the Patent Law, without the approval of the patent owner, no entity or person shall implement the relevant patent, that is, manufacture, use, offer to sell, sell or import the patented products for business purpose, or use the patented method and use, offer to sell, sell or import the products directly obtained with the patented method. Implementing the patent without the approval of the patent owner constitutes the infringement of patent rights. Any dispute in connection with this shall be resolved by the relevant parties through negotiation. If the relevant parties refuse to negotiate or the negotiation fails, the patent owner or the relevant stakeholders may file a lawsuit in the people's court or turn to the patent administration authorities for handling.

Copyright

Copyright in the PRC, including copyrighted software, is principally protected under the Copyright Law of the PRC (《中華人民共和國著作權法》) and related rules and regulations. Under the Copyright Law of the PRC, the term of protection for copyrighted software is 50 years. On November 11, 2020, the SCNPC promulgated the newly amended Copyright Law, or the New Copyright Law, which took effect on June 1, 2021. The New Copyright Law increased the cost of infringement violations and expanded its protection coverage. The Regulation on the Protection of the Right to Information Network Communication (《信息網絡傳播權保護條例》), which was latest amended on January 30, 2013, provides specific rules on fair use, statutory license, and a safe harbor for use of copyrights and copyright management technology and specifies the liabilities of various entities for violations, including copyright holders, libraries and Internet service providers. In order to further implement the Regulations on the Protection of Computer Software (《計算機軟件保護條例》) promulgated by the State Council on June 4, 1991, lastly amended on January 30, 2013 and came into effect on March 1, 2013, the State Copyright Bureau issued the Registration of Computer Software Copyright Procedures (《計算機軟件著作權登記辦法》) on February 20, 2002, which applies to software copyright registration, license contract registration and transfer contract registration with respect to software copyright.

Trademark

Registered trademarks are protected under the Trademark Law of the PRC (《中華人民共和國商標法》), promulgated by the SCNPC on April 23, 2019 and effective on November 1, 2019, and related rules and regulations. Trademarks are registered with the State Intellectual Property Office, formerly the Trademark Office of the SAIC. Where registration is sought for a trademark that is identical or similar to another trademark that has already been registered or given preliminary examination and approval for use in the same or similar category of commodities or services, the application for registration of this trademark may be rejected. Trademark registrations are effective for a renewable ten-year period unless otherwise revoked.

Domain Name

Domain names are protected under the Administrative Measures on Internet Domain Names (《互聯網域名管理辦法》) promulgated by the MIIT on August 24, 2017 and effective as of November 1, 2017. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and applicants become domain name holders upon successful registration. The domain name registration also follows the principle of "first file, first registration."

Regulation Relating To Tax

Enterprise Income Tax

The PRC enterprise income tax, or EIT, is calculated based on the taxable income determined under the applicable EIT Law of the PRC (《中華人民共和國企業所得税法》) (the "**EIT Law**") and its implementation rules, both of which became effective on January 1, 2008 and were latest amended by the SCNPC on December 29, 2018 and April 23, 2019, respectively. The EIT Law generally imposes a uniform enterprise income tax rate of 25% on all resident enterprises in China, including foreign-invested enterprises. The EIT Law and its implementation rules permit certain High and New Technologies Enterprises, or the HNTEs, to enjoy a reduced 15% enterprise income tax rate if they meet certain criteria and are officially acknowledged.

Value Added Tax

On March 23, 2016, the MOF and the STA jointly issued the Notice on the Pilot Program for Overall Implementation of the Collection of VAT Instead of Business Tax (《關於全面推開營業税改徵增值税試點的通知》), or the Circular 36, which took effect on May 1, 2016. Pursuant to the Circular 36, all of the companies operating in construction, real estate, finance, modern service or other sectors which were required to pay business tax are required to pay value-added tax, or VAT, in lieu of business tax. A VAT rate of 6% applies to revenue derived from the provision of certain services. Unlike a business tax, a taxpayer is allowed to offset the qualified input VAT paid on taxable purchases against the output VAT payable on the revenue from services provided.

On March 20, 2019, the MOF, the STA and the General Administration of Customs issued the Announcement on Policies for Deepening the VAT Reform (《關於深化增值税改革有關政策的公告》), or the Announcement 39, which came into effect on April 1, 2019, to further slash VAT rates. According to the Announcement 39, (1) the 16% or 10% VAT previously imposed on sales and imports by general VAT taxpayers is reduced to 13% or 9% respectively; (2) the 10% purchase VAT credit rate allowed for the procured agricultural products is reduced to 9%; (3) the 13% purchase VAT credit rate allowed for the agricultural products procured for production or commissioned processing is reduced to 10%; and (4) the 16% or 10% export VAT refund rate previously granted to the exportation of goods or labor services is reduced to 13% or 9%, respectively.

