This section sets forth a summary of the most significant aspects of laws and regulations relating to our business operations in PRC or our shareholders' rights to receive dividends and other distributions from us.

GENERAL REGULATORY FRAMEWORK

Infusion sets and joint implants are subject to regulatory controls governing medical devices. Manufacturers of medical devices are subject to regulation and oversight by the CFDA, and its relevant local branches. We are also subject to other PRC laws and regulations applicable to manufacturers in general. CFDA requirements include obtaining production permits, product registrations and compliance with clinical testing standards, manufacturing practices, pricing practices, quality standards, applicable industry standards, reporting procedures with respect to adverse events reporting, and advertising and packaging standards.

CLASSIFICATION OF MEDICAL DEVICES

In China, medical devices are classified into three different categories, Classes I, II and III, depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. The class to which a medical device is assigned determines, among other things, whether a manufacturer needs to obtain a production permit and the level of regulatory authority involved in granting such permit. The classification of a medical device also determines the types of product registration certificates required and the level of regulatory authority involved in granting the product registration certificates.

Class I devices are those with low risk to the human body and are subject to "general controls." Product registration certificates for Class I devices are regulated and granted by the city-level food and drug administration where the manufacturer is located. Class II devices pose medium risk to the human body and are subject to "special controls." Product registration certificates for Class II devices are regulated and granted by the provincial food and drug administration where the manufacturer is located, usually through a quality system assessment. Class III devices impose high risk to the human body, such as life-sustaining, life-supporting and implantable devices. Product registration certificates for Class III devices are regulated and granted by the CFDA under the strictest regulatory control.

Our orthopedic implant and infusion set products are both Class III devices.

PRODUCTION PERMIT

Pursuant to the Regulations on the Supervision of Medical Devices (《醫療器械監督管理條例》), in addition to the required product registration certificates, a manufacturer must obtain a production permit from the respective level of food and drug administration before commencing the manufacture of Classes II and III medical devices. In general, the SAIC and/or its local branches will not issue a business license to a manufacturer of Classes II and III medical devices before it has obtained a production permit. Accordingly, a manufacturer will not be able to commence any business operations without a production permit. No production permit is required for the manufacture of Class I devices; however, the manufacturer must notify the provincial level food and drug administration where the manufacturer is located and file for record with it.

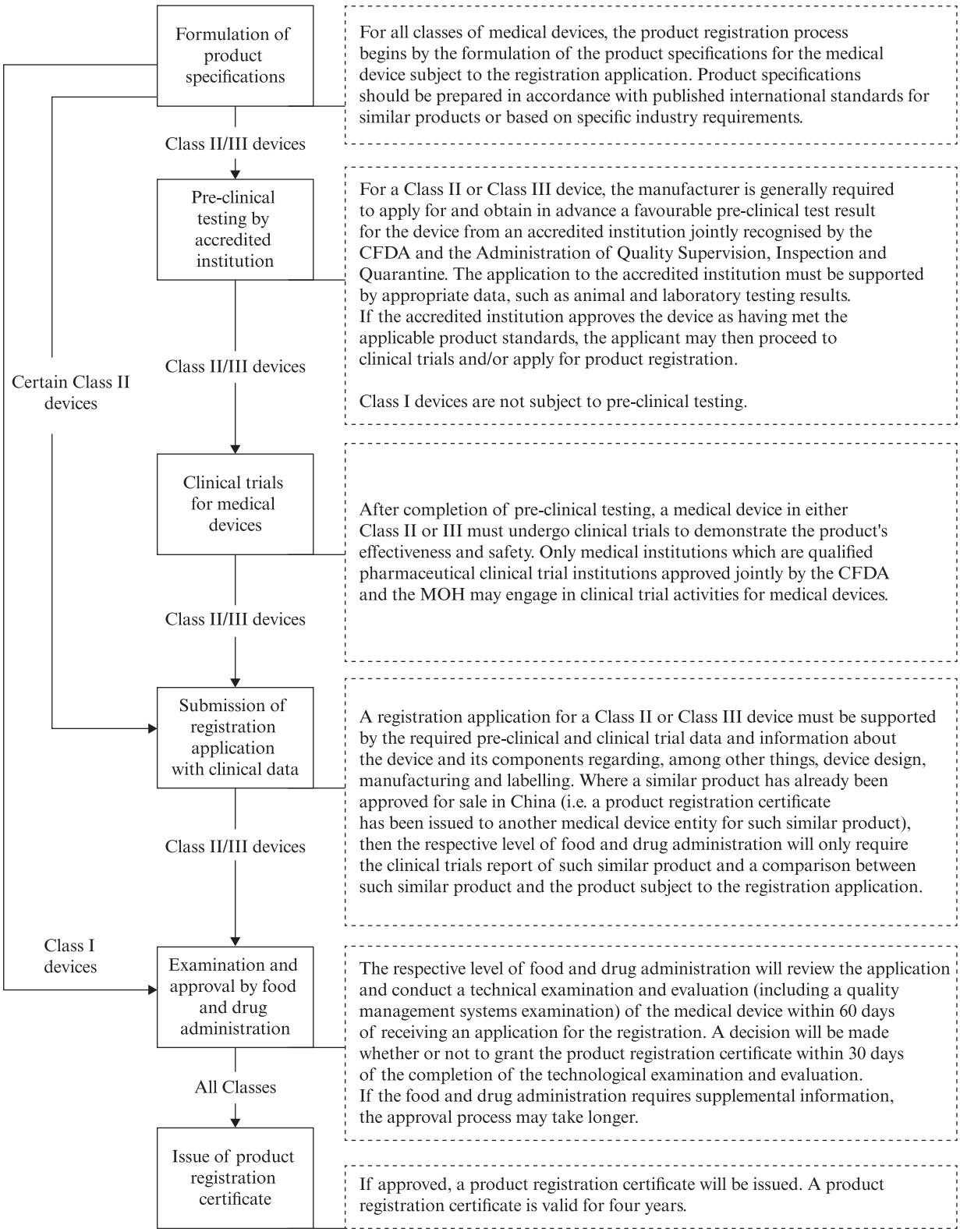
An application for the production permit for a Class II medical device is made to the provincial level food and drug administration, and will be reviewed based on a number of criteria including the qualifications of the individuals in charge of production, quality and technology; the ratio of technicians to general staff; the location, suitability and overall conditions of the production facility and warehouse; and the quality control system and capabilities of the manufacturer.

