This section sets out summaries of certain aspects of laws and regulations in the PRC and Macau, which are relevant to our Group's operation and business.

## LAWS AND REGULATIONS IN THE PRC

### Establishment, Operation and Management of a Foreign-invested Enterprise

The establishment, operation and management of corporate entities in China are governed by the PRC Company Law, which was adopted by the Standing Committee of the National People's Congress* (全國人民代表大會常務委員會) on 29 December 1993. It was last amended on 27 October 2005 and became effective on 1 January 2006. The PRC Company Law governs the establishment, corporate governance, share transfer, merger, division, change of registered capital and other aspects of companies. Foreign-invested companies are subject to the PRC Company Law. However, where laws on foreign investment have other stipulations, such stipulations shall apply.

Certain aspects including approval procedures and foreign exchange matters of a wholly foreign-owned enterprise are also regulated by the Foreign-invested Enterprise Law of the PRC* (《中華人民共和國外資企業法》) (the "**Foreign-invested Enterprise Law**"), which was promulgated on 12 April 1986 and amended on 31 October 2000, and the Implementation Regulations of the Foreign-invested Enterprise Law* (《中華人民共和國外資企業法實施細則》), which was promulgated on 12 December 1990 and amended on 12 April 2001.

Investment in the PRC conducted by foreign investors is governed by the Guidance Catalogue of Industries for Foreign Investment* (《外商投資產業指導目錄》) (the "**Catalogue**"), as amended from time to time, of which the latest edition was promulgated by MOFCOM and the NDRC of the PRC* (中華人民共和國國家發展和改革委員會) (the "**NDRC**") on 31 October 2007. The Catalogue is a tool that relevant PRC administrative authorities have used to manage and direct foreign investment. The Catalogue divides industries into three basic categories: encouraged, restricted and prohibited. Industries not listed in the Catalogue are generally open to foreign investment unless specifically barred in other PRC laws and regulations.

Foreign-invested enterprises fall in the encouraged category and in the restricted category may be limited to sino-foreign equity or contractual joint ventures, in some cases with the requirement that the Chinese partner shall be the majority shareholder. Investing in the restricted category may also be subject to higher-level government approvals. Industries in the prohibited category are closed to foreign investment.

### Importation and Exportation of goods

Pursuant to the Foreign Trade Law of the PRC* (《中華人民共和國對外貿易法》) (the "**Foreign Trade Law**"), which was promulgated on 12 May 1994 and amended on 6 April 2004 and effective from 1 July 2004, and relevant laws and regulations, foreign trade dealers engaged in import or export of goods or technologies shall register with the MOFCOM or its authorized institutions unless laws, regulations and rules promulgated by MOFCOM

provide that such registration is not required. Where foreign trade dealers fail to register as required, relevant PRC Customs shall not conduct the procedures of declaration, examination and release of the imported or exported goods.

Pursuant to the Administrative Provisions of the Customs for the Registration of Customs Declaration Units* (《中華人民共和國海關對報關單位註冊登記管理規定》), which was promulgated on 31 March 2005 and effective from 1 June 2005, as one type of declaration units, "consignee or consignor of import or export goods" is defined as any legal person, other organization or individual within the customs territory of the PRC that directly imports or exports goods in accordance with relevant provisions. Consignee or consignor of import or export goods shall register with local PRC Customs. After registering with relevant PRC Customs, consignee or consignor of import or export goods may handle their own declarations at any customs port or locality where customs supervisory affairs are concentrated within the customs territory of the PRC. A declaration registration certificate for the consignee or consignor of import or export goods issued by relevant PRC Customs shall be valid for a period of three years. The enterprise engaging in import and export goods as consignee and consignor shall renew such certificate with relevant customs 30 days ahead of the expiry date.

**Taxation**

*Enterprise income tax and withholding tax*

On 1 January 2008, the new Enterprise Income Tax Law of the PRC* (《中華人民共和國企業所得税法》) (the "**New Enterprise Income Tax Law**") and its implementing rules became effective. According to the New Enterprise Income Tax Law, a unified enterprise income tax ("**EIT**") rate of 25% applies to both domestic enterprises and foreign-invested enterprises. The Notification of the State Council on Carrying out the Transitional Preferential Policies concerning Enterprise Income Tax* (《國務院關於實施企業所得税過渡優惠政策的通知》), which was promulgated and became effective on 26 December 2007, further clarifies that from 1 January 2008, the enterprises that enjoyed a "two-year exemption and three-year half payment" of EIT and certain other tax reduction or exemptions with a specified period according to the then applicable tax laws, administrative regulations and relevant documents may, after the enactment of the New Enterprise Income Tax Law, continue to enjoy such benefits until the expiration of the applicable period. Enterprises whose preferential tax treatment have not commenced due to the fact that no profits had been generated in previous years shall enjoy such preferential tax treatment from 1 January 2008 until the expiry of relevant period.

In addition, pursuant to the New Enterprise Income Tax Law and its implementation rules and the Implementation Regulations for Special Tax Adjustments (Trial)*, (《特別納税調整實施辦法(試行)》 ), transactions in respect of the purchase, sale and transfer of products between, amongst others, enterprises under direct or indirect control by the same third party are regarded as related parties transactions. According to such laws and regulations, related parties transactions should comply with the arm's length principle (獨立交易原則); and if the failure of compliance with such principle results in reducing the income or taxable income of the enterprise or its related parties, the tax authority has the

power to make an adjustment in accordance with reasonable methods within a maximum of 10 years' time. Pursuant to such laws and regulations, any company entering into related party transactions with another company shall submit an annual related party transactions reporting form to the supervising tax authority.