Regulation Relating To Foreign Exchange And Dividend Distribution

The principal regulations governing foreign currency exchange in China are the Foreign Exchange Control Regulations of the PRC (《中華人民共和國外匯管理條例》), or the Foreign Exchange Regulations, promulgated by the State Council on January 29, 1996 and latest revised and effective on August 5, 2008. Under the Foreign Exchange Regulations and other PRC rules and regulations on a currency conversion, Renminbi is freely convertible for payments of current account items, such as trade and service-related foreign exchange

transactions and dividend payments, but not freely convertible for capital account items, such as direct investment, loan or investment in securities outside China unless prior approval of the SAFE or its local counterpart is obtained.

The SAFE promulgated the Circular on Further Simplifying and Improving Foreign Exchange Administration Policies 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 amended on December 30, 2019, which 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.

The SAFE promulgated the Circular on Reforming the Management Approach regarding the Foreign Exchange Settlement of Capital of Foreign-invested Enterprise (《關於改革外商投資企業外匯資本金結匯管理方式的通知》) (the "**SAFE Circular 19**") on March 30, 2015, which was last amended on December 30, 2019, and further issued the Circular on Reforming and Standardizing the Foreign Exchange Settlement Management Policy of Capital Account (《關於改革和規範資本項目結匯管理政策的通知》) (the "**SAFE Circular 16**") on June 9, 2016, amended on December 4, 2023. Pursuant to the SAFE Circular 19 and the SAFE Circular 16, the flow and use of the Renminbi capital converted from foreign currency denominated registered capital of a foreign-invested company shall not be used for purpose beyond its business scope, or to provide loans to persons other than affiliates unless otherwise permitted under its business scope.

On October 23, 2019, the SAFE released the Circular on Further Promoting Cross-border Trade and Investment Facilitation (《關於進一步促進跨境貿易投資便利化的通知》), which amended on December 4, 2023, allows non-investment foreign-invested enterprises to use their capital funds to make equity investments in China, provided that such investments do not violate the negative list and the target investment projects are genuine and in compliance with the laws.

According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通知》) issued by the SAFE on April 10, 2020, under the prerequisite of ensuring true and compliant use of funds and compliance and complying with the prevailing administrative provisions on use of income from capital projects, enterprises which satisfy the criteria are allowed to use income under the capital account, such as capital funds, foreign debt and overseas listing, etc., for domestic payment, without the need to provide proof of veracity to the bank beforehand for each transaction.

Regulation Relating To Safe Circular 37

SAFE promulgated the Circular on Relevant Issues Concerning Foreign Exchange Control on Domestic Residents' Offshore Investment and Financing and Roundtrip Investment through Special Purpose Vehicles (《關於境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》), or the SAFE Circular 37, on July 4, 2014, which replaced the

former circular commonly known as the "SAFE Circular 75" (《關於境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》) promulgated by SAFE on October 21, 2005. SAFE Circular 37 requires PRC residents to register with local branches of SAFE in connection with their direct establishment or indirect control of an offshore entity, referred to in SAFE Circular 37 as a "special purpose vehicle," for the purpose of overseas investment and financing, with their legally owned assets or equity interests in domestic enterprises or offshore assets or interests. SAFE Circular 37 further requires amendment to the registration in the event of any significant changes with respect to the special purpose vehicle, such as increase or decrease of capital contributed by PRC individuals, share transfer or exchange, merger, division or other material event. In the event that a PRC shareholder holding interests in a special purpose vehicle fails to fulfill the required SAFE registration, the PRC subsidiary of that special purpose vehicle may be prohibited from making profit distributions to the offshore parent and from carrying out subsequent cross-border foreign exchange activities, and the special purpose vehicle may be restricted in its ability to contribute additional capital into its PRC subsidiary. Furthermore, failure to comply with the various SAFE registration requirements described above could result in liability under PRC law for evasion of foreign exchange controls. On February 13, 2015, SAFE released "SAFE Circular 13" (《國家外匯管理局關於進一步簡化和改進直接投資外匯管理政策的通知》), under which qualified local banks will examine and handle foreign exchange registration for overseas direct investment, including the initial foreign exchange registration and amendment registration, from June 1, 2015.

Regulation Relating To Labor Laws And Social Insurance

Pursuant to the Labor Law of the PRC (《中華人民共和國勞動法》), promulgated by the SCNPC on July 5, 1994 and amended and came into effect on December 29, 2018 and the Labor Contract Law of the PRC (《中華人民共和國勞動合同法》) promulgated by the SCNPC on June 29, 2007 and amended on December 28, 2012 and came into effect 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》) promulgated by the State Council and came into effect on September 18, 2008, employers shall establish and improve labor rules and regulations according to the laws and regulations and shall strictly comply with the national standards, provide training to its employees, protect their labor rights and perform its labor obligations. Employers shall execute written labor contracts with full-time employees. Labor contracts shall be categorized into labor contracts with fixed term, labor contracts without fixed term and labor contracts to be expired upon completion of certain tasks. All employers must comply with local minimum wage standards. Violations of the Labor Contract Law of the PRC and/or the Labor Law of the PRC may result in the imposition of fines and/or other administrative and criminal liability in the case of serious violations.

