PRC REGULATORY OVERVIEW

Our business operations in the PRC are subject to a large number of laws and regulations, as well as extensive government supervision. This section sets out a summary of the major laws, regulations, rules and policies that may have a significant impact on our business operations in the PRC.

LAWS AND REGULATIONS RELATING TO THE ADMINISTRATION OF MEDICAL DEVICES

Our business operations in the PRC are subject to a number of laws and regulations relating to the administration of medical devices. The principal regulator of the medical device industry of the PRC is the National Medical Products Administration (the "NMPA") and its local branches, formerly known as the State Food and Drug Administration (the "former SFDA") and its local branches.

Classification, Registration and Filing of Medical Devices

Pursuant to the Regulations on Supervision and Administration of Medical Devices (《醫療器械監督管理條例》) promulgated by the State Council on January 4, 2000, last amended on December 6, 2024, and effective on January 20, 2025, medical devices are subject to classified management in the PRC and are classified into three categories by their degree of risk. Class I refers to low-risk medical devices with their safety and effectiveness ensured through routine administration. Class II refers to medium-risk medical devices with their safety and effectiveness under strict control and administration. Class III refers to high-risk medical devices which require special measures for strict control and administration to ensure their safety and effectiveness. Class I medical devices are subject to filing-based product administration, while Class II and Class III devices are subject to registration-based product administration. Drug supervision and administration authorities under the State Council formulate the rules and catalogs for medical device classification, timely analyze and assess the changes of risks concerning medical devices, and adjust their classification rules and catalogs based on their production, operation and use.

Pursuant to the Measures for the Administration of Registration and Filing of Medical Devices (《醫療器械註冊與備案管理辦法》) became effective on October 1, 2021, for filing domestic Class I medical devices, filing materials shall be submitted to the local drug supervision and administration authorities of the municipal people's government. Domestic Class II and Class III medical devices are subject to registration-based administration, under which Class II medical devices shall be examined by the drug supervision and administration authorities of a people's government at the provincial, autonomous region and municipal level; and Class III medical devices shall be examined by the drug supervision and administration authorities of the State Council, with a medical device registration certificate (醫療器械註冊登記證) to be issued upon approval.

The Measures for the Administration of Registration and Filing of Medical Devices sets out the details of product development, clinical evaluation, registration system verification, product registration, registration of changes, renewal registration and product filing, as well as special registration procedures such as innovative product registration procedures, priority registration procedures and emergency registration procedures.

Clinical Trials for Medical Devices

According to the Measures for the Administration of Registration and Filing of Medical Devices, clinical trials are not required for the filing of Class I medical devices but are required for the application for registering Class II and Class III medical devices. Medical devices may be exempt from a clinical trial under any of the following circumstances: (i) with a clear working mechanism, established design, mature manufacturing processes, years of application of similar medical devices on the market with no record of material adverse events, and no change to the

general purpose of the device; (ii) safety and effectiveness of the medical device proven through non-clinical evaluation; (iii) safety and effectiveness of the medical device proven through the analysis and evaluation of the data obtained from the clinical trial or application of similar medical devices.

Jointly promulgated by the former SFDA and the former National Health Commission on March 24, 2022, and effective from May 1, 2022, the Good Clinical Practice for Medical Devices (《醫療器械臨床試驗質量管理規範》) covers the entire process of a clinical trial of medical devices, including, among others, the protocol design, execution, monitoring, verification and inspection, as well as data collection, recording, analysis and conclusion and reporting procedure of a clinical trial. To carry out clinical trials of medical devices, the applicant shall organize to prepare a scientific and reasonable clinical trial protocol based on the categories, risks and intended uses of the medical devices for clinical experiments.

Special Examination Procedures for Innovative Medical Devices ("Green Path")

On October 8, 2017, the General Office of the CPC Central Committee and the General Office of the State Council jointly issued the Opinions on Deepening the Reform of the Evaluation and Approval Systems and Encouraging Innovation on Medicine and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) (the "Innovation Opinions"), which aims to encourage the innovation of medical devices. Pursuant to the Innovation Opinions, priority review and approval will be granted to innovative medical devices supported by the National Key Science and Technology Projects and the National Key Research and Development Program of the PRC, clinically trialed by the National Clinical Research Center, and approved by the management department of the National Clinical Research Center.

The Special Examination Procedures for Innovative Medical Devices (《創新醫療器械特別審查程序》), promulgated by the NMPA on November 2, 2018, and effective from December 1, 2018, elaborates on the specific conditions under which special procedures apply to the examination of medical devices.

Production Permit of Medical Devices

Pursuant to the Measures for the Supervision and Administration of Medical Device Production (《醫療器械生產監督管理辦法》) promulgated by the former SFDA on July 20, 2004, and last amended on March 10, 2022 and effective on May 1, 2022, a medical device manufacturer shall have all the following conditions: (i) production sites, environmental conditions, production equipment and professional technicians suitable for such medical devices produced; (ii) organizations or professional examination staff and examination equipment to carry out quality examinations for such medical devices produced; (iii) management systems to ensure the quality of such medical devices; (iv) after-sale services capabilities suitable for such medical devices produced; and (v) requirements in line with the provisions of the product research and development and production technique documents.

An enterprise engaged in the production of Class I medical devices shall file for the production of such devices with the municipal food and drug supervision and administration authorities in the district where the enterprise is located and submit proofs of qualifications for the production of such medical devices. Any changes to the contents of such filing proofs shall be filed. Enterprises engaged in the production of Class II and Class III medical devices shall apply for a Medical Device Production Permit (《醫療器械生產許可證》) with the drug supervision and administration authorities of the province, autonomous region or municipality where the enterprise is located, and submit proofs of qualifications for production of such medical devices and the registration certificates for such medical devices produced. For any changes to the contents of the

Medical Device Production Permit, an application shall be made to the original issuing authorities to register such changes. The Medical Device Production Permit is valid for five years, and the registrant shall apply to the original issuing authorities for renewal within 90 to 30 working days prior to the expiration date.

Medical Device Production and Quality Management Standards

Pursuant to the Quality Management Standards for Medical Device Production (《醫療器械生產質量管理規範》) (the "Production Quality Management Standards") promulgated by the former SFDA on December 29, 2014, and effective on March 1, 2015, an enterprise engaged in medical device production shall establish a sound quality management system as required under the Production Quality Management Standards and shall ensure its effective operation. The enterprise shall establish procurement control procedures and a supplier audit system to evaluate its suppliers and ensure that the products purchased meet statutory requirements. The enterprise shall keep a true, accurate, complete and traceable record of the purchase, production and inspection of raw materials. The enterprise shall manage its risks throughout the process of design and development, production, sales and after-sales services. The measures taken shall be appropriate to the risks associated with the product.

