Our products are medical devices subject to extensive regulation in the markets in which we operate, and such regulations vary from jurisdiction to jurisdiction. The following section sets out summaries of certain relevant laws, regulations and requirements that we are subject to in the key jurisdictions in which we operate.

EU REGULATORY OVERVIEW

Medical devices can be commercialized in the member states of the European Economic Area ("**EEA**") only if they meet the following requirements and obtain CE (Conformité Européenne) Mark (including countries which have signed Mutual Recognition Agreement with EU):

(1) Regulation (EU) 2017/745 on medical devices ("**MDR**").

(2) Medical Device Directive ("**MDD**") 93/42/EEC.

On May 26, 2021, MDD was repealed and replaced by the MDR which has become a regulation versus a former directive, for the manufacturers who plan to commercialize medical devices in this region. The MDR is subject to a transition period during which manufacturers of medical devices must update their technical information and processes in line with the new MDR. During the transition period, manufacturers may elect whether to put any new medical devices under the MDD's regime or under the new MDR. Under European law, a Regulation differs from a Directive since it, as a Regulation, is directly effective in each Member State, without the need for implementing legislation (which is required for a Directive). The new Medical Devices Regulation has the same basic requirements as the EU Medical Devices Directive, but is generally more stringent, especially in terms of risk classes and the oversight provided by notified bodies. There is also more emphasis on vigilance and post-market surveillance.

Device Classifications under MDD and MDR

In the EEA, based on MDD and MDR, devices are classified into Class I, Class IIa, Class IIb, and Class III. The classification is a risk-based mechanism according to the nature of human body contact and the contact duration of the medical devices. There are specific classification rules in both MDD and MDR.

Documents required for CE conformity under MDD and MDR

Generally the medical device manufacturer shall prepare the documents for device CE conformity assessment per MDD and MDR.

Under the regulatory frame of MDD, Class IIa and Class IIb devices shall have a technical file ("**TF**"). Class III device will need a design dossier ("**DD**") for the purpose of conformity assessment.

Under MDR, manufacturers of all classes will need to prepare a technical documentation ("**TD**") for the device conformity assessment.

MDD TF/DD requirements

The TF/DD shall be prepared according to the outlines in MDD with supporting documents, including a general description of the product, its intended use(s), the design specifications, the applicable standards, the pre-clinical evaluation, the clinical evaluation, the draft label and, where appropriate, instructions for use. Normally the notified body ("**NB**"), which is a third-party auditing organization that assesses quality and conformity of medical devices, will provide a format for the TF/DD. Certain part of the TF/DD shall follow the guidance issued by European Commission, e.g. MEDDEV 2.7/1 for clinical evaluation.

MDR TD Requirements

TD under MDR shall be prepared in accordance with MDR since Date of Application on May 26, 2021. Technical Documentation includes both pre-market and post market sections, the detail content requirements are listed in the Annex II and Annex III of MDR regulation (Regulation (EU) no. 2017/745).

Assessment of Conformity

Medical devices in the EU have to undergo a conformity assessment to demonstrate that they meet regulatory requirements to ensure they are safe and perform as intended. EU Member States can designate accredited notified bodies to conduct conformity assessments. For example, British Standards Institute, and TÜV SUD are accredited notified bodies. The conformity assessment procedures are outlined in both MDD and MDR. After May 26, 2021, the medical device conformity assessment shall follow the procedures per Section 2 of Chapter V in MDR according to the classification and device specialties. The manufacturer of Class IIa, IIb, III medical devices and certain Class I medical devices (device with measuring function, sterile device, and reusable surgical instrument) will need to lodge with a NB to assess the conformity to MDR and other applicable regulations (e.g. Directive 2001/83/EC for medicinal products for human use) by submitting the compiled TD per the MDR. The conformity assessment procedures also call out the requirements for the manufacturer's quality system. The assessment to quality system applies to all the aforementioned devices, but varies in system functional scope for the named Class I medical devices. Class I devices other than the specified three categories do not need NB for the conformity assessment.

Administrative requirements under MDD/MDR

Many medical devices require a CE Mark before they can be sole in the EU. The CE Mark may generally only be affixed to a medical device if the product has passed the conformity assessment per the procedures outlined in MDD/MDR, and obtained the respective CE certificates (e.g. EU quality management system certificate, and EU technical documentation assessment certificate per MDR Annex IX).

The CE certificates will have a maximum validity period of 5 years. The NB will perform surveillance audit annually and unannounced audit to the manufacturer, and the suppliers and/or subcontractors, if appropriate.

If the requirements for application of the CE Mark are not (or no longer) fulfilled, or in other cases of non-compliance with applicable medical devices law:

- the Notified Body has the power to withdraw, suspend or limit the scope of the applicable certificate of conformity, in accordance with the principle of proportionality;

- the competent supervisory authority of the EU member state or contracting state of the EEA may enforce the provisions of the MDR, e.g. by preventing the product from being put on the market, ordering a recall or shutting down a manufacturing site; and

- criminal or administrative sanctions (e.g. fines) may apply.

In principle, the manufacturer is responsible to ensure compliance with applicable provisions including affixing the CE Mark to his products. If a manufacturer does not have a physical location in the EU, he is required to appoint a so called "Authorized Representative" who ensures compliance with the regulatory requirements for medical devices set out in the MDR.

Medical Device Operation and Product Quality

Among EU laws applicable to product safety, the MDR mandates a substantial increase in safety obligations of manufacturers (e.g. Article 10 and Annex I of the MDR). For instance, medical device manufacturers are generally required to have systems for risk management, quality management and post-market surveillance. Specifically, implementing and maintaining a risk management system requires identifying and analyzing any known risks and implementing solutions to eliminate or control these risks. Medical device manufacturers generally have to conduct clinical evaluations, compile technical documentation, and undertake a conformity assessment procedure. In addition, medical device manufacturers must ensure that their authorized representatives have the necessary documentation permanently available, and that the devices are accompanied by the required information. Medical device manufacturers must also have a system for recording and reporting of incidents. If there were to be a serious incident involving the products, the reporting timeline to a health authority would typically be no later than 15 days after medical device manufacturers became aware of the incident, and two days in case of serious public health threat.

The EU rules on product safety also require that the products sold in the European Economic Area (EEA) hold certifications of conformity with the relevant harmonized standards (Article 56 of the MDR). Once medical device manufacturers completed all applicable obligations, they must draw up a declaration of conformity (Articles 10 §6 and 19 of the MDR)

and apply CE marking of conformity to our devices (Articles 10 §6 and 20 of the MDR, and Article 30 of Regulation (EC) No 765/2008). The products we sell in the EU have EC certificates and CE marking. These EC certificates cover products categorized as devices in Class IIa and Class III. Any other products we would sell in the EEA and that would not be covered by these EC certificates and/or would not have CE marking would require additional EC certification and/or CE marking. Once devices are compliant with the MDR requirements, member states cannot refuse, prohibit or restrict the making available on the market or putting into service within their territory of these devices on the basis of the MDR (Article 24 of the MDR).

Advertising and Sales Activities

Legislation on advertising and promotion of medical devices is not harmonized under European law. As a result, the legal landscape differs from one EU member or contracting state to the other. However, at the EU level, medical device manufacturers are represented by MedTech Europe, who has established a code of business practice which ensures that promotional materials are fair, balanced, objective and unambiguous. In addition, all information related to a medical device including labeling, instructions for use, presentations, brochures and advertising, must be in line with the language requirements as regulated individually by each member state.

Despite not being specific to the advertising of medical devices, further European directives such as Directive 2006/114/EC concerning misleading and comparative advertising or Directive 2005/29/EC concerning unfair business-to-consumer commercial practices can also be applicable to the medical device industry. Advertising towards doctors or other healthcare professionals may be subject to an even stricter national regulatory framework, particularly including sophisticated anti-bribery and anti-corruption laws as well as criminal laws.