Also, the New Enterprise Income Tax Law and its implementation rules stipulate that if an entity is deemed to be a non-PRC resident enterprise without an office premises in the PRC, withholding tax at the rate of 10% will be applicable to any dividends paid to it by its PRC subsidiaries, unless it is entitled to a reduction or exemptions of such tax, including by tax treaties. The PRC and the government of Hong Kong signed the Arrangement between the Mainland of the PRC and Hong Kong for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income* (《內地和香港特別行政區關於對所得稅避免雙重徵稅和防止偷漏稅的安排》) (the "**Arrangement**") on 21 August 2006. According to the Arrangement, a 5% withholding tax rate applies to dividends paid by a PRC company to a Hong Kong tax resident, provided that such Hong Kong tax resident directly holds at least 25% of the capital of such PRC company, and a 10% withholding tax rate applies if otherwise.

According to the Notice on Issues Regarding the Enforcement of Dividend Articles in Tax Treaties* (《國家稅務總局關於執行稅收協定股息條款有關問題的通知》) promulgated by the State Administration of Taxation (the "**SAT**") on 20 February 2009, to apply the dividend articles in relevant tax treaties including the Arrangement, certain requirements shall be satisfied, among which: (1) the taxpayer entitled to the preferential tax rate(s) shall be a tax resident under the tax treaties and shall be the "beneficial owner" of the dividends it receives; (2) where the dividend articles provide a preferential tax rate for the taxpayer directly holding a certain percentage (usually at least 25% or 10%) of share capital of a PRC company, such taxpayer must be a company and must satisfy such direct ownership thresholds at all times during the 12 consecutive months preceding the receipt of the dividends. The SAT further promulgated the Notice on How to Understand and Recognize the "Beneficial Owner" in Tax Treaties* (《國家稅務總局關於如何理解和認定稅收協定中「受益所有人」的通知》) on 27 October 2009, which defines the "Beneficial Owner" as individuals, enterprises or other organizations normally engaged in substantive operations, and sets forth certain adverse factors on the recognition of "beneficial owner". On 24 August 2009, the SAT issued the Administrative Measures for Non-resident Enterprises to Enjoy Treatments under Tax Treaties (For Trial Implementation)* (《國家稅務總局關於印發〈非居民享受稅收協定待遇管理辦法(試行)〉的通知》), effective on 1 October 2009, which require the non-resident enterprises to obtain the approval for enjoying the treatments under tax treaties from the competent tax authority.

Moreover, the Circular of the SAT on Strengthening the Administration of Enterprise Income Tax on Incomes from Non-resident Enterprises' Equity Transfers* (《國家稅務總局關於加强非居民企業股權轉讓所得企業所得稅管理的通知》) (the "**Circular 698**") was promulgated by SAT on 10 December 2009 and effective from 1 January 2008. According to the Circular 698, "equity transfer income" used in it refers to the income obtained by the non-resident enterprises from their transfers of the equity of PRC resident enterprises (excluding the stocks of PRC resident enterprises that are traded in the open securities markets). And where the withholding agent fails to withhold in accordance with relevant

provisions or is unable to perform the withholding obligation, the non-resident enterprise shall report and pay the EIT to the competent tax authorities where the PRC resident enterprise whose equity has been transferred within seven days upon the date of equity transfer as agreed in relevant contracts and/or agreements (where the transferring party obtains the equity transfer income in advance, the date of actual obtaining of equity transfer income shall prevail). Where the non-resident enterprise fails to report on time faithfully, the relevant provisions of administration law of tax collection shall apply. In addition, where the non-resident enterprise transfers the equity of a PRC resident enterprise to its related party and the transfer price thereof is not in consistent with the independent transaction principle and thus the taxable income amount is reduced, the tax authorities shall have the right to adjust the same in light of reasonable methods. Foreign investor's indirect transfer of the equity of a PRC resident enterprise via disposing the equity of an overseas holding company may also be subject to the Circular 698 under certain circumstances.

*Value-added tax*

Pursuant to the Provisional Regulations on Value-added Tax of the PRC* (《中華人民共和國增值税暫行條例》) which became effective on 1 January 2009 and relevant rules, all units or individuals in the PRC engaging in the sale of goods, the provision of processing, repairs and replacement services, and the importation of goods are required to pay value-added tax ("**VAT**"). VAT payable is calculated on the basis of "output VAT" minus "input VAT". The rate of VAT is 17% for those engaging in the sale or importation of goods except otherwise provided in the Provisional Regulations on Value-added Tax of the PRC and relevant rules and is 17% for those providing processing, repairs and replacement services.

*Transfer Pricing Contemporaneous Documentation Requirement*

The SAT issued the Administrative Regulation for Special Tax Adjustments (For Trial Implementation)* (特別納税調整實施辦法(試行)) (the "**STA Rules**") on 8 January 2009, which took effect retrospectively from 1 January 2008. According to the STA Rules, the New Enterprise Income Tax Law and its implementing rules, enterprises should prepare and maintain contemporaneous documents regarding related party transactions for each taxable year and submit them to competent tax authorities at their request. The contemporaneous documents mainly include information regarding organizational structure, overview of business operations, information regarding related party transactions, comparability analysis and selection and application of transfer pricing methodologies. Enterprises which meet one of the following standards are exempt from preparing contemporaneous documents: (1) the annual amount of related party purchase/sales is lower than RMB200 million and the annual amount of other related party transactions is lower than RMB40 million; (2) related party transactions are covered under an effective advance pricing arrangement; or (3) foreign shareholding percentage is lower than 50% and the related party transactions only incur among domestic associated parties. Except as otherwise stipulated by the STA Rules, enterprises should complete the preparation of contemporaneous documents for the current year before 31 May of the following year and submit the documents within 20 days upon request from tax authorities.