According to the Notice on Issuing On-site Inspection Guidelines of Medical Device Production Quality Management Standards and Three Other Guidelines (《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》) promulgated by the former SFDA on September 25, 2015, and effective on the same date, during the on-site verification of medical device registration and the on-site inspection of production licensing (including changes), the inspection team shall issue conclusive recommendations for on-site inspection according to such guidelines. The recommendations are divided into three categories, namely "pass", "fail" or "review after rectification". During supervision and inspection, the enterprise shall be required to suspend production for rectification if found to breach the requirements on key items or on general items which may have a direct impact on product quality; the enterprise shall be required to rectify within a prescribed period if only found to breach the requirements on general items which have no direct impact on product quality. Regulators shall issue the final inspection results upon reviewing the conclusive recommendations and on-site inspection information submitted by the inspection team.

Management of Medical Device Operations

Pursuant to the Measures for the Supervision and Administration of Medical Devices Operation (《醫療器械經營監督管理辦法》) promulgated by the former SFDA on July 30, 2014, and respectively amended on November 17, 2017, and March 10, 2022, an enterprise engaged in medical devices operation shall align its operation and storage premises with the scope and scale of operation, and engage quality management agencies or personnel in line with medical devices operation. An enterprise engaged in the operation of Class II medical devices shall file with the municipal drug supervision and administration authorities in the district where the enterprise is located and submit proof that the enterprise has met the conditions on the operation of such medical devices and an enterprise engaged in the operation of Class III medical devices shall apply for a Medical Device Operation Permit (《醫療器械經營許可證》) with the municipal drug supervision and administration authorities in the district where the enterprise is located, and submit proofs that the enterprise has met the conditions on the operation of such medical devices.

The drug supervision and administration authorities that have received the application for an operation permit shall issue the Medical Device Operation Permit to the enterprise which has met the requirements. The Medical Device Operation Permit is valid for five years and renewable in accordance with relevant provisions. Enterprise engaged in medical device operation shall not operate or use medical devices that are not registered or filed, or without qualification proofs, or have expired or become invalid or eliminated.

Medical device registrants, filers or manufacturers who sell medical devices at their residential or production address do not need to apply for an operation permit or undergo filing; those who store and conduct spot sales of medical devices at other venues shall apply for an operation permit or undergo filing in accordance with the regulations.

Pursuant to the Quality Management Standards for Medical Device Operation (《醫療器械經營質量管理規範》) promulgated by the former SFDA, effective on December 12, 2014, last amended on December 4, 2023 and would come effective from July 1, 2024, an enterprise engaged in the operation of medical devices shall take effective quality control measures in procurement, inspection and acceptance, storage, sales, transportation, after-sales service and other aspects, to ensure product quality and safety.

Pursuant to the Regulations on Supervision and Administration of Medical Devices, an enterprise engaged in medical device operation shall check the qualifications of the supplier and the qualification proofs of the medical devices, as well as establish an inspection record system for goods when it purchases medical devices. An enterprise engaged in the wholesale business of Class II and Class III medical devices and the retail business of Class III medical devices shall also establish a sales record system. Matters on the record shall include: (1) the name, model, specification and quantity of medical devices; (2) the production batch number, expiration date and date of sale of medical devices; (3) the name of the manufacturer; (4) the name, address and contact information of the supplier or purchaser; (5) the serial numbers of relevant license proofs. The inspection records of goods purchased and sales records shall be true and kept for a period of time as prescribed by the food and drug supervision and management authorities of the State Council.

Tender Management for Medical Device Procurement

Pursuant to the Notice of the Ministry of Health on Further Strengthening the Administration of Centralized Procurement of Medical Devices (《衛生部關於進一步加強醫療器械集中採購管理的通知》) promulgated on June 21, 2007, all non-profit medical institutions organized by governments, industries and state-owned enterprises at all levels shall participate in the centralized procurement of medical devices.

Pursuant to the Notice of Opinions on Reform of Pricing System of Pharmaceuticals and Medical Services (《關於印發改革藥品和醫療服務價格形成機制的意見的通知》) issued on November 9, 2009, the State shall strengthen the regulation on the pricing of medical devices. For high-value medical devices, especially implantable (interventional) medical devices, efforts shall be made to result in reasonable pricing by such measures as limiting the price difference rate during circulation and publishing market price information. High-value medical devices usually refer to medical devices that act directly on the human body with strict safety requirements, considerable clinical consumption and relatively high prices.

According to the Work Standards on Centralized Procurement of High-Value Medical Consumables (Trial) (《高值醫用耗材集中採購工作規範(試行)》) issued on December 17, 2012, online centralized procurement of high-value medical consumables (the "Centralized Procurement") shall be led by the government and carried out in provinces (autonomous regions and municipalities). Medical institutions, medical supplies manufacturers and operators shall engage in such procurement through the centralized procurement work platform established by provinces (autonomous regions and municipalities). The centralized procurement authorities of each province (region or municipality) are responsible for preparing a catalog of high-value medical devices for centralized procurement in their respective administrative region. The high-value medical consumables listed in the centralized procurement catalog can be procured through open bidding, an invitation for tendering or other means prescribed by state laws and regulations. After the purchase price is determined, the public medical institutions in the region concerned shall engage in procurement strictly at public bidding prices.

On July 19, 2019, the General Office of the State Council issued the Notice on Issuing the Reform Plan for the Management of High-value Medical Consumables (《關於印發<治理高值醫用耗材改革方案>的通知》) (the "High-Value Medical Consumables Notice"). Pursuant to the High-Value Medical Consumables Notice, high-value medical consumables are medical supplies that act directly on the human body, with strict safety requirements, high clinical use, relatively high prices and heavy financial burden on the public. The High-value Medical Consumables Notice sets out reform plans for regulating high-value medical consumables, including: (i) the National Healthcare Security Bureau, the National Medical Products Administration and the National Health Commission will gradually unify the classification and numbering of high-value medical consumables for national medical insurance by the end of 2020, and explore the application for connecting the registration, procurement and use of high-value medical consumables; (ii) an access system will be established for the high-value medical consumables under basic medical insurance, with management based on the high-value medical consumables catalog and improvement of the dynamic adjustment mechanism for the catalog. The National Health Commission and the Ministry of Finance (the "MOF") shall introduce access management measures by the end of June 2020; (iii) the mark-ups of medical supplies in public medical institutions shall be abolished by the end of 2019, with procurement prices applied to all medical supplies (including high-value medical consumables) in public medical institutions; and (iv) the National Healthcare Security Bureau, the MOF and the National Health Commission shall prepare and implement policies on the medical insurance payment. Meanwhile, efforts shall be made to prepare the standards for medical insurance payment regarding high-value medical consumables and establish a dynamic adjustment mechanism. Medical insurance funds and patients shall bear their respective expenses for high-value medical consumables under medical insurance payment standards. Medical institutions shall be guided to further reduce procurement prices according to the guidelines in the High-Value Medical Consumables Notice.

Centralized Volume-Based Procurement

On March 5, 2018, the National Health Commission, the Ministry of Finance, the National Development and Reform Commission, the Ministry of Human Resources and Social Security, the National Administration of Traditional Chinese Medicine, and the General Office of the State Council's Medical Reform Office jointly issued the Notice on Consolidating the Achievements of Eliminating Drug Price Mark-ups and Further Deepening Comprehensive Reform of 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 called for the deepening of comprehensive reforms in public hospitals, including the implementation of centralized procurement for high-value medical consumables by category.