Product Liability

The set of product liability rules applicable to medical devices in the EEA is contained among others in the MDR, and in general product liability laws based on national laws implementing the Directive 85/374/EEC on Product Liability ("PLD") and on national laws of torts of practically all EU member states. These product liability regimes apply in parallel.

Under the MDR, medical device manufacturers must assume responsibility for compliance with all EU legal texts applicable to these devices. The MDR adds that manufacturers are responsible for their devices once they are on the market. Natural or legal persons may claim compensation for damage caused by defective devices in accordance with the applicable EU and national laws. In addition, the MDR requires medical device manufacturers to have systems in place to cover our financial responsibility in relation to our potential liability under the PLD (the PLD requirements will be presented below), without prejudice to more protective measures under national law.

The national laws implementing the PLD create a strict liability regime (i.e. without fault). Under the PLD, liability principally rests upon the "producer" of the defective product, component part or raw material. The notion of "producer" covers (i) any person who, by putting his name, trade mark or other distinguishing feature on the product, presents himself as the producer; (ii) any importer which has imported the defective product, component or raw material into the EU market; and (iii) any supplier (e.g. the retailer, distributor or a wholesaler) if the producer cannot be identified. For the products we sell in the EU and the ones sold by our distributors in the EU, we qualify as a producer.

Liability under the PLD could be limited if medical device manufacturers can prove that the consumer's negligence caused or contributed to the damage. Liability under the PLD will expire after three years starting from the date on which the claimant became aware or reasonably could have become aware of the damage and its cause, the defect and the identity of the producer. Irrespective of knowledge, a producer's liability expires ten years from the date on which the producer put the product into circulation. National laws of torts of EU member states also provide other liability regimes which are for example fault-based (negligence). A claimant may seek to recover damages beyond the limitations mentioned above under these other regimes.

Post Market Surveillance and Vigilance

Starting from May 26, 2021, as regulated by MDR per Chapter VII, the post market surveillance (PMS) and vigilance of a medical device shall have a PMS system to actively gather and analysis the PMS data throughout the device's lifetime. Proactive PMS plan and report shall be performed at an appropriate frequency based on the device's risk-based class. For Class IIa, IIb and III medical devices, as the result of the PMS plan, a Periodic Safety Update Report ("**PSUR**") will be generated either biennially (for IIa) or annually (for IIb and III) and made available to the NB and competent authorities. The medical device manufacturers are also requested by the regulation to report serious incidents and field safety corrective actions, additionally the trend report for any statistical significant increase in the frequency or severity of the non-serious incidents. The aforementioned reporting and PSUR submission shall follow the electronic system established by European Commission.

Import Requirements

We sell our products in the EU to distributors. Under the MDR, strict requirements on manufacturers, importers and distributors of medical devices in the European Economic Area (EEA) are imposed. Failure to comply with the regulatory requirements may render medical device manufacturers to lose their marketing approvals or be subject to fines or other sanctions. Also, as a condition to granting marketing approval of a product, the applicable regulatory agencies may require a company to conduct additional clinical trials or remediate Current Good Manufacturing Practice ("cGMP") issues, the results of which could result in the subsequent loss of marketing approval, changes in product labeling or new or increased concerns about side effects or efficacy of a product. Medical device manufacturers must also have a named

person responsible for regulatory compliance, who possesses the requisite expertise in the field of medical devices. Medical device manufacturers must assign a Basic UDI-DI code to the device and provide the code to the UDI database.

It should be noted that under the MDR, an importer, distributor or any natural or legal person is the one who must assume the obligations incumbent on manufacturers if it does any of the following: (a) it makes available on the EEA market a device under its own name, registered trade name or registered trademark, except if the manufacturer agreed to be identified as such on the label and to be responsible for the MDR manufacturers obligations;(b) it changes the intended purpose of a device already placed on the market or put into service; and (c) it modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected (Article 16 of the MDR).

Our EU distributors sell our products under our company name, they do not change the intended purpose of our devices and they do not modify them in a way that affects their compliance with applicable requirements. In addition, to the best of our knowledge the activities of our customers who are end-users (e.g. hospitals) do not fall within any of the three above-mentioned categories. Therefore, our specific obligations as manufacturers under the MDR are not transferred to our distributors or end-users customers.

Intellectual Property

Each of the 27 member states of the EU has its own intellectual property law which covers the acquisition, maintenance and enforcement of intellectual property rights. Aspects of the national intellectual property laws are controlled by EU regulations, directives and treaties for harmonization purposes and to set a minimum standard. The national intellectual property laws provide for monopolies limited in time and scope with respect to, inter alia, inventions, trademarks, and works of copyright, including computer software, films and recorded music. Upon expiration of all applicable intellectual property rights, the underlying invention or work of copyright automatically becomes part of the public domain and may be freely used by the public and further developed or improved to make new inventions and new developments or works of copyright.

International treaties in the field of intellectual property set forth minimum monopoly standard levels that contracting states agree to maintain in their territory. The EU member states are members of most international intellectual property treaties and maintain standards that in some cases exceed the minimal standards set in those treaties.

It is the national intellectual property offices that have the authority to facilitate formal protection for intellectual property through the registration of patents, designs, trademarks and appellations of origin.

In parallel, some rights may also be registered with and/or managed by central offices such as the European Union Intellectual Property Office ("**EUIPO**") or the European Patent Office ("**EPO**"). In addition, certain regulations provide for the protection designations of origin, protected geographical indications and traditional specialties. Most granted rights are subject to the examination of an application. The EU does not maintain a formal copyright registry, but, to our best of knowledge, some of the member states offer a discretionary option to register copyrights.

Patents

Each of the 27 member states of the EU has its own national patent law, but there are regulations, directives and treaties to try to harmonize certain aspects of the national laws. All member states of the EU are members of the Paris Convention for the Protection of Industrial Property, members of the PCT, and members of the European Patent Convention ("**EPC**"). In general, in the EU, the owner of a patentable invention may apply to a national patent office or to the EPO for a patent.

Most Member States define a patentable invention on the basis of the EPC, which states that a patentable invention must be new, industrially applicable and based on an inventive step.

Each of these has detailed criteria under either the EPC or the national law of the member states. The EPC and the national law of the member states have adopted the "first to file" standard; if more than one applicant applied for a patent for the same invention, the patent will be granted to the applicant who first validly applied for it. The term of a patent is 20 years from the date of filing.

However, in the EU member states, Regulation (EC) No 469/2009 permits the granting of Supplementary Protection Certificates, which in practical effect extend the term of patents for specific pharmaceutical products by up to 5 years. A further six months' extension can be obtained under Regulation (EC) No 1901/2006 for certain pharmaceutical products for children.

The EU "Enforcement Directive" (2004/48/EG) provides that all EU member states must have in place injunction procedures for stopping infringements of intellectual property rights.

Environmental Protection

In the Netherlands, waste prevention and handling is regulated in the Dutch Environmental Management Act, which implements the European Union Waste Framework Directive and sector-specific EU waste legislation. Waste generated at a production site in the Netherlands has to be separated and records of waste disposal have to be kept. Non-hazardous industrial waste, such as the packaging waste from goods delivered to the site or household like waste, is generally collected by municipal authorities or can be disposed of at the drop-off point of the municipal waste disposal site. Collection or waste disposal charges are generally due. Hazardous waste has to be kept separated at all times and may only be disposed of by

surrendering it to a certified waste collector/transporter that transports the waste to an authorized processor. In addition, cross-border transport of waste is regulated by the European Union Regulation on the Transboundary Shipment of Waste. Notifications or approvals and financial security may be required for the shipment of waste, depending on the type of waste. Shipment of hazardous waste requires both prior approval of both the sending and the receiving member states and provision of financial security.