**Foreign Currency Exchange**

According to the Foreign Exchange Administration Rules of the PRC* (《中華人民共和國外匯管理條例》) (the "**Foreign Exchange Administration Rules**") which was promulgated by the State Council of the PRC* (中華人民共和國國務院) on 29 January 1996, amended on 14 January 1997 and further amended and became effective on 1 August 2008. Under the Foreign Exchange Administration Rules and the Administrative Provisions on the Settlement, Sale and Payment of Foreign Exchange* (《結匯、售匯及付匯管理規定》) which was implemented on 1 July 1996 and other relevant provisions, Renminbi is generally convertible for payments of current account items without the approval of foreign exchange administrative authorities, such as trade and service-related transactions (by providing commercial documents evidencing such transactions) and dividend payments made by foreign-invested enterprises (by providing certain evidencing documents such as board resolutions), but only convertible upon the approval of the relevant foreign exchange administrative authorities and approval or file with the relevant governmental authorities (where necessary) for capital account items, such as the transfer of foreign currency capital of foreign-invested enterprises, foreign institutions' and foreign individuals' direct investment in PRC, PRC institutions' and PRC individuals' offer and/or transaction of securities, derivative products and foreign loan. Foreign-invested enterprises are also allowed to retain foreign currency income under current account items (subject to a cap approval by relevant foreign exchange administrative authorities).

**Apply net proceeds from the Global Offering in the PRC**

According to Foreign Exchange Administration Rules, its relevant implementation rules and guidelines, other relevant PRC laws and regulations and requirements of PRC governmental authorities and their relevant branches, subject to conditions, proceedings and requirements prescribed therein, a foreign investor may apply its foreign exchanges (such as net proceeds from the global offering) in the PRC by the following methods: (i) increasing the registered capital of its PRC subsidiaries; (ii) establishing a new PRC subsidiary; (iii) acquiring equity interests in the other companies in the PRC; and/or (iv) providing shareholder loans to its qualified subsidiaries in the PRC in an amount not exceeding the difference between the investment amount and the registered capital of such subsidiary. However, both the total investment amount and the registered capital of Huizhou Junyang is USD5,000,000; and both the total investment amount and the registered capital of Chum Baokang Medical is HK$1,200,000. If Huizhou Junyang or Chum Baokang Medical intends to use the net proceeds from the Global Offering through obtaining shareholder loans from our offshore subsidiary, the Group may have to adjust such total investment amount and the registered capital according to relevant PRC laws, regulations and regulatory rules. Our PRC Legal Advisers are of the view that if our Company's PRC subsidiaries, their shareholders and other relevant parties meet all statutory conditions and requirements, including but not limited to requirements and conditions of competent branch of NDRC, MOFCOM and/or SAFE, after completion of all approval, registration, filing or other relevant statutory and administrative procedures required by relevant PRC laws, regulations and rules, there will be no material legal impediment for our Company to apply the net proceeds from the Global Offering in the PRC by the four methods mentioned above.

**Product Quality**

The Product Quality Law of the PRC* (《中華人民共和國產品質量法》) (the "**Product Quality Law**"), which was promulgated on 22 February 1993, amended on 8 July 2000 by the Standing Committee of the National People's Congress and implemented on 1 September 2000.

The Product Quality Law is applicable to activities of production and sale of any product within the territory of the PRC, and the producers and sellers shall be liable for product quality responsibilities in accordance with the Product Quality Law. Moreover, products that may endanger the health of people and the safety of person and property shall be subject to random inspections conducted by relevant administrative authorities.

**Consumer Protection**

The Law on the Protection of the Rights and Interests of Consumers of the PRC* (《中華人民共和國消費者權益保護法》) (the "**Consumer Protection Law**") was promulgated on 31 October 1993 and implemented on 1 January 1994 by the Standing Committee of the National People's Congress.

The Consumer Protection Law sets out the rights of consumers and the obligations of sellers. According to the Consumer Protection Law, the rights and interests of consumers when purchasing or using commodities or receiving services include the right that the safety of person and property will not be harmed, the right to know the facts concerning commodities purchased and used or services received, and the right to fair dealing, and so on. All manufacturers and distributors involved must ensure that the commodities and services provided meet the standards of safeguarding the safety of person and property.

**Anti-Monopoly Law**

Pursuant to the Anti-Monopoly Law of PRC* (《中華人民共和國反壟斷法》) (the "**Anti-Monopoly Law**"), "dominant market position" shall refer to a position where an operator may control the prices of commodities, their quantity, and other terms of transaction within relevant markets, or obstruct or otherwise effect the entrance of other operators into relevant markets. Operators who is in a dominant market position shall be prohibited from engaging in such practices which may be classified as an abuse of said position as selling products at unfairly high or purchasing at unfairly low prices, selling products at a price lower than cost without just cause, refusing to conduct transactions with the counter party without just cause, forcing the counter party to conduct transactions only with itself or operators designated by it without just cause, conducting tie-in sales or adding other unreasonable conditions in a transaction without just cause, discriminating between trading counter parties of the same qualifications without just cause, or other activities recognized by the anti-monopoly authorities as abuse of dominant market position.

Furthermore, where an operator violates the provisions of the Anti-Monopoly Law by abusing their dominant market position, the anti-monopoly authorities shall order a termination of relevant activities, confiscate the illegal earnings, and impose a fine of between 1% and 10% of the previous year's sales income.

**Anti-Unfair Competition Law**

The principal legal provisions governing the competition among the business operators are set out in the Anti-Unfair Competition Law of the PRC* (《中華人民共和國反不正當競爭法》) (the "**Anti-Unfair Competition Law**"). According to the Anti-Unfair Competition Law, operators shall follow the principle of voluntariness, equality, fairness, honesty and good faith, and observe generally recognized business ethics. And acts of operators in violation of the Anti-Unfair Competition Law, with a result of damaging the legal rights and interests of other operators, and disturbing the socio-economic order shall constitute unfair competition. Where an operator commits unfair competition in violation of the Anti-Unfair Competition Law and causes damage to other operator, it or he shall bear the responsibility for compensating for the damages caused. Where the losses suffered by such other operator are difficult to calculate, the amount of damages shall be the profit gained by the infringer during the period of infringement through the infringing act. The infringer shall also bear all reasonable costs paid by such other operator in investigating the unfair competition activities committed.