With the approval of the State Council, on April 30, 2021, the National Healthcare Security Administration, together with the National Development and Reform Commission, the Ministry of Industry and Information Technology, the Ministry of Finance, the National Health Commission, the State Administration for Market Regulation, the National Medical Products Administration and the Logistics Support Department of the Central Military Commission, jointly issued and implemented the Guiding Opinions on Carrying Out Centralised Volume-Based Procurement and Use of High-Value Medical Consumables Organised by the State (《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》). Under this framework, the state organizes volume-based procurement for high-value medical consumables that are widely used in clinical settings, involve high procurement amounts, are mature in clinical application, subject to sufficient market competition, and are relatively homogenous in quality. Medical device marketing authorization holders whose products fall within the scope of such procurement and meet the relevant eligibility requirements may participate. All public medical institutions are required to participate in the volume-based procurement of high-value medical consumables. Local provinces form procurement alliances and establish joint procurement offices to undertake the specific work and promote the orderly implementation of centralized volume-based procurement.

On May 14, 2024, the National Healthcare Security Administration issued the Notice by the General Office of the National Healthcare Security Administration on Strengthening Regional Collaboration and Advancing the Expansion and Quality Enhancement of Centralized Procurement in 2024 (《國家醫療保障局辦公室關於加強區域協同做好2024年醫藥集中採購提質擴面的通知》). Under this framework, the centralized volume-based procurement of drugs and high-value medical consumables continues to be organized by the national joint procurement offices for drugs and consumables, respectively, with all provinces required to participate and implement the arrangements. Regional procurement alliances at the provincial level are encouraged to further align with national arrangements and, where conditions permit, be upgraded to nationwide procurement alliances. Leading provinces are expected to strengthen coordination with the National Healthcare Security Administration and invite all provinces to participate, thereby forming a national centralized procurement alliance ("全國聯採"). The National Healthcare Security Administration will provide overall guidance and coordinate expert technical support to promote standardization and best practices. Leading provinces are required to draw on experience from both national and local procurement initiatives, conduct thorough research, gather stakeholder input, and formulate procurement rules tailored to specific product categories, thereby promoting a more standardized and structured procurement process. In principle, all provinces are expected to participate in the national centralized procurement alliance.

"Two Invoice System" (兩票制) for Medical Devices

Pursuant to the Notice on Opinions on the Implementation of the "Two Invoice System" in Pharmaceutical Procurement by Public Medical Institutions (for Trial Implementation) (《印發關於在公立醫療機構藥品採購中推行兩票制的實施意見(試行)》) issued on December 26, 2016, the "Two Invoice System" refers to one invoice from the pharmaceutical manufacturer to the distribution enterprise and one invoice from the distribution enterprise to the medical institution. Wholly-owned or holding commercial company (limited to one commercial company nationwide) and domestic general agent of foreign pharmaceutical products (limited to one domestic general agent nationwide) set up by a drug manufacturer or an integrated science, industry and trade group-type enterprise that only sells the pharmaceutical products of the enterprise (group) can be treated as a production enterprise. The transfer of pharmaceutical products between a pharmaceutical distribution group-type enterprise and its wholly-owned (holding) subsidiaries or between its wholly-owned (holding) subsidiaries can be considered not as one invoice, but is allowed to be issued one invoice at most.

Pursuant to the Notice on Consolidating the Achievements of Cancelling Pharmaceutical 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》) issued on March 5, 2018, the classified centralized procurement of high-value medical consumables shall be implemented, and the "Two Invoice System" for the purchase and sale of high-value medical consumables shall be gradually implemented.

Pursuant to the High-Value Medical Consumables Notice, local authorities are encouraged to reduce the processes for the circulation of high-value medical consumables and promote open and transparent purchase and sale through means such as the "Two Invoice System" after considering the actual situation.

At present, some provinces in the PRC have issued relevant regulations on the "Two-Invoice System" for medical supplies. Nevertheless, there is no clear regulation and exact implementation timeline for the "Two-Invoice System" for medical devices, with the reform still in progress. Going forward, the implementation of the "Two-Invoice System" for medical devices in the PRC will bring uncertainties to the Company's business development and operations.

Advertising Supervision of Medical Devices

The State Administration for Market Regulation (SAMR) promulgated the Interim Administrative Review Measures for the Advertisements of Pharmaceutical Products, Medical Devices, Dietary Supplements and Formulated 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 "Interim Review Measures") on December 24, 2019, which became effective on March 1, 2020. The Interim Review Measures and Regulations on Supervision and Administration of Medical Devices stipulate that medical device advertising shall not be released without review, with the content of medical device advertising subject to the registration certificate or filing proof or the product description of registered or filed products approved by pharmaceutical supervision and administrative authorities. Medical device advertising involving medical device name, scope of application, mechanism of action or structure and composition, etc., shall not exceed the scope of the registration certificate or filing proof or the product description of registered or filed products. The validity period of advertising approval number of medical devices shall be consistent with the shortest validity period prescribed in product registration documents, filing proofs or production license documents. If the product registration documents, filing proofs or production license documents do not specify the validity period, the advertising approval number shall be valid for two years.

Medical Device Recall, Monitoring and Re-evaluation of Adverse Events

Pursuant to the Administrative Regulations for Medical Device Recall (《醫療器械召回管理辦法》) promulgated by the former SFDA on January 25, 2017, and effective on May 1, 2017, medical device recalls shall be classified, according to the severity of medical device defects, as: (i) Class I recall: where the use of the medical device is likely to cause or has caused serious health hazards; (ii) Class II recall: where the use of the medical device may or has caused temporary or reversible health hazards; or (iii) Class III recall: where the use of the medical device is less likely to cause harm but still need to be recalled. Medical device manufacturers should determine the class of recall according to the circumstances, and design and implement the recall plan scientifically according to the sales and use of medical devices. If Class I recall is implemented, a medical device recall announcement shall be published on the website of the State Drug Administration and the main media. If Class II or Class III recall is implemented, a medical device recall announcement shall be published on the website of the pharmaceutical supervision and administrative authorities of the province, autonomous region or municipality.

Pursuant to the Administrative Measures for the Monitoring and Re-evaluation of the Adverse Events on Medical Devices (《醫療器械不良事件監測和再評價管理辦法》) issued by the SAMR and the National Health Commission on August 13, 2018 and effective on January 1, 2019, a medical device marketing licensee (the "Licensee") shall be capable of quality management and assuming corresponding responsibilities to ensure the safety and effectiveness of medical devices, establish a monitoring system of medical device adverse events, and report such events directly to the monitoring technical institution for such events (the "Monitoring Institution").

The enterprises in operation authorized by the Licensee to sell and the units that use medical devices should report the adverse events of medical devices to the Licensee and monitoring agencies. The Licensee shall evaluate the adverse events identified, improve product quality according to the evaluation results and report such results and quality improvement measures to the monitoring body; if approval from the original registration authority is required, an application shall be submitted in accordance with regulations.