JAPAN REGULATORY OVERVIEW

Competent Authorities and Regulation

Pharmaceuticals and Medical Devices Agency ("**PMDA**") under Japan Ministry of Health, Labor and Welfare ("**MHLW**") is the regulatory agency for medical device control and approve. Placing medical device onto Japan market shall follow the Pharmaceutical and Medical Device Act. MHLW also issued series of regulations covering product classification, registration, quality system, PMS and guidances on specific product or topic, e.g. MHLW Ministerial Ordinance No. 169, 2004 for Manufacturing Control and Quality Control for Medical Devices and In-vitro Diagnostic Reagents, Japanese Medical Device Nomenclature, and Notice No. 0401038 the standard for approval for PTCA catheter.

Medical Device classification

Medical devices are categorized as four classes, namely Class I, II, III and IV, respectively for General medical devices (Class I), controlled medical devices (Class II) and special controlled medical devices (Class III and IV).

Pharmaceutical and Medical Device Act

Manufacturers and sellers of medical devices in Japan are primarily subject to the supervision of the Minister of Health, Labor and Welfare of Japan (the "Minister") under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices of Japan (the "Pharmaceutical and Medical Device Act"). A part of the work performed under the authority of the Minister is delegated to prefectural governors.

Under the Pharmaceutical and Medical Device Act, a person who intends to conduct the business of selling, leasing or providing medical devices that are manufactured (including outsourcing the manufacturing process to a third party) or imported is required to obtain from the Minister a manufacturing and sales license that has to be renewed every five years. The Minister has the power not to grant the license if (i) the quality control methods for the Designated Products are not in conformity with the Quality Management System ("QMS") standards as stipulated by the ministerial ordinance of the Ministry of Health, Labor and Welfare of Japan (the "MHLW"); (ii) the post-sales safety control (i.e., the collection and analysis of information and data necessary for proper use, including those related to quality, effectiveness and safety, and necessary measures to be taken based on the results thereof) methods of the medical device are not in conformity with the Good Vigilance Practice

standards as stipulated by the ministerial ordinance of the MHLW; or (iii) an applicant falls under certain disqualifying provisions of the Pharmaceutical and Medical Device Act. Manufacturers and sellers that have obtained the manufacturing and sales license must appoint a qualified general manufacturing and sales supervisor to supervise product quality control and post-sales safety control. Such manufacturer and seller must also comply with various other items stipulated by the ministerial ordinances of the MHLW in the process of conducting the licensed business.

In order to conduct the business of manufacturing medical devices, the manufacturer is also required to make a renewable, five-year manufacturing registration with the Minister for each manufacturing site, which is classified in accordance with the ministerial ordinance of the MHLW. The Minister has the power not to register the manufacturing site if an applicant falls under certain disqualifying provisions of the Pharmaceutical and Medical Device Act.

In addition, the manufacture or sale of medical devices requires (i) product approval from the Minister, (ii) third party certification or (iii) registration for each kind of product, depending on the type of the medical device.

If any manufacturing and sales license holder becomes aware of matters concerning the effectiveness and safety prescribed by the ministerial ordinance of the MHLW, such as an alleged harm due to a defect in the medical device or an infection occurring from use of the medical device, the manufacturing and sales license holder must notify the Minister in accordance with the ministerial ordinance of the MHLW. Subject to the severity of the incident, the notification must generally be made within 15 or 30 days of the license holder becoming aware of the incident.

Furthermore, under the Pharmaceutical and Medical Device Act, the Minister or a prefectural governor may take various measures to monitor the activities of licensed manufacturers and sellers. For example, if deemed necessary to monitor their compliance with the laws and regulations, the Minister or a prefectural governor may require licensed manufacturers and sellers of medical devices to submit reports or carry out inspections at their factories or offices. The Minister has the power to order licensed manufacturers and sellers to temporarily suspend the selling, leasing or providing the medical devices in order to prevent or mitigate any risks to public health. Further, the Minister may revoke a license granted to or registration made by a manufacturing and sales license holder, or order a temporary business suspension under certain limited circumstances such as the violation of laws relating to medical devices.

Registration and Marketing of Medical Device

In relation to medical devices to be placed on Japan market, there are two types of licenses: (i) a business license and (ii) a license for a product, in Japanese regulation on medical devices.

With respect to the business license, a company who intends to engage in the business of manufacturing medical devices must obtain registration for each manufacturing facility (a company who intends to manufacture medical devices in a foreign country and export such medical devices to Japan must obtain registration as a Foreign Manufacturer of Medical Devices for each manufacturing facility). Our Group has obtained a Registration Certificate for Manufacturing Medical Devices for the manufacturing of medical devices in Japan.

In addition, a company who intends to engage in the business of marketing medical devices must obtain a marketing license in accordance with the criteria for medical devices set forth in the following table:

Criteria for medical devices	**Criteria for license**
Specially-controlled medical devices	First-class marketing license for medical devices
Controlled medical devices	Second-class marketing license for medical devices
General medical devices	Third-class marketing license for medical devices

With respect to the license for a product, a company who intends to market medical devices must make a notification (todokede), or obtain certification (ninsho) or marketing approval (shonin) for each product, depending on the class of the product (with respect to medical devices to be manufactured in foreign countries and exported to Japan, a Foreign Manufacturer of Medical Devices (which is referred to as a "person with special approval for foreign-manufactured medical devices"), instead of the marketer, can (and is not obliged to) apply for the marketing authorization of such product, but the marketing authorization will belong to the marketer (which is referred to as a "designated holder of marketing authorization for foreign-manufactured medical devices") appointed by such applicant even in such case). Our Group has obtained a First-Class Marketing License for Medical Devices (第一種醫療機器製造販売業許可證), a Sales License for Specially Controlled Medical Devices, etc. (高度管理醫療機器等販売業許可證) issued by Ohta-ku and a Sales License for Specially Controlled Medical Devices, etc. (高度管理醫療機器等販売業許可證) issued by Shibuya-ku for its sales and marketing activities of medical devices in Japan.

U.S. REGULATORY OVERVIEW

The U.S. Food and Drug Administration's Regulation of Medical Devices

In the United States, the Food and Drug Administration (FDA) regulates medical devices under the Federal Food, Drug, and Cosmetic Act ("**FDCA**") and its implementing regulations.

I. Classification of Medical Device in the U.S.

Medical devices are classified as Class I, Class II and Class III in the U.S. based on elevated risks from general control and special control to premarket approval. The regulatory requirements varies per the product class. In U.S. Code of Federal Regulation, Part 21 (Title 21 CFR) sets the classification regulations and the corresponding controls by product group from Part 862 (clinical chemistry and clinical toxicology devices) through Part 892 (radiology devices).

Class I devices possess minimal potential risk for patients and are comparatively simpler in design than Class II and Class II devices. Due to the lowest risk Class I devices pose to patients, they are typically subject only to FDA's general control provisions such as device registration and listing; prohibition against adulteration and misbranding; notification and repair, replacement and refund; record keeping; unique device identifiers and device tracking, as applicable; adverse event and other reporting; Good Manufacturing Practice requirements embodied in FDA's Quality System Regulation ("QSR"); and in limited instances, premarket notification.

Class II devices possess risk level between Class I and Class III; most medical devices are Class II devices. Class II devices are devices which the abovesaid general controls are not sufficient to ensure their safety and effectiveness. The FDCA imposes special controls on top of general controls. Special controls are usually device-specific, and include performance standards, post market surveillance, patient registries, special labelling requirements, and pre market data requirements. Class II devices are usually subject to premarket notification requirements (i.e. 510(k) clearance). Our JADE NC Balloon Catheter and Scoreflex PTA BTK scoring balloon, for example, are Class II devices.

Class III devices possess the highest risk level to patients, they are usually devices used to sustain or support life, implants and can present potential unreasonable risks of illness and injury. General controls in the abovesaid cannot ensure the saety and effectiveness of Class III devices. Class III devices are subject to premarket approval requirements. For example, our TricValve and Sapphire 3 Semi compliant balloon are Class III devices.