**Environmental Protection**

The major PRC environmental regulations applicable to us include the Environmental Protection Law of the PRC* (《中華人民共和國環境保護法》) (the "**Environmental Protection Law**") promulgated and implemented by the Standing Committee of the National People's Congress on 26 December 1989, the Law of the PRC on Prevention and Control of Water Pollution* (《中華人民共和國水污染防治法》) implemented on 1 June 2008, the Law of the PRC on Prevention and Control of Atmospheric Pollution* (《中華人民共和國大氣污染防治法》) effective as of 1 September 2000, the Law of the PRC on Prevention and Control of Environmental Pollution by Noise* (《中華人民共和國環境噪聲污染防治法》) effective as of 1 March 1997, the Administrative Regulation for Collect and Use of Pollutant Discharge Fee* (《排污費徵收使用管理條例》) effective as of 1 July 2003, and the Administrative Measures of Collection Standard of Pollutant Discharge Fee* (《排污費徵收標準管理辦法》) effective as of 1 July 2003. According to the aforesaid laws and regulations:

— Units that cause environmental pollution and other public hazards shall incorporate the work of environmental protection into their plans, establish a responsibility system for environmental protection, and shall adopt effective measures to prevent and control the pollution and harms caused to the environment by waste gas, waste water, waste residues, dust, malodorous gas, radioactive substance, noise, vibration and electromagnetic radiation generated in the course of production, construction or other activities;

— Enterprises and institutions that discharge pollutants must report to and register with the relevant environmental protection authorities; and

— Enterprises and institutions that discharge pollutants shall pay pollutant discharge fee in accordance with relevant laws and regulations.

Government authorities shall impose different penalties for activities that in violation of the Environmental Protection Law depending on the individual circumstances. Such penalties include warnings, fines, orders to correct within specified time limit, orders to stop production, orders to re-install installations for the prevention and control of pollution which have been removed or left unused, imposition of administrative sanctions against relevant responsible persons by the unit to which they belong or by the competent department of the government, or orders to suspend operations or close down.

According to the Regulations on the Administration of Construction Project Environmental Protection* (《建設項目環境保護管理條例》), which was promulgated and effective from 29 November 1998, and the Classified Directory for Environmental Impact Assessment Administration of Construction Project* (《建設項目環境影響評價分類管理名錄》) effective as of 1 October 2008, a construction unit should, in the phase of construction project feasibility study, submit the construction project environmental impact report, environmental impact statement or environmental impact registration form for approval. For a construction project that necessitate no feasibility study pursuant to relevant provisions, the construction unit should, prior to the start of the construction of the construction project, submit the construction project environmental impact report, environmental impact statement or environmental impact registration form for approval. Besides, the construction unit should, upon the completion of the construction project, file an application with the competent department of environmental protection administration that examined and approved the said construction project environmental impact report, environmental impact statement or environmental impact registration form for acceptance checks on completion of matching construction of environmental protection facilities required for the said construction project.

**Labour Contracts and Occupational Protection**

Pursuant to the Labour Contract Law of the PRC* (《中華人民共和國勞動合同法》) (the "**Labour Contract Law**"), which was adopted by the Standing Committee of the National People's Congress on 29 June 2007 and became effective on 1 January 2008, to establish a labour relationship, a written labour contract should be concluded. In the event that no written labour contract is concluded at the time when a labour relationship is established, such a written contract should be concluded within one month from the date when the employee starts to work for the employer. Where the employer fails to conclude a written labour contract with the employee for more than one month but less than a year from the date when the employee starts to work for the employer, the employer shall pay the employee times his salary for each month. In addition, if the employer fails to conclude a written labour contract with the employee within one year from the date when the employee starts to work for the employer, it shall be deemed that the employer has concluded a non-fixed term labour contract with the employee. Except for certain circumstances specified in the Labour Contract Law, an employer is obligated to enter into a non-fixed term labor contract with an employee if the employer continues to employ such employee after finishing two consecutive fixed-term labor contracts and the employer also has to pay compensation to employees if the employer terminates such non-fixed term labour contract except for certain circumstances specified in the Labour Contract Law. Compensation is

also required when the labour contract expires, except for certain circumstances including that employer intends to renew the labour contract with employee under the same terms or better terms but the employee refuses to renew.

Pursuant to the Law of The PRC on Prevention and Control of Occupational Diseases* (《中華人民共和國職業病防治法》), which was adopted by the Standing Committee of the National People's Congress on 27 October 2001 and became effective on 1 May 2002, for construction projects, including projects to be constructed, expanded or altered, and projects for technical renovation and introduction which may produce occupational diseases hazards, the unit responsible for the construction project shall, during the period of feasibility study, submit to the health administrative department a preliminary assessment report on such hazards. The said department shall, within 30 days from the date it receives the report, make a decision and inform the unit in writing. Where a unit fails to submit such a report to or its report is not approved by the relevant health administrative department, relevant authorities shall not grant approval to construct such project.

Furthermore, for construction projects that produce serious occupational diseases hazards, the design of the protective facilities shall be subject to examination by the health administration department. Only when the design conforms to the national norm for occupational health and meet the requirements for occupational health, construction can be started. And before the construction project is completed for inspection and acceptance, the construction unit shall assess the effect of the control of occupational disease hazards when the project is completed and ready for inspection and acceptance. The facilities for prevention of occupational diseases may be put into formal operation and use only after they have passed the inspection by the public health administration department.