In addition, according to the Social Insurance Law of the PRC (《中華人民共和國社會保險法》) promulgated by the SCNPC on October 28, 2010, amended and came into effect on December 29, 2018 and the Regulations on the Administration of Housing Funds (《住房公積金管理條例》) amended by the State Council and came into effect on March 24, 2019 and the Provisional Regulations on Collection and Payment of Social Insurance Premiums (《社會保

險費徵繳暫行條例》) amended by the State Council and came into effect on March 24, 2019, employers in China shall pay premium for basic pension plans, medical insurance, unemployment insurance, maternity insurance, work-related injury insurance, and housing funds for their employees at the applicable rates based on the amounts stipulated by the laws. If they fail to pay required amount of premiums to local administrative authorities on time or in full, they may be required to settle the overdue amount, subject to fine or be compulsory enforced by the court.

U.S. REGULATORY OVERVIEW

Regulations Relating to Medical Devices

In the United States, the FDCA, FDA regulations and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. The FDA regulates the design, manufacturing, servicing, sale and distribution of medical devices, including molecular diagnostic test kits and instrumentation systems. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Unless an exemption applies, each medical device we wish to distribute commercially in the United States will require marketing authorization from the FDA prior to distribution. The two primary types of FDA marketing authorization applicable to a device are premarket notification, also called 510(k) clearance, and premarket approval, also called PMA approval. The type of marketing authorization is generally linked to the classification of the device. The FDA classifies medical devices into one of three classes (Class I, II or III) based on the degree of risk the FDA determines to be associated with a device and the level of regulatory control deemed necessary to ensure the device's safety and effectiveness. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are deemed to pose the least risk and are subject only to general controls applicable to all devices, such as requirements for device labeling, premarket notification and adherence to the FDA's current Good Manufacturing Practices, or cGMP, known as the Quality System Regulations, or QSR. Class II devices are intermediate risk devices that are subject to general controls and may also be subject to special controls such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or post-market surveillance. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls and include life sustaining, life-supporting or implantable devices, devices of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

Most Class I devices and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from the FDA. Some Class I devices that have not been so exempted and Class II devices are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III require PMA approval prior to commercial marketing. The PMA approval process is more stringent, time-consuming and expensive than the 510(k) clearance process, however, the 510(k) clearance process has also become increasingly stringent and expensive.

If FDA has not issued a regulation classifying a particular type of device as Class I, and if there is no known predicate for a device, the device is automatically Class III, regardless of the risk the device poses. If a device is automatically/statutorily classified into Class III in this manner, a company can petition FDA to reclassify the category of devices into Class II or Class I via a process known as the De Novo Classification Request process. This direct De Novo process allows a company to request that a new product classification be established without the company first submitting a 510(k) notification for the device. When FDA agrees that the device is Class II or Class I and grants a De Novo Request, the device may then be marketed under the FDCA and can serve as a predicate for future 510(k) submissions.

EUROPEAN UNION REGULATORY OVERVIEW

Regulation Relating to Medical Devices

The EU consists of member states residing in the European Union and has a coordinated system for the authorization of medical devices. As of May 26, 2021, the EU has adopted Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009. The Medical Device Regulation 2017/745, or EU MDR repeals Directive 93/42/EEC, which concerns medical devices, and Directive 90/385/EEC, which concerns active implantable medical devices, as of 26 May 2021. The EU allows a transition period from Directive 93/42/EEC and Directive 90/385/EEC to Regulation (EU) 2017/745, that will end 26 May 2024.

The EU MDR aims to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and considering the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (the "**TFEU**"), this Regulation harmonizes the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market thus allowing them to benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for medical devices by ensuring, among other things, that data generated in clinical investigations are reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

The system of regulating medical devices operates by way of a certification for each medical device. Each certificated device is marked with CE mark which shows that the device has a Certificat de Conformité. There are national bodies known as Competent Authorities in each member state which oversee the implementation of the EU MDR within their jurisdiction. The means for achieving the requirements for CE mark varies according to the nature of the device. Devices are classified in accordance with their perceived risks, similarly to the U.S. system. The class of a product determines the requirements to be fulfilled before CE mark can be placed on a product, known as a conformity assessment. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be sold throughout the European Union without further conformance tests being required in other member states.