FDA also provide an online classification database to allow the users to identify the product classification by product general name. The database will return the classification, the corresponding regulation number and submission type.

II. FDA Regulatory Regime

The FDA has three levels of clearance for medical devices; 510(k), premarket approval and the De Novo Pathway, each of which needs specific criteria to be fulfilled in order to be granted. Such three levels of clearance and their respective criteria are summarized as below:

Level of FDA Clearance	**Description**
510(k) Clearance	A 510(k) clearance is granted when it has been shown to be at least as safe and effective as another similar, legally marketed medical device. The submitter seeking this clearance must provide substantial proof of equivalence in their application. Without an approval of being substantially equivalent to the other medical device, the one pending approval cannot be legally marketed.
Premarket Approval "**PMA**"	Premarket approval is issued to Class III medical devices which have a large impact on human health and as such, their evaluation undergo more thorough scientific and regulatory processes to determine their safety and effectiveness. In order to approve an application, the FDA determines that the device's safety and effectiveness is supported by satisfactory scientific evidence. Upon approval, the applicant can proceed with commercialization of the product.
De Novo Pathway	Regarding the de novo classification, it is used to classify those novel medical devices for which there are no legally commercialized counterparts, but which offer adequate safety and effectiveness with general controls. The FDA performs a risk based assessment of the device in question before approval and allowing the device to be commercialized.

Investigational Device Exemption

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data. All clinical evaluations of investigational devices, unless exempted, must have approved IDEs before any study can be initiated.

Clinical evaluation of devices that have not been cleared for marketing requires:

- an investigational plan approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by the FDA;

- informed consent from all patients;
- labeling stating that the device is for investigational use only;
- monitoring of the study; and
- required records and reports.

Breakthrough Device Program

The Breakthrough Devices Program is a voluntary program for certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the Breakthrough Devices Program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment and review, while preserving the statutory standards for 510(k) clearance, premarket approval, and De Novo marketing authorization, in order to protect and promote public health.

The Breakthrough Devices Program offers manufacturers an opportunity to interact with the FDA's experts through several different program options to efficiently address topics as they arise during the premarket review phase, which can help manufacturers receive feedback from the FDA and identify areas of agreement in a timely way. Manufacturers can also expect prioritized review of their submission.

Our TricValve was designated as a "breakthrough device" by the FDA in December 2020 as it provides for more effective treatment in irreversibly debilitating human conditions and offers significant advantages over existing approved or cleared alternative medical devices. The designation also indicates that the product represents breakthrough technology and its availability is in the best interest of patients. After the designation, the product was entitled to an expedited process of the development, assessment, and review by the FDA.

III. Regulatory pathway for Medical Device in the U.S.

Generally speaking most of Class I medical devices are subject to general control, and can be put into market after establishment registration and device listing. Most of Class II medical devices will need a 510(k) notification to FDA, and after the receipt of the 510(k) clearance, the product can be put into market on the basis of fulfilling the other special control requirements outlined in Title 21 CFR. Normally Class III device will need Premarket Approval from FDA.

General controls usually include device registration and listing, Good Manufacturing Practice requirements embodied in Part 820 Quality System Regulation ("**QSR**") of Title 21 CFR. Special controls, per Title 21 CFR, include device specific performance standards, postmarket surveillance, patient registries, special labeling requirements, and premarket data requirements.

For instance, per regulation 870.5100 of Title 21 CFR, a standard Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter is classified as Class II. The special control for this device is "Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty ("**PTCA**") Catheters." While per the same regulation, a Cutting/scoring PTCA Catheter is classified as Class III, and will need approval before commercial distribution.

IV. Pre-Clinical and/or Clinical Evaluations

The marketing authorization for medical devices requires a developer of the medical device in development to prepare information and data demonstrating the device's safety and effectiveness. Certain devices, such as implantable devices, their safety and effectiveness may need to be demonstrated through clinical evaluations. When conducting clinical evaluations, the manufactuerers, sponsors, clinical investigators and institutional review boards are subject to the FDA regulation known as the Good Clinical Practices, and various regulations regarding gnformed consent (21.C.F.R.50) responsibilities of Institutional Review Boards ("IRBs") (21 C.F.R. 56), certain disclosure requirements for clinical investigators (21 C.F.R. 54), and regulatory requirements for Investigational Devices (21 C.F.R. 812) need to be complied with.

Investigational Device Exemptions

Before starting clinical evaluations, the FDA may request the sponsors to submit IDE applications, usually when there is a significant risk device that will be used in the clinical studies, or when the clinical study is exempt from the informed consent requirement or if the FDA deemed necessary otherwise. A significant risk device is a device that is intended to be used as an implant, or a device to be used in supporting or sustaining human life, or a device intended to be used with substantial importance in diagnosing, curing, mitigating, or treating disease; or otherwise a device which can prevent impairment of human health; and therefore possesses the potentially serious risks to the health, safety and welfare of the test subject. If the FDA requires the sponsors to submit an IDE application, then the clinical study cannot proceed until the FDA has approved the IDE application. Vice versa, if a device to be studies is not a significant risk device, then an FDA's review of the IDE application will not be necessary. If the sponsors or investigators want to make changes to the investigation plan that may affect its scientific soundness; study indication; or the rights, safety, or welfare of human subjects, IDE supplements must be submitted to and approved by the FDA.

The FDA may disapprove and deny an IDE application upon review if the FDA has reasons to believe that the risks to the test subjects outweigh the anticipated benefits to the test subjects or the data and information to be collected or gained. The FDA can disapprove and deny an IDE application if it believes there isn't adequate informed consent, the clinical studies are scientifically unsound, or it questions the safety and the effectiveness of the devices. The FDA can also disapprove and deny an IDE application if the sponsors fail to respond to the FDA's requests for additional information, if there is/are untrue statement(s) of material facts or omission of material facts in the application, or the FDA has other concerns in general.

Clinical Studies for Medical Devices

There are several types of clinical studies that may be needed to demonstrate the safety and effectiveness of a medical device in development; they are early feasibility studies, traditional feasibility studies and pivotal studies.

An early feasibility study is a limited clinical investigation of a medical device before non-clinical testing can be used, or information is lacking for advancing the development process. Early feasibility studies are designed to test specific indications, for example, to test an innovative device for a new or existing intended use, or a commercialized device for a new clinical application, and usually involve limited number of test subjects, typically less than ten. A traditional feasibility study aims to provide preliminary safety and effectiveness information or data on a final or near-final product design, for the purpose of preparing for a pivotal study. A traditional feasibility study does not necessarily need to be preceded by an early feasibility study. A pivotal study is a clinical study that is design to provide definitive evidence of a device's safety and effectiveness for its specific indication. Pivotal studies are usually conducted on a statistically justified testing group size. A pivotal study may or may not be preceded by a traditional feasibility test.

The sponsors may start the clinical studies 30 days after the FDA receives the IDE application, but sponsors cannot proceed with the clinical studies if the FDA notifies the sponsor of any delay.

Informed Consent Requirement

Given the fact that many devices used in the abovementioned clinical studies have not previously been approved by the FDA for its safety and effectiveness, most FDA regulations require informed consent from test subjects so to ensure that the subjects are fully aware of the potential risks involved with participating in the clinical study along with other necessary information. FDA regulations require the investigator of a clinical investigations to obtain legally effective informed consent from the test subjects before the investigation can begin. Although there are exemptions from the informed consent requirement, it is still required for most clinical investigations.

Institutional Review Boards (IRBs)

IRBs are designated to ensure, in advance and periodically, that appropriate measures are taken to protect the rights, safety and welfare of humans subjects in a research. The IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. IRBs use a group process to review research protocols and related materials (e.g., the informed consent documents referenced above) and they must monitor and review an investigation throughout the clinical study. If an IRB decides that a clinical investigation involves a significant risk device, then it must inform the investigator and the sponsor if necessary. The sponsor may not proceed with the investigation until the FDA has approved it.