**Manufacturing and selling of Medical Devices/Appliances**

According to the Administrative Provisions on Administration and Supervision of Medical Device* (《醫療器械監督管理條例》) promulgated and implemented by the State Council of PRC on 1 April 2000 and other relevant regulations, medical devices are divided into three categories: Category I, Category II and Category III. Manufacturing of Category I medical devices shall be approved by city level drug administrative authorities; manufacturing of Category II medical devices shall be approved by provincial drug administrative authorities; whereas manufacturing Category III medical devices shall be approved by the drug administrative department of the State Council. Category II medical devices and Category III medical devices shall also pass the clinical verification. In addition, the establishment of enterprises manufacturing Category I medical devices shall be recorded at the provincial drug administrative authorities, while the establishment of enterprises manufacturing Category II medical devices and Category III medical devices shall be approved by provincial drug administrative authorities and obtain the Licence for Medical Device Manufacturer* (《醫療器械生產企業許可證》) from the same. The Medical Device Registration Certificate and the Licence for Medical Device Manufacturer shall be valid for 4 and 5 years, respectively.

The basic requirements for the establishment of enterprise for manufacturing of Category I medical devices or Category II medical devices and for obtaining the relevant "Medical Device Manufacturing Enterprise License" mainly include the following: (i) it shall conform to the State's development planning and the industrial policies; (ii) it shall have professional technicians who have commensurable qualifications for the specification of the medical devices manufactured by the production enterprise; (iii) it shall have production premises and environment which are commensurable to the requirements for manufacturing the medical devices; (iv) it shall have production equipment that can meet the specifications of the medical devices manufactured by it, including the storage installation and equipment; (v) it shall maintain a quality inspection department or personnel and equipments for conducting inspection on finished products manufactured by it; (vi) it shall establish product quality management system, including purchasing, test for purchasing, storage, delivery re-examination, quality tracing system and adverse event report system; (vii) it shall have technology training and the after-sales service ability corresponding to the medical device product, or designate the third party to provide technology support; and (viii) it shall pass the examination and inspection of the competent authority.

Category I medical devices and Category II medical devices manufactured by the enterprise which have obtained the "Medical Device Manufacturing Enterprise Licence" shall be registered with relevant drug administrative authorities of different levels and obtain the Medical Device Registration Certificate* (《醫療器械註冊證書》) in order to be manufactured, sold and distributed in the PRC. More particularly, in the event that the enterprise intends to register certain Category II medical devices, it shall meet the production requirements by relevant drug administrative authorities or the relevant quality system requirements and certain tests have to be carried out by a medical device testing institution accredited by relevant drug administrative authorities and General Administration of Quality Supervision, Inspection and Quarantine of the PRC* (國家質量監督檢驗檢疫總局), and it is only after the medical devices having been tested to have fulfilled various applicable product standards, such medical devices can be used for clinical trial or can they be applied for registration. In addition, in order to complete the registration, Category II medical devices are also required to pass the clinical trial.

According to the Administrative Provisions on Administration and Supervision of Medical Device* (《醫療器械監督管理條例》) and relevant regulations, enterprise which is engaged in selling the Category I medical devices shall be recorded with competent food and drug administrative authority at the provincial level. Except as otherwise stipulated in relevant laws and regulations, enterprise which is engaged in selling the Category II and Category III medical devices shall be examined and approved by competent food and drug administrative authority at the provincial level and shall obtain License for Enterprise Dealing with Medical Devices* (《醫療器械經營企業許可證》) from such authority. In the absence of such License, local administrative bureau for industry and commerce shall not issue business license for enterprise which is engaged in selling medical devices. The validity period of the License for Enterprise Dealing with Medical Devices is five years. Upon the expiration thereof, such license shall be re-examined and issued by competent administrative authority.

According to the Administrative Regulations on Random Sampling for Medical Device Quality Supervision of PRC for Trial Implementation* (《國家醫療器械品質監督抽驗管理規定(試行)》), the State Food and Drug Administration and relevant local food and drug administrative authorities in China shall conduct inspections on medical devices on a random basis. The products selected are required to comply with the relevant PRC laws, regulations and national standards then in force. The result will be released to the public.

**Printing Business**

Pursuant to the Regulations on the Administration of Printing Industry* (《印刷業管理條例》) promulgated by the State Council on 2 August 2001, the State adopts the license system for printing operations. Such regulations regulate the operations of printing publications, as well as the packaging and decoration materials on printed objects. Pursuant to the Regulations on the Administration of Printing Industry* (《印刷業管理條例》), no unit or individual may undertake printing operations without obtaining the Printing Business Licence* (《印刷經營許可證》) according to these regulations. The General Administration of Press and Publication of the PRC* (中國新聞出版總署) promulgated the Interim Measures on the Qualifications of Printing Operators* (《印刷業經營者資格條件暫行規定》) on 9 November 2001, which specify the qualifications required for enterprises engaged in printing operations. Printing operators must satisfy such qualification requirements in order to obtain approval for their establishment and Printing Business Licence* (《印刷經營許可證》) from the competent press and publication administration.

Huizhou Junyang has obtained the Printing Business Licence* (《印刷經營許可證》) since 1 January 2006. Such permit was renewed on 1 January 2010. As advised by the PRC Legal Advisers, Huizhou Junyang has complied with the aforementioned PRC laws and regulations relating to printing business in all material aspects during the Track Record Period.

**Social Insurance and Housing Fund**

According to the Regulations on Work-Related Injury Insurance* (《工傷保險條例》) effective as of 1 January 2004, the Interim Measures concerning the Maternity Insurance for Enterprise Employees* (《企業職工生育保險試行辦法》) effective as of 1 January 1995, the Interim Regulations concerning the Levy of Social Insurance* (《社會保險費徵繳暫行條例》) effective as of 22 January 1999, the Interim Measures concerning the Management of the Registration of Social Insurance* (《社會保險登記管理暫行辦法》) effective as of 19 March 1999 and the Regulations concerning Housing Fund* (《住房公積金管理條例》) effective as of 3 April 1999 and amended on 24 March 2002, enterprises and institutions in the PRC shall provide their employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, occupational injury insurance and medical insurance, as well as housing fund and other welfare plans.