NMPA has established a national monitoring information system for medical device adverse events, to strengthen the monitoring information network and database construction on medical device adverse events. A monitoring agency designated by NMPA is responsible for the unified management of information collected on medical device adverse events and providing feedback information on the monitoring of such events to relevant monitoring agencies, the Licensee, enterprises in operation or the units that use such devices.

Export of Medical Device Products

Pursuant to the Regulations on Supervision and Administration of Medical Devices, manufacturers of medical devices for export shall ensure that such medical devices meet the requirements of the importing country (region).

According to the Regulations on the Application and Issuance of Medical Device Exporting Certificates (《醫療器械產品出口證明申辦規定》) promulgated on January 6, 1996, the former SFDA examines the safety and legality of medical device products manufactured by enterprises in the PRC, and issues export certificates in accordance with international practices to certify that the products have been legally manufactured in the PRC.

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 on June 1, 2015 and effective on September 1, 2015, if the registration certificate and production permit for a medical device have been obtained in the PRC, or the medical device registration and production filing have been completed, the drug supervision and administration authorities may issue an Export Sales Certificate for Medical Device Product (醫療器械產品出口銷售證明) to the relevant manufacturing enterprise. The validity term of the Export Sales Certificate for Medical Device Product shall not exceed the earliest deadline for the various documents submitted by the enterprise in the application materials, with the maximum validity term not to exceed two years.

Registration and Recordation of Imported Medical Devices

In accordance with the Regulations on Supervision and Administration of Medical Devices, a registration and recordation system is applied for imported medical devices. To file imported Class I medical devices for record, an overseas medical device manufacturer shall, through its representative office established in the PRC or the corporate enterprise designated as its agent in the PRC, submit record filing documents and documents supporting the market launch of such medical devices approved by the competent department of the country (region) where the overseas medical device manufacturer is located to the State Drug Administration for record filing.

To export Class II and/or Class III medical devices to the PRC, an overseas medical device manufacturer shall, through its representative office established in the PRC or the corporate enterprise designated as its agent in the PRC, submit to the State Drug Administration the registration documents and the documents supporting market launch of such medical devices approved by the competent department of the country (region) where the overseas medical device manufacturer is located. The imported medical devices of Class II and Class III that meet the safety and effectiveness requirements shall receive approval for issuance of registration certificates, and a medical device registration certificate shall be valid for five years. If the medical device registration certificate needs to be renewed upon the expiration of its validity period, an application for registration renewal shall be filed with the original registration authority six months before the validity period expires.

OTHER LAWS AND REGULATIONS

Laws and Regulations on Corporation and Foreign Investment

Pursuant to the Company Law of the People's Republic of China (《中華人民共和國公司法》) (the "Company Law") promulgated by the Standing Committee of the National People's Congress (the "NPC") last amended on December 29, 2023 and came into effect on July 1, 2024, a company established in the PRC may be in the form of a limited company with liability and joint stock limited companies. Both shall have the status of legal persons. The liability of shareholders of a limited company with liability and a joint stock limited company is limited to the amount of

registered capital they have contributed or shares they have subscribed for. The Company Law shall also apply to foreign-invested companies. Where laws and implementation regulations on foreign investment have other stipulations, such stipulations shall apply.

On March 15, 2019, the Foreign Investment Law of the People's Republic of China (《中華人民共和國外商投資法》) (the "Foreign Investment Law") was promulgated by the NPC and came to effect on January 1, 2020. According to the Foreign Investment Law, foreign investments are entitled to pre-entry national treatment and are subject to the negative list management system. The pre-entry national treatment means that the treatment given to foreign investors and their investments at the stage of investment access is not lower than that of domestic investors and their investments. The negative list management system means that the PRC implements special management measures for the access of foreign investment in specific fields. Foreign investors shall not invest in any prohibited areas stipulated in the negative list and shall meet the conditions stipulated in the negative list before investing in any restricted areas.

The Special Management Measures (Negative List) for the Access of Foreign Investment 2024 (《外商投資准入特別管理措施(負面清單)(2024年版)》) (the "2024 Negative List") was promulgated by NDRC and MOFCOM on September 6, 2024, and came into effect on November 1, 2024. The 2024 Negative List set out the entry restrictions for foreign investment in different industries in the PRC.

Laws and Regulations on Overseas Investment

The Measures for the Administration of Overseas Investment (《境外投資管理辦法》) was promulgated by the MOFCOM, last amended on September 6, 2014, and came into effect on October 6, 2014. As defined under the Measures for the Administration of Overseas Investment, overseas investment means that the enterprises legally incorporated in the PRC own the non-financial enterprises or obtain the ownership, control, operation and management rights and other rights of the existing non-financial enterprises in foreign countries through incorporation, merger, and acquisition and other means. The MOFCOM and competent authorities of its provincial branches implement filing and approval management respectively, according to the different overseas investments by enterprises.

The Measures for the Administration of Overseas Investment of Enterprises (《企業境外投資管理辦法》) was promulgated by the NDRC on December 26, 2017, and came into effect on March 1, 2018. Pursuant to this, overseas investment refers to the investment activities of an enterprise in the PRC to acquire the ownership, control, operation and management rights, and other relevant interests outside the PRC, either directly or through a foreign enterprise under its control, by means of investing in assets, equity, or providing financing and/or guarantees. Overseas investment shall be carried out in accordance with certain procedures, including approval, filing, reporting, and supervision and inspection of overseas investment projects.

Laws and Regulations on Customs

According to the Customs Law of the People's Republic of China (《中華人民共和國海關法》) promulgated by the Standing Committee of the NPC on January 22, 1987, last amended and came into effect on April 29, 2021, the Customs of the People's Republic of China is the PRC's entry and exit customs supervision and administration authority and is responsible for the supervision of the transport vehicles, goods, freight items, postal items and other items entering into and departing from the PRC, and collecting tariff and other duties and charges. When a consignee or consignor of import or export goods or a customs clearing enterprise handles customs declaration procedures, they shall register with the customs in accordance with law.

Laws and Regulations on Environmental Protection

Pursuant to the Environmental Protection Law of the People's Republic of China (《中華人民共和國環境保護法》) promulgated by the Standing Committee of the NPC on December 26, 1989, and last amended on April 24, 2014, and came into effect on January 1, 2015, the waste discharge licensing system has been implemented in the PRC and entities that discharge medical sewage to water directly or indirectly shall obtain a waste discharge license. Furthermore, installations for the prevention and control of pollution at a construction project must be designed, built and commissioned simultaneously with the principal part of the project.

Laws and Regulations on Production Safety

Pursuant to the Production Safety Law of the People's Republic of China (《中華人民共和國安全生產法》) last amended by the Standing Committee of the NPC on June 10, 2021 and came into effect on September 1, 2021, the production and business operation entities shall (i) comply with this law and other laws and regulations on safety production, strengthen the management of safety production, establish a sound responsibility system for safety production for all employees and a system of rules and regulations on safety production; (ii) increase the investment and guarantee of safety production funds, materials, technologies, and personnel, improve safety production conditions, and boost safety production standardization and informatization; (iii) 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.