FDA regulations govern that IRBs are group of professionals that has been engage to review and monitor biomedical research on human subjects. IRBs have to be registered. IRBs must fully comply with all applicable IRB regulation requirements. The FDA does periodic inspections of the IRB's records and procedures to determine compliance with the regulations.

V. U.S. Pricing and Reimbursement

Sales of medical devices in the U.S. market, will depend, in part, on their coverage by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. Therefore, pricing of our products are predominately subject to market forces.

The Patient Protection and Affordable Care Act (ACA) came into effect in 2010. The ACA intends to widen the coverage of health insurance, including for at least a portion of drug costs, through the combination of insurance market reforms, an expansion of Medicaid and its subsidies. The ACA has many provisions designed to generate the enough revenues to fund the expanding coverage and to lower the costs of Medicare and Medicaid. The ACA also included provisions that created programs requiring all individuals to have health insurance with limited exceptions, and imposed increased taxes, shifting the industry to value-based care. One of these taxes is a 2.3% excise tax on United States sales of most medical devices.

General legislative cost control measures may also affect reimbursement for our products. The Budget Control Act of 2011, as amended, resulted in the imposition of 2% deductions in Medicare (but not Medicaid) payments to providers in 2013 and, except for a suspension from May 1, 2020 through December 31, 2020, will remain in effect through 2030 unless additional Congressional action is taken. Significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

VI. Quality system and Post-market Requirements

Quality System Regulation

Putting a medical device onto the U.S. market, from a manufacturer perspective, is legally bonded with quality system compliance to Part 820 of Title 21 CFR, the QSR. Similar as ISO13485 but as a high level regulation, QSR covers the typical operation functions including design control, document control, purchasing control, production and process control and etc. All the applicable requirements shall be fulfilled according to the functions of the entity for the marketed devices.

As one of the initiator of Medical Device Single Audit Program ("MDSAP"), FDA accepts compliance to the QSR if the manufacturer passes the MDSAP audit.

Factory inspection for Quality system compliance

FDA performs on-site inspection of factories if necessary. FDA categorizes the results of its on-site inspection as follows:

- No action indicator ("**NAI**") which means no observations are found during the inspection;

- Voluntary action indicator which represents non-conformity(ies) in Form 483 requiring the manufacturer's response;

- Official action indicator ("**OAI**") which means systematic issues usually caused by major findings or multiple findings, in case of OAI, the manufacturer will receive a warning letter.

The recent FDA inspection to OrbusNeich was a pre-PMA inspection at the end of December of 2020 with the result of NAI.

Establishment Registration and Device Listing

Establishment registration and device listing typically happen after either 510(k) clearance or PMA approval, or for devices exempted from premarket notification, before placing the products onto market. Besides the manufacturer, certain companies will also be required for the registration including the contract manufacturer, contract sterilizer, initial importer and among others. This registration enables the agency to keep track of the establishment information for medical devices that are being marketed in the United States. Foreign manufacturers will need a U.S. agent as the liaison with FDA. All facilities must renew their registrations between October 1 and December 31 of each fiscal year.

Device listing as part of the establishment registration will need the manufacturer to provide the cleared/approved product information and the products exempted from premarket notification.

The online system which is known as FDA Unified Registration and Listing System will then return a Firm Establishment Identifier number for the entity and a listing number(s) for the device which will be used for the Unique Device Identifier ("**UDI**") system uploading in the Global Unique Device Identification Database ("**GUDID**").

Labeling and Packaging

Part 801 of Title 21 CFR outlines the requirements to labeling including general requirements and special requirements for specific devices, as well as the UDI requirements.

UDI includes a Device identifier, a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and a Production identifier, a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:

– Lot or batch number within which a device was manufactured;

– Serial number of a specific device;

– Expiration date of a specific device;

– Date a specific device was manufactured;

– Distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

The FDA Unique Device Identification System final rule (UDI Rule) requires device labelers (typically, the manufacturer) to:

– Include a unique device identifier (UDI) on device labels and packages, except where the rule provides for an exception or alternative.

  • If a device is intended for more than one use and intended to be reprocessed before each use, the device labeler must also mark the UDI directly on the device.

– Submit device information to the GUDID.

Promotion and advertising materials are considered as part of the product labeling and subjected to regulatory control.

Medical Device Reporting

FDA requires certain parties to report to FDA adverse events and product problems if the adverse events and product problems meet certain requirements. This mandatory requirement applies to manufacturers, importers, and device user facilities. In particular, manufacturers must submit a Medical Device Report ("**MDR**") to FDA within 30 days of receiving or otherwise learning of information that reasonably suggests that their devices may have caused or contributed to a death or serious injury, or malfunctioned and the device or a similar device that the manufacturer markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to occur again. In addition, manufacturers must provide a five-day report to FDA within five working days once becoming aware from any source that remedial action is necessary for preventing an unreasonable risk of substantial harm to the public health, or if FDA requests such a written report. Similar requirements exist for importers and device user facilities.

MDR may be submitted through FDA's electronic Medical Device Reporting database, and must include known or reasonably known information such as patient information (e.g., name, gender, etc.), outcomes of the adverse event, date of the event, date of the report, device information including the brand name, product code, and model number, and any remedial action taken. There is also a requirement to file Supplemental Reports upon learning information that would have been included in the MDR, had it been known at the time of filing. FDA considers a Supplemental Report to be required when new facts prompt the company to alter or supplement any information or conclusions contained in the original MDR or in any prior supplemental reports. The supplemental information must be submitted within one month (30 calendar days) following receipt of the information.

VII. Advertisements of Medical Devices in the U.S.

A product can be subject to different regulatory schemes (drug, device, food, cosmetic, consumer product, etc.) depending on how the FDA categorizes them based on their intended use. The FDA regulates the labels, labelling and advertising of over-the-counter, prescription and restricted medical devices. Labels and labelling of medical devices must contain specific information, including but not limited to:

- statement of identity;
- manufacturer, packer and/or distributor;
- net quantity;
- directions for usage;
- frequency and duration of administration or application;

- statements of all conditions, purposes, or uses for which such device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the device is commonly used;

- warning statements (if any);

- indication for use;

- Risks (if applicable);

Labels, labeling and advertisement of medical devices cannot claim that a device is safe and effective for uses which that FDA has not reviewed and approved. Non-compliance or violation of these advertising and promotion requirements may render the products misbranded or adulterated for lack of a cleared premarket notification or premarket approval, and subject the product and/or the company to enforcement actions. Off-label promotion violations may too render a device adulterated or misbranded, and subject the company, its employees, and officers to significant civil and criminal liabilities including fines and incarceration, and may also constitute a violation of the False Claims Act.

VIII. Registration and Listing

Under the FDCA, all person and parties that own or operate any establishment which engages in manufacturing, preparing, propagating, compounding or processing a medical device, needs to be registered with the FDA, in order to allow the FDA to keep track of the establishment information for medical devices that are being marketed and sold in the United States. All facilities must renew their registrations between October 1 and December 31 of each fiscal year, failures of which constitutes a violation of the FDCA.

The FDA also requires a list of the medical devices in commercial distribution from the owner of operator of the establishment (including specification developers, medical device sterilizers, medical device repackagers or relabelers, reprocessors of a single use device, manufacturers of components or accessories that are packaged for commercial distribution, or initial importers of medical devices), or if applicable, the parent, subsidiary, or affiliate of the owner or operator. The list must be provided at the time of registering the establishment. Any changes must be reflected on FDA's database within 30 days of such change, failures of which constitutes a violation of the FDCA.

HONG KONG REGULATORY OVERVIEW

In Hong Kong, an entity involving medical device distribution and sales are subjected to regulatory controls including the requirements to the entity, and the listing requirements. Regulatory requirements to the entity include commercial registration, company listing, medical device listing and other applicable corporation laws and regulations.