**Intellectual Property Rights**

*Patent*

The Patent Law of the PRC* (《中華人民共和國專利法》) (the "**Patent Law**") was revised on 27 December 2008 by the Standing Committee of the National People's Congress and effective from 1 October 2009. According to the Patent Law, an "invention" refers to any new technical solution relating to a product, a process or improvement thereof; an "utility model" refers to any new technical solution relating to the shape, the structure, or their combination, of a product, which is fit for practical use; a "design" means any new design of the shape, pattern or their combination, or the combination of colour and shape or pattern, of a product, which creates an aesthetic feeling and is fit for industrial application.

After the grant of the patent right for an invention or utility model, or a design, except where otherwise stipulated in the Patent Law, no unit or individual shall without the authorization of the patent owner, exploit such patent, that is, to make, use, offer to sell, sell or import the patented product, or use the patented methods, and use, offer to sell, sell or import the product directly obtained by using the patented methods, for production or operation purposes. The patent right for inventions shall be valid for twenty years and the patent right for utility models and designs shall be valid for ten years, commencing from the date of application.

As advised by the PRC Legal Advisers, except as disclosed in this prospectus, the PRC subsidiaries of our Group has complied with the PRC laws and regulations set out in this section in all material aspects.

## LAWS AND REGULATIONS IN MACAU

**Operation of commercial offshore**

Pursuant to the laws and regulations of Macau, the legal regime in relation to the principal business activities of Two-Two-Free in Macau is based on Decree Law No. 58/99/M of 18 October ("**Law of Offshore Business**") and mainly regulated by the Macao Trade and Investment Promotion Institute (澳門貿易投資促進局) ("**IPIM**").

Under the Law of Offshore Business, Two-Two-Free is required to obtain authorization of registration from the Macao Trade and Investment Promotion Institute for the establishment of a commercial offshore company. Two-Two-Free has duly obtained the authorization of offshore services and has been authorized to establish and operate as a commercial offshore company in Macau to conduct the principal business activities of Two-Two-Free pursuant to the certificate of authorization of offshore services no. DSO/134/2003.

As an authorized commercial offshore company, Two-Two-Free shall comply with all the regulations and conditions stated under the Law of Offshore Business, including that Two-Two-Free is not allowed to conduct any trade or business activities with residents of Macau or carry through any transactions in Patacas except such transactions which are

necessary for the constitution or operation of the commercial offshore company. The Law of Offshore Business further regulates that Two-Two-Free shall adopt and prepare its financial statements in accordance with the generally accepted accounting principles of Macau and must be operated at a single location.

Furthermore, the Law of Offshore Business specially prohibits Two-Two-Free to proceed with any operations and activities reserved to the credit institutions, financial companies, financial agencies and insurers by laws of Macau or provide any services to any parties besides its subsidiary institution or branch office. Two-Two-Free shall submit the annual accounting and audit reports with the related audited financial statements to the IPIM every accounting period. Otherwise, the authorization of offshore services will be revoked; moreover, fine and cautious measures will be imposed in accordance with the Law of Offshore Business.

**Taxation**

As Two-Two-Free is established as an offshore company in Macau based on Law of Offshore Business. Two-Two-Free is applicable of the taxation regime stated in the Law of Offshore Business and is exempt from the Macau taxes, including profit tax with regard in the offshore business and the industrial tax.

As advised by the Macau Legal advisers, as there are no applicable Macau rules and regulations governing transaction among related companies in Macau, the business arrangement of Two-Two-Free will not be subject to any transfer pricing exposure. Since there is no dividend withholding tax chargeable under the tax regime in Macau, dividend withholding taxes are not applicable to Two-Two-Free.

**Labour related matters**

The legal regime in relation to labour matters in Macau is mainly based on the following legislations:

18th of October — Decree Law No. 58/93/M (approval of social security regime);

14th of August — Decree Law No. 40/95/M (approval of legal regime of reparation of damages caused by industrial accidents and occupational diseases);

22nd of May — Decree Law No. 37/89/M (approval of general regulation of working safety and hygiene of office, service and commercial establishment);

18th of February — Decree Law No. 13/91/M (determination of sanctions for the incompliance of general regulation of working safety and hygiene of office, service and commercial establishments);

27th of July — Law No. 4/98/M (Framework Law on Employment Policy and Worker's Rights);

2nd of August — Law No. 6/2004 (Law of Illegal Immigration and Expulsion);

14th of June — Administrative Regulation No. 17/2004 (Regulation on Prohibition of Illegal Work);

18th of August — Law No. 7/2008 (Labour Relation Law);

15th of October — Law No. 21/2009 (Law of Hiring non residents workers).

The legal regime of labour matters in Macau is developed based on 27th of July 1998 — Law No. 4/98/M (Framework Law on Employment Policy and Worker's Rights) which prescribes general principles and directions of labour legislations in different aspects.

In addition to the above-mentioned legislations, 18th of August — Law No. 7/2008 (Labour Relation Law) plays an important role in the labour legal regime which has become effective since 1 January 2009 and has replaced the "old labour law" — 3rd of April 1989 — Decree-Law No. 24/89/M (Labour Relations, Juridical System). It stipulates the basic requirements and conditions for all labour relations, except those which have been excluded explicitly therein. In general, such requirements and conditions stipulated cannot be waived by mutual agreement. All the working conditions of labour relations should not be worse than the basic conditions stipulated in such law.