Laws and Regulations on Intellectual Property Rights

Trademarks

Pursuant to the Trademark Law of the People's Republic of China (《中華人民共和國商標法》) promulgated by the Standing Committee of the NPC on August 23, 1982, last amended on April 23, 2019, and came into effect on November 1, 2019, and the Implementation Rules of the Trademark Law of the People's Republic of China (《中華人民共和國商標法實施條例》) passed by the State Council on August 3, 2002, last amended on April 29, 2014 and came into effect on May 1, 2014, registered trademarks in the PRC include goods marks, service marks, collective marks and certification marks. Registration of a trademark shall be made by the Trademark Office of the China National Intellectual Property Office and shall be valid for 10 years. Upon expiry, a trademark registration shall be valid for ten years for each renewal after completion of renewal procedures if it is necessary to be used continuously.

Patents

Pursuant to the Patent Law of the People's Republic of China (《中華人民共和國專利法》) (the "Patent Law") promulgated by the Standing Committee of the NPC on March 12, 1984, and last amended on October 17, 2020, and came into effect on June 1, 2021 and the Implementation Rules of The Patent Law of the People's Republic of China (《中華人民共和國專利法實施細則》) last amended by the State Council on December 11, 2023 and came into effect on January 20, 2024, patents in China are divided into invention patent, utility model patent or design patent. The invention patent shall be valid for 20 years, the utility model patent shall be valid for 10 years, and the design patent shall be valid for 15 years, all commencing from the date of application. The patent right entitled to its owner shall be protected by the laws. Any person shall be licensed or properly authorized by the patent owner before he/she/it can use such patent. Otherwise, it shall constitute an infringement of the patent right.

Copyright

According to the Copyright Law of the PRC (《中華人民共和國著作權法》) promulgated by the SCNPC, which was latest amended in November 2020, and its related Implementing Regulations, Chinese citizens, legal persons, or other organizations shall, whether published or not, own copyright in their works, which include, among others, works of literature, art, natural science, social science, engineering technology and computer software. Pursuant to the Regulation on Computers Software Protection (《計算機軟件保護條例》) promulgated by the State Council on June 4, 1991 and latest amended on January 30, 2013, and the Measures for the Registration of Computer Software Copyright (《計算機軟件著作權登記辦法》) promulgated on February 20, 2002 and latest amended on June 18, 2004, the National Copyright Administration is mainly responsible for the registration and management of software copyright in China and recognizes the China Copyright Protection Center as the software registration organization. The China Copyright Protection Center shall grant certificates of registration to computer software copyright applicants in compliance with the regulations.

Laws and Regulations on Anti-Unfair Competition

According to the Anti-Unfair Competition Law of the People's Republic of China (《中華人民共和國反不正當競爭法》) (the "Anti-Unfair Competition Law") amended by the Standing Committee of the NPC and came into effect on April 23, 2019, unfair competition refers to the conduct of an operator who, in the course of production and operation activities, violates the Anti-Unfair Competition Law, disrupts the order of market competition and harms the lawful rights and interests of other operators or consumers. According to the Anti-Unfair Competition Law, operators shall follow the principles of voluntariness, equality, fairness, and honesty in market transactions, and abide by laws and business ethics. Operators who violate the Anti-Unfair Competition Law shall bear civil, administrative, or criminal liabilities based on specific situations.

According to the Interim Provisions of the State Administration for Industry and Commerce on Banning Commercial Bribery (《國家工商行政管理局關於禁止商業賄賂行為的暫行規定》) (the "Provisions on Banning Commercial Bribery") promulgated by the State Administration for Industry and Commerce on November 15, 1996, commercial bribery refers to the use of money or other means by a business operator to bribe an entity or individual for the sale or purchase of goods. The term "other means" refers to the provision of any kind of domestic and overseas trips, study tours, and other means of benefit other than the payment of money. According to the Anti-Unfair Competition Law and the Provisions on Banning Commercial Bribery, the supervisory and inspection department may impose a fine according to the severity of the case and confiscate any illegal proceeds.

Laws and Regulations on Employment and Social Security

The Labor Law of People's Republic of China (《中華人民共和國勞動法》) promulgated by the Standing Committee of the NPC on July 5, 1994, and last amended on December 29, 2018, provides that an employer shall develop and improve its rules and regulations to safeguard the rights of its workers. Labor safety and health facilities must comply with relevant national standards. Workers engaging in special industries shall receive specialized training and obtain the specific qualification for that industry.

The Labor Contract Law of People's Republic of China (《中華人民共和國勞動合同法》) promulgated by the Standing Committee of the NPC on June 29, 2007, last amended on December 28, 2012, and came into effect on July 1, 2013, and the Implementation Regulations on Labor Contract Law of the People's Republic of China (《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, regulates the relationship between an employer and its employees, and contains specific provisions involving the terms of the labor contract.

According to the Provisional Regulations on the Collection and Payment of Social Insurance Premium (《社會保險費徵繳暫行條例》), the Regulations on Work Injury Insurance (《工傷保險條例》), the Regulations on Unemployment Insurance (《失業保險條例》) and the Trial Measures on Employee Maternity Insurance of Enterprises (《企業職工生育保險試行辦法》), an enterprise in the PRC must provide a benefit plan for their employees, which include basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance. An enterprise must provide social insurance by processing social insurance registration with local social insurance agencies, and must pay or withhold relevant social insurance premiums for or on behalf of its employees.

The Social Insurance Law of the People's Republic of China (《中華人民共和國社會保險法》) promulgated by the Standing Committee of the NPC on October 28, 2010, last amended and came into effect on December 29, 2018, regulates basic pension insurance, unemployment insurance, maternity insurance, work injury insurance and medical insurance, and has elaborated in detail the legal obligations and liabilities of an employer who does not comply with relevant laws and regulations on social insurance.

On July 31, 2025, the Supreme People's Court issued the Interpretation II of the Supreme People's Court on the Application of Law in the Trial of Labor Dispute Cases (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》), which came into effect on September 1, 2025. The interpretation provides, among others, that any agreement or undertaking between an employer and an employee under which the employee agrees or undertakes that the employer need not pay social insurance premiums shall be deemed invalid by the people's courts. Where an employer fails to pay mandatory social insurance premiums in accordance with the law, and the employee terminates the employment contract on such grounds pursuant to Article 38(3) of the PRC Labor Contract Law, and claims severance payment, the people's courts shall uphold the employee's claims. If the employer subsequently makes supplementary payments of social insurance premiums as required by law, and requests the employee to return the previously paid severance compensation, the people's courts shall uphold such a claim.