An application for the production permit of a Class III medical device is also reviewed by the provincial level food and drug administration, but subject to further criteria which primarily require an even more stringent quality control system having been put in place. A production permit, once obtained, is valid for five years and is renewable upon expiration.

PRODUCT REGISTRATION FOR MEDICAL DEVICES

Pursuant to the Administrative Measures for the Registration of Medical Devices (《醫療器械註冊管理辦法》) promulgated by the CFDA effective August 9, 2004, before a medical device can be manufactured for commercial distribution, a manufacturer must register and obtain a registration certificate for the medical device by proving its safety and effectiveness to the satisfaction of the respective levels of the food and drug administration. Domestically manufactured Class III devices are subject to direct review by the CFDA whereas Classes I and II devices are reviewed and approved by the provincial and local food and drug administration, respectively.

The following diagram sets out the typical application procedures for registering a medical device:



DISTRIBUTION LICENSE

A distributor must undergo examination and approval procedures and obtain a distribution license in order to engage in the sales and distribution of Classes II and III medical devices in China. A distribution license is valid for five years and is renewable upon expiration.

TENDERING PROCESSES FOR MEDICAL DEVICES

Centralized procurement processes are required for medical devices. On June 21, 2007, the MOH issued 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》), which requires that all non-profit medical institutions under all levels of government and state-owned enterprises participate in the centralized procurement. Public tendering shall be the principal method of centralized procurement. On February 28, 2011, the General Office of the State Council issued the 2011 Pilot Reform Arrangement of Public Hospitals (《2011年公立醫院改革試點工作安排》), which provides that tendering process, which is one of the centralized procurement methods, be applied to implantable (invasive) medical consumables.

We are subject to the regulations on centralized procurement processes. On December 17, 2012, the MOH and five other related governmental authorities issued the Administrative Norms on Centralized Procurement of High Value Medical Consumables (for Trial Implementation) (《高值醫用耗材集中採購工作規範(試行)》), which allows manufacturers of medical consumables to bid directly with hospitals during the process of centralized procurement and in accordance with the requirements of the centralized procurement documents. Such manufacturers are required to truthfully furnish, on the centralized procurement system, letters of authorization and qualification certificates of products and enterprises, which are authentic, effective and valid, ex-factory prices for the past two to three years, supply-guarantee letters, and lists of authorized dealers.

The government agencies in charge of centralized procurement in each province, autonomous region and municipality are also responsible for producing the catalogues of centralized procurement, which are effective within their respective jurisdictions. Each province may also explore and set its own methods of centralized procurement based on local practices.

CONTINUING CFDA REGULATION

We are subject to continuing regulation by the CFDA. Our products are subject to, among others, the following regulations:

Renewal of Permits and Certificates

Production permits are valid for five years from their issuance date while product registration certificates expire after four years. An application for renewal of these permits and certificates must be made with the respective food and drug administration within the prescribed timeframe prior to their expiry. Failure to renew the relevant permit and/or certificate on time may result in fines being imposed by the CFDA or revocation of the permit and/or certificate. If production of a particular medical device has stopped for two consecutive years or more, the product registration certificate will no longer be renewable. Anyone who wishes to resume production of such device in China must apply for a new product registration certificate afresh.

Changes to Content of Permits and Certificates

Any changes to the contents or particulars stated in the production permit must be reported to the CFDA.

Similarly, if any of the contents stated in the product registration certificate is changed, an application for the modification or re-registration of the product registration certificate must be filed with the CFDA within 30 days after the change occurs. In the event of significant modification to an approved medical device, such as changes to (i) the model and specification of the device; (ii) location of the production facility; (iii) product standards; (iv) function, structure and composition of the device, or (v) application scope of the device, a re-registration may be required. A modification filing will be sufficient with respect to changes of a minor nature, such as changes to the device name.