Regulatory Requirements to Medical Device Company in Hong Kong

Regulatory requirements to a medical device company can be divided into general corporation laws and regulations, and then the laws and regulations issued by Medical Device Division (formerly known as Medical Device Control Office) under Department of Health ("**DOH**").

Laws and Regulations on the General Business in Hong Kong

Business Registration and other General Regulations

All companies incorporated or registered in Hong Kong (including "shelf" companies and Hong Kong companies carrying out business outside Hong Kong) are required to register. In addition, every person carrying on any business in Hong Kong has to apply for business registration.

Where the business of a company or person is carried out through a branch of the business, application for branch registration is also required.

Once registered, the corporation shall comply with other applicable social and financial regulations, including employment, fund schemes, occupational and health safety, tax etc.

Listing Requirements under Medical Device Administrative Control System

Per the Guidance Notes: GN-01, Overview of the Medical Device Administrative Control System ("**MDACS**"), issued by DOH, the importer, local manufacturer and the distributor may be listed in the MDACS per GN-07, GN-08 and GN-09 respectively, though the requirements now is voluntary.

If an oversea manufacturer of the medical devices does not have an office in Hong Kong, a Local Responsible Person ("**LRP**") is required, and will need to take the obligations of application for listing medical devices, complaint handling, reporting of adverse events and other field actions as per GN-01. LRP will need to be listed while a device listing which will be required for the usage of a device in public hospital as explained in the section below.

Listing and Classification of a Medical Device

As per GN-01, listing of a device is voluntary. However, since using a medical device in public hospital will need the approval from Hospital Authority ("**HA**"). The application to HA will reference the listing number of the device, which makes the listing of a device as necessary.

Medical device classification in Hong Kong adopts the classification rules promulgated by the International Medical Device Regulator Forum. According to TR-003, Classification Rules for Medical Devices, Medical Devices are classified as Class I, II, III, IV for low risk devices, low-moderate risk devices, moderate-high risk devices and high risk devices.

Class I devices are free from the listing. Other devices shall follow GN-02: Guidance Notes for Listing Class II/III/IV General Medical Devices to prepare the application with supporting documents, and then submit to Medical Device Division. Medical Device Division will review the application and issue a Certificate of Listing after the completeness of review. The certificate will be valid for 5 years and renewal of the certificate shall be started at least 3 months before the expiry date as per GN-01.

Product Quality and Liability

The contract sale of medical devices in Hong Kong are governed by the Sale of Goods Ordinance (Cap. 26) ("SOGO"). SOGO provisions impose certain implied terms, conditions and/or warranties on the goods sold, including goods supplied must be of merchantable quality; reasonably fit for the purpose for which the purpose made known to the seller; and corresponds with the description and sample (if applicable).

The Consumer Goods Safety Ordinance (Cap. 456) imposes a statutory duty on manufactures, importers and suppliers of consumer goods, medical devices included, to ensure the reasonable safety having considered all the relevant circumstances of their products. Under the Consumer Goods Safety Ordinance (Cap. 456), it is an offence for a person to supply, manufacture or import into Hong Kong consumer goods which fail to meet the general safety requirements or product-specific safety requirements. Failure of compliance may result in product withdrawal, fines and/or imprisonment. The Consumer Goods Safety Regulations (Cap. 456A) requires that any warning or caution related to the safe keeping, use, consumption or disposal of any consumer goods must be given in both English and Chinese. The warning or caution label must be legible and placed in a conspicuous position on the consumer goods, or any package of the consumer goods, or on a label securely affixed to the packaging or a document enclosed in the package.

Packaging, Advertising and Promotion

Under the Trade Descriptions Ordinance (Cap. 362), false trade descriptions, false, misleading or incomplete information, false marks and misstatements in respect of goods supplied are prohibited. The Trade Descriptions Ordinance (Cap. 362) requires information or instructions related to the good to be marked, accompanied with the goods, or to be included in advertisements.

The Undesirable Medical Advertisements Ordinance (Cap. 231) prohibits the use of any advertisements that will likely lead to the use of any surgical appliance or treatment, including the use of medicine and surgical appliances, of certain diseases or conditions, including, among others, any disease of the heart or cardiovascular system, including rheumatic heart disease, arteriosclerosis, coronary artery disease, arrythmias, hypertension, cerebrovascular disease, congenital heart disease, thrombosis, peripheral artery disease, oedema, retinal vascular change and peripheral venous disease.

Transfer Pricing Laws and Regulations in Hong Kong

Regulations concerning transfer pricing between associated enterprises can be found in the Inland Revenue Ordinance (Chapter 112 of the Laws of Hong Kong) (the "**IRO**") and the comprehensive double taxation agreements (the "**DTAs**") between Hong Kong and other countries or territories, including the Mainland China.

Under section 60 of the IRO, where it appears to an assessor that for any year of assessment any person chargeable with tax has not been assessed or has been assessed at less than the proper amount, the assessor may, within the year of assessment or within six years after the expiration thereof, assess such person at the amount or additional amount which, according to his judgment, such person ought to have been assessed, and, provided that where the non-assessment or under-assessment of any person for any year of assessment is due to fraud or wilful evasion, such assessment or additional assessment may be made at any time within 10 years after the expiration of that year of assessment.

Section 61A of the IRO stipulates that where it would be concluded that person(s) entered into or carried out transactions for the sole or dominant purpose to obtain a tax benefit (which means the avoidance or postponement of the liability to pay tax or the reduction in the amount thereof), liability to tax of the relevant person(s) will be assessed (a) as if the transaction or any part thereof had not been entered into or carried out; or (b) in such other manner as the supervising authority considers appropriate to counteract the tax benefit which would otherwise be obtained.

The DTAs contain provisions mandating the adoption of arm's length principle for pricing transactions between associated enterprises. The arm's length principle uses the transactions of independent enterprises as a benchmark to determine how profits and expenses should be allocated for the transactions between associated enterprises. The basic rule for DTA purposes is that profits tax charged or payable should be adjusted, where necessary, to reflect the position which would have existed if the arm's length principle had been applied instead of the actual price transacted between the enterprises.

The Departmental Interpretation and Practice Notes No. 45–Relief from Double Taxation due to Transfer Pricing or Profit Reallocation Adjustments issued by the Inland Revenue Department in April 2009 makes it available that where double taxation arises as a result of transfer pricing adjustments made by the tax authorities of another jurisdiction, a Hong Kong taxpayer may potentially claim relief under the tax treaty between Hong Kong and that country (jurisdictions that entered into tax arrangements with Hong Kong includes the Mainland China).

The Inland Revenue Department also issued Departmental Interpretation and Practice Notes No. 46 ("**DIPN 46**") in December 2009 on Transfer Pricing Guidelines – Methodologies and Related Issues. As stated in DIPN 46, transfer pricing documentation is not mandatory under the IRO and the taxpayers are not expressly required to create specific documents showing compliance with the arm's length principle. The Inland Revenue Department further issued Departmental Interpretation and Practice Notes No. 48 in March 2012 which provides a mechanism for taxpayers to pre-agree their transfer pricing arrangements with the Inland Revenue Department.

In July 2018, the Inland Revenue (Amendment) (No. 6) Ordinance 2018 (the "**Amendment Bill**") was enacted to introduce a legislative framework to codify how the pricing for the supply of goods and services between associated parties should be determined and implemented. Codified international transfer pricing principles include, amongst others, the arm's length principle for provision between associated persons, the separate enterprises principle for attributing income or loss of non-Hong Kong resident person, and the three-tier transfer pricing documentation relating to the master file, local file and country-by-country reporting. Based on the Amendment Bill, a person who have a Hong Kong tax advantage if taxed on the basis of a non-arm's length provision (the "**advantaged person**") will have income adjusted upwards or loss adjusted downwards. The advantaged person's income or loss is to be computed as if arm's length provision had been made or imposed instead of the actual provision. If the advantaged person fails to prove to the satisfaction of the assessor of the Inland Revenue Department ("**IRD**") that the amount of the person's income or loss as stated in the person's tax return in an arm's length amount, the assessor of the IRD must estimate an amount as the arm's length amount and, taking into account the estimated amount (a) make an assessment or additional assessment on the person; or (b) issue a computation of loss, or revise a computation of loss resulting in a smaller amount of computed loss, in respect of that person pursuant to section 50AAF of the IRO. In July 2019, the Inland Revenue Department further issued the Departmental Interpretation and Practice Notes No. 58 ("**DIPN 58**"), No. 59 ("**DIPN 59**") and No. 60 ("**DIPN 60**") to set out interpretations to the Amendment Bill.