The Regulations on the Administration of Housing Provident Fund (《住房公積金管理條例》) promulgated by the State Council on April 3, 1999, and last amended and came into effect on March 24, 2019, stipulates that an employer shall register with the Housing Provident Fund Management Centre for housing provident fund contributions and set up a housing provident fund account for its employees. The housing provident fund contributions paid by an individual employee and housing provident fund contributions paid by his/her employer shall vest to the individual employee.

Laws and Regulations on Information Security and Data Privacy

According to the Civil Code of the PRC, natural persons' personal information is legally protected. Organizations and individuals must obtain, use and protect personal information in accordance with the law, and are prohibited from illegal collection, use, processing, transmission, sale or disclosure of such information. The Personal Information Protection Law of the People's Republic of China (《中華人民共和國個人信息保護法》), promulgated by the Standing Committee of the NPC on August 20, 2021 (effective November 1, 2021), further clarifies the obligations and responsibilities of personal information processors, imposing higher protective requirements for sensitive personal information processing. The Cybersecurity Law of the People's Republic of China (《中華人民共和國網絡安全法》), revised by the Standing Committee of the NPC on October 28, 2025 (effective January 1, 2026), emphasizes that network operators must process personal information in compliance with the Civil Code and the Personal Information Protection Law. It mandates adherence to the principles of legality, legitimacy and necessity, requires explicit disclosure of collection rules and obtaining data subject consent, and prohibits collection of irrelevant personal information. Network operators shall not leak, tamper with or damage collected personal information, or provide it to third parties without consent (except for anonymized data). The Data Security Law of the People's Republic of China (《中華人民共和國數據安全法》),

promulgated by the Standing Committee of the NPC on June 10, 2021 (effective September 1, 2021), establishes a classified and hierarchical data protection system. Entities engaged in data processing shall establish sound full-process data security management systems, conduct security education and training, and adopt corresponding technical and necessary measures to ensure data security in compliance with legal requirements.

The Measures for Cybersecurity Review (《網絡安全審查辦法》) (the "Measures (2021)") was promulgated by the Cyberspace Administration of China (the "CAC") on December 28, 2021, which provided that: (1) network platform operators holding personal information of more than one million users shall be subject to cybersecurity review by the Cybersecurity Review Office prior to listing abroad; (2) critical information infrastructure operators (the "CIIO") procuring network products and services that affect or may affect national security shall be subject to cybersecurity review; and (3) network platform operators carrying out data processing activities that affect or may affect national security shall be subject to cybersecurity review.

On September 24, 2024, the Regulations on Network Data Security Management (《網絡數據安全管理條例》) (the "Network Data Security Management Regulations") was promulgated by the State Council and will become effective as of January 1, 2025. The Network Data Security Management Regulations apply to the network data handling activities conducted within the territory of the PRC and stipulates that if the network data handling activities affect or may affect national security, a national security review must be conducted in accordance with relevant regulations. The Network Data Security Management Regulations restate and further specify the legal requirements for personal information, cross-border transfer of important data and personal information, data handling activities in network platform services and also provides intensified requirements for important data handlers and large-scale Internet platform service providers. Any failure to comply with such requirements may subject the data processor to, among others, suspension of services, fines, revocation of relevant business permits or licenses, and other penalties.

The Measures for Security Evaluation for the Transfer of Data to Foreign Countries (《數據出境安全評估辦法》), promulgated by the CAC on July 7, 2022 (effective September 1, 2022), establishes the regulatory framework for cross-border data transfer, specifying the requirements and procedures for security evaluation of cross-border transfer of important data or personal information collected/generated in China. The Measures for Standard Contracts for the Transfer of Personal Information to Foreign Countries (《個人資訊信息標準合同辦法》), issued by the CAC on February 22, 2023 (effective June 1, 2023), mandates that personal information processors conducting cross-border transfer via standard contracts must meet specified conditions and file the signed contracts with local provincial-level cyberspace authorities. The Provisions on Promoting and Regulating Cross-border Flow of Data (《促進和規範數據跨境流動規定》, the "Promoting Provisions"), promulgated by the CAC on March 22, 2024, adjusts the scope, exemption conditions and procedures for cross-border data transfer security evaluation and personal information transfer standard contract filing.

Pursuant to the aforesaid measures and regulations, if a data processor provides data to foreign countries and meets one of the following conditions, he/she shall declare the security evaluation of data transfer to foreign countries to the CAC through the local provincial-level Internet information department: (1) the critical information infrastructure operator provides personal information or important data to foreign countries; and (2) a data processor other than the critical information infrastructure operator provides important data to foreign countries, or provides more than 1 million people's personal information (excluding sensitive personal information) or more than 10,000 people's sensitive personal information to foreign countries cumulatively from January 1 of the current year, provided that exemptions under Articles 3 to 6 of the Promoting Provisions are met. A data processor other than the critical information infrastructure operator shall conclude and file a standard contract with overseas recipients for provision of personal information abroad or go through the authentication on protection of personal information under the following circumstances: (1) provides more than 100,000 but less than 1 million people's personal information (excluding

sensitive personal information) to foreign countries cumulatively from January 1 of the current year; (2) provides less than 10,000 people's personal information (excluding sensitive personal information) to foreign countries cumulatively from January 1 of the current year, provided that exemptions under Articles 3 to 6 of the Promoting Provisions are met.

Laws and Regulations on Leasing

According to the Civil Code, an owner of immovable or movable property is entitled to possession, use, earnings, and disposal of such property in accordance with the law. Subject to the consent of the lessor, the lessee may sublease the leased premises to a third party. Where a lessee subleases the premises, the lease contract between the lessee and the lessor remains valid. The lessor is entitled to terminate the lease if the lessee subleases the premises without the consent of the lessor. Moreover, pursuant to the Civil Code, if the mortgaged property has been leased and transferred for occupation prior to the establishment of the mortgage right, the original tenancy shall not be affected by such mortgage right. On December 1, 2010, the Ministry of Housing and Urban-Rural Development promulgated the Administrative Measures on Leasing of Commodity Housing (《商品房屋租賃管理辦法》), which became effective on February 1, 2011. According to such measures, the lessor and the lessee are required to complete property leasing registration and filing formalities within 30 days from execution of the property lease contract with the development authorities or real estate authorities of the municipality or county where the leased property is located. If a company fails to do as aforesaid, it may be ordered to rectify within a stipulated period, and if such company fails to rectify, a fine ranging from RMB1,000 to RMB10,000 may be imposed on each lease agreement.

Laws and Regulations on Foreign Exchange and Taxation

Foreign Exchange

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 was amended on January 14, 1997, and 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 the 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.

According to the Notice of the State Administration of Foreign Exchange on Issues Concerning the Foreign Exchange Administration of Overseas Listing (《國家外匯管理局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, a domestic company shall, within 15 business days from the date of the end of its overseas listing issuance, register the overseas listing with the local branch office of state administration of foreign exchange at the place of its establishment; the proceeds from an overseas listing of a domestic company may be remitted to the domestic account or deposited in an overseas account, but the use of the proceeds shall be consistent with the content of the document and other disclosure documents.