Other Ongoing Regulations

We are subject to continuing regulation by the CFDA. Our products are subject to, among others, the following regulations:

- the CFDA's quality system regulations which require medical device manufacturers to create, implement and follow certain design, testing, control, documentation and other quality assurance procedures;

- the CFDA's quality surveillance system which imposes mandatory adverse event monitoring and reporting obligations on medical device manufacturers, distributors and medical institutions. Such entities are required to set up an adverse event monitoring system, which shall include the maintenance of a logbook recording

incidents of adverse reaction and other events involving their products. They must also comply with various reporting obligations to the relevant authorities. For example, manufacturers of Classes II and III medical devices are required to file an annual adverse event report to the provincial level adverse event monitoring authorities reporting on any recently occurred adverse event incidents; and

- according to "Medical Device Recall Management Measures (for Trial Implementation)" (《醫療器械召回管理辦法(試行)》) issued by the MOH, medical device manufacturers should immediately decide to make a voluntary recall when a defective product was found in defect investigation.

Further, Classes II and III devices may also be subject to special controls applicable to them, such as supply purchase information, performance standards, quality inspection procedures and product testing devices which may not be required for Class I devices.

We are also subject to inspection and market surveillance by the CFDA to determine compliance with regulatory requirements. The CFDA is empowered to institute a number of enforcement actions, including:

- fines, injunctions and civil penalties;
- mandatory recall or seizure of our products;
- the imposition of operating restrictions, partial suspension or complete shutdown of production; and
- criminal prosecution.

GOOD MANUFACTURING PRACTICES

The CFDA issued the "Good Manufacturing Practice for Medical Apparatus and Instruments (for Trial Implementation)" (the "GMP") in December 16, 2009. The GMP came into operation in January 1, 2011 with two relevant standards — "Implementation Regulations on Criterions for the Quality Control of Implanted Medical Devices Manufacturing (for trial implementation)" and "Implementation Regulations on Criterions for the Quality Control of Sterilised Medical Devices Manufacturing (for Trial Implementation)." Manufacturing companies are required to comply with the newly established GMP standard.

QUALITY CONTROL OF CLASS III MEDICAL DEVICES

The rules and regulations regarding quality control of Class III of medical devices primarily include the following:

- On August 9, 2004, the China Food and Drug Administration issued the Measures for the Administration of Medical Device Registration (《醫療器械註冊管理辦法》), which provides that "Class III medical devices are subject to registration tests by the medical device test organizations recognized by the SFDA and the General Administration of Quality Supervision, Inspection and Quarantine. Such medical devices shall be proved to conform to the applicable product standards through tests before the medical devices are used for clinical trial or an application is submitted for registration."

- On July 23, 2008, the China Food and Drug Administration issued the Provisions on Enhance and Regulate the Registration Administration of Medical Devices (《關於進一步加強和規範醫療器械註冊管理的暫行規定》), which provides that during the checking process of the quality management system, the Food and Drug Administrations of all the provinces shall check the application documents (especially the clinical trial report) and producing processes of samples submitted by the applicants, and the SFDA shall inspect the checking results of the application documents mentioned above if necessary.

PRODUCT LIABILITY AND CONSUMER PROTECTION

Product liability claims may arise if the products sold have any harmful effect on consumers. The injured party can claim for damages or compensation. The General Principles of the Civil Law of China (《民法通則》), which became effective on January 1, 1987 amended on August 27, 2009, states that manufacturers and sellers of defective products causing property damage or injury shall incur civil liabilities.

The Product Quality Law of the PRC (《中華人民共和國產品質量法》) was enacted in 1993 and amended in 2009 to strengthen quality control of products and reinforce consumers' rights. Under this law, manufacturers and operators who produce and sell defective products may be subject to confiscation of earnings from such sales, the revocation of business licenses and imposition of fines, and in severe circumstances, may be subject to criminal liability.

Product Liability

The PRC Tort Law (《中華人民共和國侵權責任法》) was promulgated on December 26, 2009 and came into effect on July 1, 2010. Under this law, a patient who suffers injury from a defective medical device can claim for damages from either the medical institution or the manufacturer. If the patient claims for damages from the medical institution, the medical institution has the right to claim for repayment from the manufacturer.

The PRC Law on the Protection of the Rights and Interests of Consumers (《中華人民共和國消費者權益保護法》) was promulgated on October 31, 1993 and enacted from January 1, 1994 amended on August 27, 2009 to protect consumers' rights when they purchase goods or services. All business operators must comply with this law when they manufacture or sell goods and/or provide services to customers. In some cases, medical device manufacturers and distributors may be subject to criminal liability if their goods or services lead to the death or injuries of patients or other third parties.

OTHER REGULATIONS

Laws regulating medical device manufacturers and distributors cover a broad array of subjects. We must comply with numerous additional state and local laws relating to matters such as safe working conditions, manufacturing practices, environmental protection and fire hazard control.