As an employer, Two-Two-Free shall comply with the conditions required under 22nd of May — Decree Law No. 37/89/M (approval of general regulation of working safety and hygiene of office, service and commercial establishment) for its working places in order to provide a safe and clean working condition for its employees, failing which fine and cautious measures will be imposed on Two-Two-Free according to 18th of February 1991 — Decree Law No. 13/91/M (determination of sanctions for the incompliance of general regulation of working safety and hygiene of office, service and commercial establishments).

Pursuant to the statutory requirements stipulated under 18th of October — Decree Law No. 58/93/M (approval of social security regime) and 4th of August — Decree Law No. 40/95/M (approval of legal regime of reparation of damages caused by industrial accidents and occupational diseases), Two-Two-Free is obliged to participate and contribute to the mandatory social security funds and to obtain compulsory industrial accident insurance for its employees in Macau in accordance with relevant applicable legislations, failing which an administrative fine will be imposed on Two-Two-Free as legal sanction.

All employees of Two-Two-Free are required to be Macau residents, non-permanent or permanent, holders of working permits in case of foreign workers. Hiring of non-resident workers by Two-Two-Free shall comply with the 15th of October — Law No. 21/2009 (Law of Hiring non-resident workers) to obtain the working permits for foreign workers. Except for certain limited situations stated under 14th of June — Administrative Regulation No. 17/2004 (Regulation on Prohibition of Illegal Work) workers other than Macau residents or holders of working permits will be considered as illegal workers in Macau and the employers will be criminally liable under 2nd of August — Law No. 6/2004 (Law of Illegal Immigration and Expulsion) and subject to an administrative fine according to the above-mentioned administrative regulation.

The regulatory authorities in charge of labour safety, social security regime and insurance matters are the Labour Department of Macau (澳門勞工事務局), Social Security Fund of Macau (澳門社會保障基金) and Monetary Authority of Macau (澳門金融管理局), respectively.

**Environmental Protections**

The fundamental legislations in respect of the legal regime of safety and environmental law of Macau, which are applicable to every individual and corporate entity, are the Basic Law of Macau, the Law No. 2/91/M of 11th of March which is known as the organic environmental law of Macau (the "**Macau Environment Law**"), 14th of November — Decree Law 54/94/M regarding prevention and control of ambient noise ("**Law of Prevention and Control of Ambient Noise**") and series of international conventions in related fields applicable in Macau.

Article 119 of the Basic Law of Macau states that "The Macau Special Administrative Region shall carry out the protection of environment in accordance with law". To implement this article together with the Macau Environmental Law, Law of Prevention and Control of Ambient Noise and other applicable international conventions, certain environmental legislations in the form of law, decree law and administrative regulations have been enacted in various domains such as natural heritage protection, air, sea and sound pollutions, hygiene of environment, chemical goods, etc.

As a general rule prescribed in the Macau Environmental Law, any violation of the environmental legislations will, subject to civil liability, administrative fine or criminal punishment, depend on the type of violations and also administrative injunction may also be obtained to cease environmental infringement.

Besides, according to the Law of Prevention and Control of Ambient Noise, any work which may produce annoying noise is forbidden to be conducted during Sunday and public holiday and between 8:00 p.m. and 8:00 a.m. (next day) of weekday.

The regulatory authority in charge of environmental protection matters is the Environmental Protection Bureau of Macau (澳門環境保護局).

As advised by the Macau Legal Advisers, except as disclosed in this prospectus, Two-Two-Free has complied with the Macau laws and regulations set out in this section in all material respects.

## LAWS AND REGULATIONS IN THE UNITED KINGDOM AND EUROPEAN UNION

The Group has engaged the English Legal Advisers to advise on the laws relating to antidumping, product safety, product labelling and packaging which are applicable to the importing and distributing of the Group's products in the UK. Where such laws are based on European Union laws, this has been identified.

**Antidumping and other Import Duties**

*Antidumping*

The current legislation concerning antidumping is contained in Council (EC) Regulation No. 1225/2009 which applies in the UK and the rest of Europe.

A company could be considered to be "dumping" if it is exporting a product to the EU at prices lower than the normal value of the product (the domestic prices of the product or the cost of production) on its own domestic market. The European Commission ("**the Commission**") is responsible for investigating allegations of dumping by exporting producers in non-EU companies. The Commission usually opens an investigation after receiving a complaint from the Community producers of the product concerned but can also do so on its own initiative.

Following receipt of the complaint, the Commission will publish a notice in the EU's Official Journal opening an antidumping proceeding. The maximum time limit for an investigation under these proceedings is 15 months. The detailed findings are published in the Official Journal, for example, as a regulation imposing antidumping duties or terminating the proceeding without duties being imposed.

Antidumping measures can be imposed by the Commission if their investigations have shown the following:

- there is dumping by the exporting producers in the country/countries concerned; and
- material injury has been suffered by the Community (countries comprising the EU "**Community**") industry concerned; and
- there is a causal link between the dumping and injury found; and
- the imposition of measures is not against the Community interest.

If the investigations find that the above four conditions have been met, then antidumping measures can be imposed on imports of the product concerned. The measures imposed usually take the form of an ad valorem duty (in order to bring the price of the product more in line with the prices normally paid for that product in an EU country) but could also be specific duties or price undertakings.

The duties are paid by the importers in the EU and collected by the national customs authorities of the EU countries concerned.

Following investigation by the Commission pursuant to a number of complaints, antidumping duties were imposed on plastic bags entering the EU from PRC and Thailand under Council Regulation (EC) No. 1425/2006. Duties were imposed on imports of plastic

sacks and bags containing at least 20% by weight of polyethylene and of a thickness not exceeding 100 micrometers. The Commission issued a list confirming the appropriate rate of duty to impose on each of the companies that they investigated.

In general, the companies on the list are paying around 7–8%. Huizhou Junyang is included in the list of companies and a rate of duty ("**ADD**") of 4.8% has been imposed.