PRC REGULATORY OVERVIEW

Laws and Regulations Relating to Medical Devices Administration

Our business operations in the Mainland China are subject to a number of laws and regulations relating to the medical devices administration. The main regulatory authorities of the PRC's medical devices industry are National Medical Products Administration (國家藥品監督管理局) ("**NMPA**") and its local counterparts, whose predecessor were China Food and Drug Administration (國家食品藥品監督管理總局) ("**CFDA**") and its local counterparts.

Classification of Medical Devices

According to the Regulation on the Supervision and Administration of Medical Devices (醫療器械監督管理條例) ("**Regulation on Medical Devices**") which was promulgated on January 4, 2000 and latest amended on February 9, 2021 by the State Council, the PRC implements classified administration of medical devices which are classified as Class I, Class II and Class III based on the degree of risks from low to high. Class III medical devices are those with high risks, such as life sustaining, life-supporting or implantable devices, whose safety and effectiveness shall be ensured through special measures for strict control and management.

The classification of a medical device, among others, determines (i) whether a manufacturer or a seller needs to obtain a production license or an operation license in order to manufacture or sell this medical device in the PRC and which level of regulatory authority has jurisdiction over such license and (ii) which type of registration requirements is applicable to such medical device.

During the Track Record Period and as of the Latest Practicable Date, our finished medical products were all registered as Class III medical devices with NMPA.

Registration of Medical Devices

According to the Measures for the Administration of Medical Devices Registration and Filing (醫療器械註冊與備案管理辦法) promulgated by the State Administration for Market Regulation ("**SAMR**") on August 26, 2021 and effective from October 1, 2021, Class III medical devices are subject to product registration-based administration. NMPA is responsible for reviewing the registration of both domestic and imported Class III medical devices and issuing the relevant registration certificates.

A. Technical requirements and registration testing

As stipulated by the Measures for the Administration of Medical Devices Registration and Filing (醫療器械註冊與備案管理辦法), prior to applying for the registration of Class III medical devices, the registrant shall draw up the product technical requirements applicable to such medical devices. The product technical requirements shall mainly include the functional and safety indicators that can be objectively assessed for the finished medical devices products and testing methods.

Furthermore, it is required to conduct registration testing in accordance with the product technical requirements and submit a testing report to apply for the registration of Class III medical devices. The testing report of such medical device products submitted for registration can be self-testing report issued by the applicant itself or the testing report issued by a qualified medical device testing institution. Only those medical devices testing as qualified can be further submitted to conduct clinical trials or apply for registration.

B. Clinical evaluation

Clinical evaluation is required for the registration of Class III medical devices, with some specific exceptions. According to the Regulation on Medical Devices and the Measures for the Administration of Medical Devices Registration and Filing (醫療器械註冊與備案管理辦法), in the clinical evaluation, the safety and effectiveness of medical devices can be proved through (i) clinical trials or (ii) the analysis of clinical literatures and materials, by taking into account the product feature, clinical risk, existing clinical data, etc., and medical devices may be exempt from clinical evaluation under any of the following circumstances: (i) the medical device has clear working mechanisms, finalized design and mature manufacturing process, and the medical devices of the same type that are available on the market have been used in clinic for years without any record of serious adverse event, and the medical device will not change the general purposes thereof; (ii) the safety and effectiveness of such medical device can be proved through other non-clinical evaluation methods. NMPA has the authority to formulate, adjust and publish the catalog of the medical devices exempt from clinical evaluation (the "**Exemption Catalog**").

As of the Latest Practicable Date, the latest version of the Exemption Catalog was the Notice on Publishing Medical Device Catalog Exempted from Clinical Evaluation (關於發布免於臨床評價醫療器械目錄的通告) promulgated by NMPA on September 16, 2021 and effective on October 1, 2021.

During the Track Record Period and as of the Latest Practicable Date, certain of our balloons and microcatheter products have been listed in the Exemption Catalog and therefore had been exempted from clinical evaluation.

C. Registration process

The registrant shall apply for medical devices registration after completing the safety and effectiveness research of the medical devices, and shall be well prepared to accept the the quality management system verification. The application documents shall include the applicable technical requirements, registration testing report and clinical trial evaluation report (if applicable) and other documents as required by the regulators. For medical devices which meet the requirements of safety, effectiveness, and quality control, the medical devices regulatory authority will issue a medical device registration certificate.

The medical device registration certificate is valid for 5 years. In the event of any substantial change of the design, raw material, production process, scope of application or use methods, etc., that may affect the safety and effectiveness of the registered Class III medical devices, the registrant shall apply for the registration of such change; in the event of any other change of the registered Class III medical devices thereof, registrant shall apply for filing of such change. If the medical device registration certificate needs to be renewed upon expiration, the registrant shall make the application for registration renewal at least 6 months prior to the expiry date of the medical device registration certificate.

We obtained the Class III medical device registration certificates for our stents and angioplasty balloons in the PRC, which are within the validity term as of the Latest Practicable Date.

Production Supervision and Quality Management

Medical Devices Production License

According to (i) the Regulation on Medical Devices, (ii) the Measures for the Supervision and Administration of the Production of Medical Devices (醫療器械生產監督管理辦法) promulgated by CFDA on July 30, 2014 and latest amended on November 17, 2017 and (iii) the measures of the same name of (ii) which was promulgated by SAMR on March 10, 2022 and was effective and replaced (ii) on May 1, 2022, the enterprises which intend to engage in the production of Class III medical devices shall apply for medical devices production license (醫療器械生產許可證) at the provincial level of the medical product regulatory authority which will issue to the applicant a medical device production license if the relevant requirements are satisfied. The medical device production license is valid for five years. In the event of a change to the content of the medical device production license, the manufacturer shall make an application to license-issuing authority for change of licensed items or change of registered items (as the case may be). If medical device production license needs to be renewed upon expiration, the manufacturer shall make the application for renewal within the prescribed time limit prior to the expiry date of the medical device production license.

As of the Latest Practicable Date, ONM Shenzhen held the medical device production license with the expiry date of July 17, 2024, which was issued by Guangdong Medical Product Administration on May 15, 2020.

Quality Assurance

As stipulated by the Regulation on Medical Devices and the Measures for the Supervision and Administration of the Production of Medical Devices (醫療器械生產監督管理辦法), the medical device manufacturing enterprises shall comply with the standards of medical devices production and quality assurance, establish a quality assurance system and maintain its effective operation. The medical device manufacturing enterprises shall conduct comprehensive self-inspection on the performance of the quality assurance system on a regular basis. A medical device manufacturer shall record the process for procurement, manufacturing or inspection of raw materials and shall assure the record to be true, accurate and complete and be traceable.

The Medical Devices Good Manufacturing Practice (醫療器械生產質量管理規範) which was promulgated by CFDA on December 29, 2014 and came into effect on March 1, 2015, sets out the detailed requirements for the medical device production enterprises to establish and effectively maintain a quality control system commensurate with the medical devices produced and to integrate the risk management into the whole process of medical device design, development, production, sale and after-sales service where the measures to be taken shall be compatible with the risk relating to the products.