Taxation

Enterprise Income Tax

The Enterprise Income Tax Law of the PRC (《中華人民共和國企業所得税法》) ("the EIT Law"), promulgated by the NPC on March 16, 2007, came into effect on January 1, 2008, and amended on February 24, 2017, and December 29, 2018, as well as the Implementation Rules of the EIT Law (《中華人民共和國企業所得税法實施條例》) (the "Implementation Rules"), promulgated by the State Council on December 6, 2007, came into force on January 1, 2008 and amended on December 6, 2024, are the principal law and regulation governing enterprise income tax in the PRC. According to the EIT Law and its Implementation Rules, a uniform 25% enterprise income tax rate is imposed to both foreign invested enterprises and domestic enterprises, except where tax incentives are granted to special industries and projects. The enterprise income tax rate is reduced to 20% for qualifying small low-profit enterprises. The high-tech enterprises that need full support from the PRC's government will enjoy a reduced tax rate of 15% for Enterprise Income Tax.

Value-Added Tax (the "VAT")

Pursuant to the Value-added Tax Law of the PRC, which took effective on January 1, 2026, entities and individuals engaged in sale of goods, services, intangible assets and immovables and importation of goods within the territory of the PRC are VAT payers of VAT and shall pay the VAT in accordance with the law and regulation. The rate of VAT for the sale of goods is 17% unless otherwise specified, such as the rate of VAT for the 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 STA issued the Notice of on Adjusting VAT Rates (《財政部、國家税務總局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 STA and the General Administration of Customs jointly issued the Announcement on Relevant Policies for Deepening the VAT Reform (《財政部、國家税務總局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 on Overseas Securities Offering and Listing by Domestic Companies

On February 17, 2023, the CSRC promulgated the Overseas Listing Trial Measures and relevant supporting guidelines, which came into effect on March 31, 2023. The Overseas Listing Trial Measures comprehensively improve and reform the existing regulatory regime for overseas offering and listing of PRC domestic companies' securities and regulate both direct and indirect overseas offering and listing of PRC domestic companies' securities. Any domestic company that is deemed to conduct overseas offering and listing activities shall file with the CSRC in accordance with the Overseas Listing Trial Measures.

The Overseas Listing Trial Measures provide that the overseas securities offering and listing will be considered a direct overseas offering by a PRC domestic company if the issuer is a company limited by shares registered and established in Chinese Mainland.

Pursuant to the Overseas Listing Trial Measures, an issuer shall file with the CSRC within three business days after its application for initial public offering is submitted to competent overseas securities regulators.

On February 24, 2023, the CSRC and three other relevant government authorities jointly promulgated the Provisions on Strengthening the Confidentiality and Archives Administration Related to the Overseas Securities Offering and Listing by Domestic Enterprises (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) (the "Provision on Confidentiality"),

which came into effect on March 31, 2023. Pursuant to the Provision on Confidentiality, where a domestic enterprise provides or publicly discloses any document or material that involving state secrets and working secrets of state agencies to the relevant securities companies, securities service institutions, overseas regulatory authorities and other entities and individuals, it shall report to the competent department with the examination and approval authority for approval in accordance with the law, and submit to the secrecy administration department of the same level for filing. The working papers formed within the territory of the PRC by the securities companies and securities service agencies that provide corresponding services for the overseas issuance and listing of domestic enterprises shall be kept within the territory of the PRC, and cross-border transfer shall go through the examination and approval formalities in accordance with the relevant provisions of the State.

H-share Full Circulation

"Full circulation" means listing and circulating on the stock exchange of the domestic unlisted shares of an H-share listed company, including unlisted domestic shares held by domestic shareholders prior to overseas listing, unlisted domestic shares additionally issued after overseas listing, and unlisted shares held by foreign shareholders. On November 14, 2019, the CSRC issued the Guidelines for the "Full Circulation" Program for Domestic Unlisted Shares of H-share Listed Companies (《H股公司境內未上市股份申請"全流通"業務指引》) (the "Guidelines for the Full Circulation"), which was partly revised on August 10, 2023 by CSRC.

According to the Guidelines for the Full Circulation, shareholders of domestic unlisted shares may determine by themselves through consultation the amount and proportion of shares, for which an application will be filed for circulation, provided that the requirements laid down in the relevant laws and regulations and set out in the policies for state-owned asset administration, foreign investment and industry regulation are met, and the corresponding H-share listed company may be entrusted to file the said application for full circulation. To apply for full circulation, an H-share listed company shall file the application with the CSRC according to the administrative filing procedures necessary for the Overseas Listing Trial Measures.

REGULATORY OVERVIEW IN THE UK

Regulations on Medical Devices in the UK

The Medicines and Healthcare Products Regulatory Agency ("**MHRA**") performs market surveillance of medical devices on the UK market and is able to take decisions over the marketing and supply of devices in the UK. The MHRA is responsible for the designation and monitoring of UK conformity assessment bodies.

Summary of Key Requirements for Placing a Device on the Great Britain Market

(1) a new route to market and product marking (the UKCA marking) is available for manufacturers wishing to place medical devices on the Great Britain market

(2) all medical devices, including IVD medical devices ("**IVDs**"), custom-made devices and systems or procedure packs, need to be registered with the MHRA before they are placed on the Great Britain market

(3) if you are a medical device manufacturer based outside the UK and wish to place a device on the Great Britain market, you need to appoint a single UK Responsible Person for all of your devices, who will act on your behalf to carry out specified tasks, such as registration.

A valid CE mark is a CE marking that enables the medical device to be placed on the EU market.

Legislation that Applies in Great Britain

Devices are regulated under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) ("**UK MDR 2002**") which, prior to the end of the transition period (following the UK's departure from the EU), gave effect in UK law to the directives listed below:

- Directive 90/385/EEC on active implantable medical devices
- Directive 93/42/EEC on medical devices
- Directive 98/79/EC on in vitro diagnostic medical devices

This means that the current Great Britain route to market and UKCA marking requirements are based on the requirements derived from the above EU legislation.

Requirements for Manufacturing and Supplying Services in Great Britain

Manufacturers wishing to place a device on the Great Britain market need to register with the MHRA. Where a manufacturer is not established in the UK, they must appoint a UK Responsible Person to register and act on their behalf. Manufacturers must comply with relevant product marking and conformity assessment requirements for medical devices.

Registrations in Great Britain

The government has put in place legislation to extend acceptance of CE marked devices in Great Britain beyond 30 June 2023 as outlined in the summary above.

All medical devices, including IVDs, custom-made devices and systems or procedure packs must be registered with the MHRA before being placed on the Great Britain market. In Great Britain, devices will be required to conform to the UK MDR 2002, with transitional arrangements for acceptance of CE marked medical devices as set out above, in order to be registered with the MHRA.

The MHRA will only accept registration of devices from manufacturers where the manufacturer is based in the UK. If the manufacturer is based outside the UK, they must appoint a UK Responsible Person. This UK Responsible Person will then assume certain responsibilities on behalf of the manufacturer as described below in the guidance for UK Responsible Persons, including registering the device with the MHRA.