Any companies that commenced exporting plastic bags to the UK since the publication of the Regulation in 2006 therefore have an antidumping duty of 28.8% imposed on import of the plastic bags into the EU. This is much higher than any of the rates imposed on any of the listed companies.

*Import Duties*

Pursuant to Council Regulation (EC) No. 2658/1987 and Council Regulation (EC) No. 2261/1998, a basic rate of 6.5% of import duty ("**Import Duty**") is charged on the Group's products imported into the UK plus value added tax ("**VAT**") (currently 17.5% in UK). The Import Duty is a standard rate across all EU countries. However, VAT is specific to the UK (other EU countries may have an equivalent regime). The importers are responsible for payment of the duties.

In relation to imports into UK, it is the English Legal Advisers' view that if the Group's products have been freely circulated and entered the country, then this suggests that all the duties (including Import Duty, ADD and VAT) will have been paid and received by the national revenue and customs office (which in the UK is HM Revenue and Customs).

**Product safety, product labelling and packaging**

*Safety*

In order to be classified as capable of being used to carry clinical waste in the UK, a plastic bag must meet the requirements of "The European Agreement concerning the International Carriage of Dangerous Goods by Road" ("**ADR**") which is an international convention concerning transportation of hazardous substances which the UK has signed up to.

The bags must meet the following requirements:

- They must be capable of passing a number of ISO tests e.g. they must comply with ISO 7765-1:1988 "Plastics film and sheeting — Determination of impact resistance by the free-falling dart method — Part 1: Staircase methods" and ISO 6383-2:1983 "Plastics — Film and sheeting — Determination of tear resistance. Part 2: Elmendorf method".

- Each bag must have an impact resistance of at least 165g and a tear resistance of at least 480g in both parallel and perpendicular planes with respect to the length of the bag.

- The maximum net mass of each plastic bag should be 30kg.
- The bags should be capable of being sealed and should be leak proof.

Whilst there are no requirements that are specific to clinical aprons themselves, the English Legal Advisers have advised that it is important that they be suitable for disposal as clinical waste e.g. they are capable of being incinerated.

*Labelling/markings on the plastic bags*

In order to comply with UN requirements, which are mandatory in the UK under the Hazardous Waste (England and Wales) Regulations 2005, bags that are used for hazardous waste and, in particular, clinical waste, should be marked as "Clinical Waste" and display certain codes. Typical markings will begin with the code 5H4/Y */S.

Bags for use in the household do not require any specific markings, although it is customary for them to carry a warning of the dangers of suffocation.

*Packaging*

The packaging of items entering the EU is subject to SI 2003 No. 1941 — The Packaging (Essential Requirements) Regulations 2003 (as amended by SI 2004/118) which implemented the European Directive 94/62/EC. The regulations relate to anyone who is responsible for packing or filling products into packaging or importing packed or filled packaging into the UK. Nobody may place the product on the market unless it fulfils the Essential Requirements specified under the Regulations (the "**Essential Requirements**"). In outline, the Essential Requirements are:

- Packaging volume and weight must be the minimum amount to maintain the necessary levels of safety, hygiene and acceptance for the packed product and for the consumer;
- Packaging must be manufactured so as to permit reuse or recovery in accordance with specific requirements; and
- Noxious or hazardous substances in packaging must be minimised in emissions, ash or leachate from incineration or landfill.

*Labelling the packaging*

The most important issue in relation to labelling is that any information on the labels must be accurate. Inaccuracy can attract criminal liability.

The duty to not mislead applies to both the writing and illustrations on the packaging. It must not be misleading about quantity or size; composition; method of manufacture; place and date of manufacture; fitness for stated purpose and endorsements by people or organisations.

## LAWS AND REGULATIONS IN THE UNITED STATES OF AMERICA IN RELATION TO (I) ANTI-DUMPING AND (II) TORTS

### US Anti-Dumping

The US Department of Commerce issued an antidumping order on 9 August, 2004 covering polyethylene retail carrier bags exported from the People's Republic of China, 69 Fed Reg. 48201 (9 August, 2004) (the "**2004 Antidumping Order**") which covers specific bag products including polyethylene bags with handles. Chinese entities exporting to the US will be subject to the highest outstanding dumping margin of 77.57% unless it is proven to the US Department of Commerce that the Chinese entity is separate and independent from the PRC government and that the company's prices are not set by the PRC government.

The Group currently exports its products into the US through its wholly owned subsidiary, Two-Two-Free. As of the Latest Practicable Date, Two-Two-Free was not involved in any antidumping investigation nor has it proved that it is separate and independent from the PRC government. Thus it will be subject to an antidumping cash deposit rate of 77.57% if it exports products that are covered by the 2004 Antidumping Order. However, we do not sell polyethylene bags with handles to the US, i.e. the bags that the Group is currently exporting to the US are outside the scope of products covered by the 2004 Antidumping Order. As such, we are not subject to the 2004 Antidumping Order as long as we do not export polyethylene bags with handles to the US. Furthermore, according to US anti-dumping laws, it is the US importer who would be liable for the antidumping duties, and not the PRC exporter or producer.

As a result, so long as we do not export polyethylene bags with handles to the US and since it is the importer who is liable for payment of antidumping duties, our operations are not subject to the 2004 Antidumping Order and the Group will not be liable for any antidumping duties in the United States.

### Tort law

Product liability law in the United States imparts a duty on manufacturers, importers and distributors to warn about product hazards that are reasonably foreseeable. Injuries resulting from foreseeable product hazards (for example, a thin-film bag suffocating an infant) can lead to significant damages verdicts even in the absence of regulation. However, if the Group's products are sold exclusively to hospitals and clinics, the risk of litigation and an adverse verdict is reduced by the presumed expertise and knowledge of the hospitals and clinics.