Failure to register the devices will mean that manufacturers are unable to lawfully place the device on the Great Britain market.

If the manufacturer is a Northern Ireland-based manufacturer and has already registered the device with the MHRA for the purposes of the Northern Ireland market, it can then be placed on the Great Britain market and will not need to undergo any further registration in Great Britain.

UKCA Mark and Conformity Assessment Bodies

UKCA Marking

The UK Conformity Assessed ("**UKCA**") marking is a UK product marking used for certain goods, including medical devices, being placed on the Great Britain market. The UKCA marking is not recognised in the EU, EEA or Northern Ireland markets, so relevant products require a CE marking for sale in these markets.

Manufacturers of medical devices can use either the UKCA marking or the CE marking on devices they place on the Great Britain market until 30 June 2023. The government has introduced measures to extend acceptance of CE marked devices in Great Britain beyond 30 June 2023 as outlined in the summary above.

Where third party conformity assessment is required for UKCA marking, a UK Approved Body is needed. However, manufacturers of non-sterile and non-measuring Class I devices and general IVDs can self-certify against the UKCA marking.

UKCA marking requirements are currently based on the requirements of the relevant Annexes to the Directives listed below, which have been modified by Schedule 2A to the UK MDR 2002:

- Directive 90/385/EEC on active implantable medical devices
- Directive 93/42/EEC on medical devices
- Directive 98/79/EC on in vitro diagnostic medical devices

Class I Medical Device and General IVD Manufacturers

Manufacturers of Class I medical devices and general IVDs can self-declare the conformity of their devices against the UK MDR 2002, before affixing a UKCA marking and placing the device on the Great Britain market.

Manufacturers of Class I medical devices that are sterile or have a measuring function must use a UK Approved Body to undertake third party conformity assessment in order to affix the UKCA marking and place their devices on the Great Britain market.

CE marking and Notified Bodies

Recognition of CE Certificates for the Great Britain Market

In addition to the UKCA marking regime, the UK government currently recognises certain CE-marked devices under transitional arrangements.

Currently, under the UK MDR 2002, a CE marked device with a valid certificate is viewed as meeting the UKCA marking requirements whilst the CE marking continues to be recognised in Great Britain — depending on the type of device and legislation it complies with this is until 30 June 2030 at the latest. This includes devices placed on the market that:

- were CE marked in accordance with the EU MDD or EU AIMDD (prior to 26 May 2021), or in accordance with the EU IVDD (prior to 26 May 2022);
- are CE marked in accordance with the EU MDR or EU IVDR

As set out above in more detail, the government has introduced measures to extend acceptance of CE marked medical devices in Great Britain beyond 30 June 2023.

Therefore, any enforcement or market surveillance powers available in respect of the UKCA marking also apply to CE marked devices placed on the Great Britain market.

Labelling Requirements

Medical devices placed on the Great Britain market must have a UKCA marking or a CE marking, depending on which legislation the device has been certified under.

Where relevant, the number of the Approved Body or Notified Body must also appear on the label.

Devices can have both the CE and UKCA markings present on the labelling. However, the name and address of the UK Responsible Person, where applicable, needs to be included on product labelling or the outer packaging, or the instructions for use in cases where the UKCA marking has been affixed (including when devices have been dual marked).

Post-market surveillance and vigilance

Once a medical device has been placed on the UK market, the manufacturer is required to submit vigilance reports to the MHRA when certain incidents occur in the UK that involve their device. They must also take appropriate safety action when required. The manufacturer must ensure their device meets appropriate standards of safety and performance for as long as it is in use.

The notification and evaluation of adverse incidents and field safety corrective actions involving medical devices is known as the medical device vigilance system.

Reporting Obligations

The requirement to report falls to the manufacturer, the UK Responsible Person, and the Authorised Representative based in Northern Ireland.

The manufacturer, UK Responsible Person or Authorised Representative shall notify the MHRA about incidents and FSCAs which meet the reporting criteria; this includes Periodic Summary Reports and Trend Reports.

The manufacturer has the responsibility for investigating incidents and for taking any corrective action necessary.

Where an incident occurs from the combined use of two or more separate devices (and/or accessories) that different manufacturers make, each manufacturer (or their UK Responsible Person or Authorised Representative) should submit a report to the MHRA.

The manufacturer should notify the MHRA immediately upon becoming aware that one of its devices may have caused or contributed to an event meeting the above criteria.

If after becoming aware of a potentially reportable incident it is unclear whether the event meets the reporting criteria above, the manufacturer must submit a report within the relevant timeframe.

Waste Electrical and Electronic Equipment

Electrical and electronic equipment ("**EEE**") is regulated to reduce the amount of waste electrical and electronic equipment ("**WEEE**") incinerated or sent to landfill sites.

Reduction is achieved through various measures which encourage the recovery, reuse and recycling of products and components.

The Waste Electrical and Electronic Equipment Regulations 2013 (as amended) is the underpinning UK legislation.

Medical device manufacturing generally falls under the WEEE regime, with some specific exceptions. Penlon manufactures display equipment, which can be categorised as a producer.

Producer obligations

Register as a producer annually. How producers do this depends on how much EEE they have placed on the UK market in the previous calendar year (also known as a compliance year):

- if they place less than 5 tonnes of EEE on the UK market in a compliance year, they can register directly with their environmental regulator as a small producer

- if they place more than 5 tonnes of EEE on the market, they must join a producer compliance scheme ("**PCS**")

The PCS takes on their obligations to finance the collection, treatment, recovery and environmentally sound disposal of household WEEE collected in the UK.

Patents, Trademarks and Designs

Patents

In the UK, patents are subject to the Patents Act 1977 (PA 1977). The Act came into force on 1 July 1978 and, as patents last for 20 years, it now governs all UK patents still in force.

Patents in the UK, as in the European Economic Area ("**EEA**"), have a duration of 20 years from their filing date, subject to payment of renewal fees and not being invalidated.

Patent law in the UK conforms to the standards imposed by the Paris Convention, TRIPS and the EPC. A patent may only be granted for an invention if that invention fulfils all the following criteria: (i) it is new; (ii) it involves an inventive step; (iii) it is capable of industrial application; and (iv) it is not specifically excluded from protection as a patent. (Section 1, PA 1977.)

Trademark

The law relating to UK registered trade marks is contained primarily in the Trade Marks Act 1994 ("**TMA**"), which implemented the 2008 Trade Marks Directive (2008/95/EC) and its successor, the 2015 Trade Marks Directive (2015/2436). The UK trade marks register is administered by the registrar of trademarks from within the UK Intellectual Property Office.

Design

The principal statute governing registered designs in the UK is the Registered Designs Act 1949 ("**RDA 1949**"). Following the end of the Brexit UK-EU transition period, further amendments were made to the RDA 1949 to accommodate the revised designs landscape. The principal change was the introduction of the re-registered design to compensate holders of rights in the unitary EU registered Community designs ("**RCDs**") for the loss of the rights in the UK. Essentially, re-registered designs are treated like UK registered designs.