Post-Market Quality Surveillance

In accordance with the Administration Measures for Medical Device Adverse Events Monitoring and Re-evaluation (醫療器械不良事件監測和再評價管理辦法), the holder of medical device registration certificate is obliged to collect information with respect to medical device adverse events and report to the monitoring technical regulators timely. The medical device adverse events are classified as individual medical device adverse events and group medical device adverse events. In the event an individual medical device adverse event occurs, the holder is required to conduct investigations immediately and report within 7 days in case of death or within 20 days in case of serious injury, possible serious injury or possible death. In the event a group medical device adverse event occurs, the holder, other business operator or user who is aware of the group medical device adverse event shall report to the competent regulators within 12 hours.

The Administrative Measures for Medical Device Recalls (醫療器械召回管理辦法), which was promulgated on January 25, 2017 and came into effect on May 1, 2017, regulates that a medical device manufacturer, as the responsible person for controlling and eliminating product defects, shall take the initiative to recall defective products. Medical device manufacturers shall determine the level of recall based on the specific situation and properly formulate and implement the recall plan based on the recall level and the sale and use of the medical devices.

According to the Regulation on Medical Devices, the medical devices regulatory authorities have the authority to conduct onsite supervision and inspection on product samples. In practice, NMPA and its local counterparts may publish the results of inspection on the product samples on their websites.

Product Liability

According to the Civil Code of the PRC (中華人民共和國民法典) which was passed by the National People's Congress (全國人民代表大會) on May 28, 2020 and effective on January 1, 2021, if a patient suffers damages due to defects of medical devices, the patient is entitled to claim compensation against the manufacturer of such medical devices or the medical institution. If a patient claims compensation against the medical institution, the medical institution has the right to recover the compensation from the manufacturer of such medical devices after it pays the compensation to the patient.

The Product Quality Law of the PRC (中華人民共和國產品質量法), which was passed by the Standing Committee of the National People's Congress (the "**SCNPC**") on February 22, 1993 and latest amended on December 29, 2018, applies to all production and marketing activities within the territory of the PRC. Pursuant to this law, a manufacturer shall be responsible for the quality of products it manufactures and shall be liable for compensation for damages (including personal injuries and property damages) caused by its products with defects. In addition, the enterprise, which manufactures or sells the products failing to meet the national or industry standards for ensuring human health, personal safety and property safety, may face the administrative liabilities, such as suspension of production or sales activities, payment of penalties and confiscation of illegal income, and, in serious scenario, revocation of business license, and it may even face the criminal liabilities if such act constitutes a crime.

Sales or Distribution of Medical Devices

Medical Device Operation License

Under the Measures for the Supervision and Administration of the Operation of the Medical Devices (醫療器械經營監督管理辦法) promulgated on July 30, 2014 and latest amended on November 17, 2017 by CFDA and the measures of the same name of the former which was promulgated by SAMR on March 10, 2022 and was effective and replaced the former on May 1, 2022, the enterprise to engage in the operation activities of Class III medical devices shall obtain the medical device operation license (醫療器械經營許可證) from the municipal level of medical product regulatory authority and operation activities of medical devices include wholesale and retail of medical devices in which the enterprises engaging are required to establish the sales record system. The medical device operation license is valid for five years. In the event of a change to the medical device operation license, the enterprise shall make an application to license-issuing authority for change of the license. If medical device operation license needs to be renewed upon expiration, the enterprise shall make the application for renewal within the prescribed time limit prior to the expiry date of the medical device operation license.

As of the Latest Practicable Date, ONM Shenzhen held the medical device operation license with the expiry date of July 26, 2023, which was issued by Shenzhen Administration for Market Regulation on July 27, 2018 and re-issued on February 8, 2021.

Centralized Procurement of Medical Devices

In the PRC, the public medical institutions are required to, implement the centralized procurement for their purchase of the high-value medical consumables which are brought into the centralized procurement scope. The Code 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, provides that (i) the provincial level government should establish and maintain the online centralized procurement platform of high value medical consumables and formulate the centralized procurement catalog for its administrative region; (ii) all public medical institutions in that administrative region should purchase through the centralized procurement platform the high value medical consumables listed in the centralized procurement catalog and cannot purchase, in principle, the ones not listed in the above catalog; and (iii) the manufacturer of the high value medical consumables (including the deemed manufacturer, such as the PRC general agent for imported products) should directly bid on the centralized procurement platform.

In recent years, the PRC governments strengthened the implementation of centralized procurement system of high-value medical consumables with the aim of improving the pricing mechanism and reducing the inflated prices of the high-value medical consumables.

On July 19, 2019, the General Office of the State Council of the PRC promulgated the Notice on Printing and Distributing the Reform Plan on Managing High-value Medical Consumables (關於印發《治理高值醫用耗材改革方案》的通知). One of the key tasks of the reform plan is to improve the methods of classified and centralized procurement by, among others, (i) requiring all the public medical institutions to purchase the high-value medical consumables on the procurement platforms via public trading or "sunlight" procurement; and (ii) encouraging the provincial governments to carry out the centralized procurement of the high-value medical consumables, which are in large clinical demand, high purchase amount, mature clinical use and produced by multiple enterprises, by means of collecting or combining the demand from multiple hospitals in one provincial region or even several provincial regions and having volume-based negotiations with bidders. The above task was scheduled to start in the second half of 2019 with continuous improvement. After the issuance of the above reform plan, vascular interventional balloon products were gradually brought into the scope of the centralized procurement (also known as volume-based procurement and/or the centralized volume-based procurement, hereinafter referred to as "centralized procurement") in Jiangsu, Hubei, Zhejiang, Sichuan, Shanxi, Liaoning, Jilin, Heilongjiang, Guangdong, Beijing, Tianjin, Hebei and other regions from the second half of 2019 to 2021 according to their centralized procurement notices and were expected to be implemented across the PRC.

On April 30, 2021, eight departments of the State Council jointly promulgated the Guidance on Centralized Volume-based Procurement and Use of High-Value Consumables Organized 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), which provides the overall norms and requirements on the centralized procurement by specifying that, among others, (i) the scope of centralized procurement will include the high-value medical consumables that are in large clinical demand, high purchase amount, mature clinical use, fully competitive market and high level of homogenization; and (ii) the enterprises eligible to participate in the centralized procurement shall be the registrant of medical device in the scope of centralized procurement and shall meet the relevant requirements on quality standards, production capacity, supply stability and enterprise credit.

The above policies influenced the PRC sales environment of the high-valued medical consumables in the scope of centralized procurement mainly in the following respects: (i) the manufacturers (including the deemed manufacturer, such as the general agent of the imported products) or the holders of the medical device registration certificate are required to directly participate in the bidding or tender process of the centralized procurement, and (ii) the end prices of the high-value medical consumables within the scope of centralized procurement generally drop significantly caused by the pricing mechanism of the bidding or tender process and volume-based negotiations for preferential price.

As of the Latest Practicable Date, seven out of 13 products we sold in the PRC market were included in the scope of centralized procurement. Our sales activities in the PRC market was affected by the implementation of the above policies and, as a result, starting from 2021 we started to directly participate in the sales activities in the PRC and changed our distribution model in the PRC from the exclusive distributorship for the entire PRC market to the combination of direct sales (mainly for our products in the scope of centralized procurement) and regional distributors (mainly for our products outside the scope of centralized procurement).

Two-Invoice System

In the PRC, some provinces or regions implement the "Two-Invoice System" in the procurement of the medical consumables. According to the rules mentioned below, the "Two-Invoice System" (兩票制) means that in the distribution chains of the medical consumables only two value-added tax invoices (增值税發票) can be issued when the medical consumables are ultimately sold to the public medical institutions, one is the value-added tax invoice issued by a manufacturer or a deemed manufacturer (such as the PRC domestic general agent of the imported medical devices) to its distributor, the other one is the value-added tax invoice issued by such distributor to a public medical institution.

On June 24, 2016, the National Health and Family Planning Commission together with other ministries issued the Main Points of Special Governance to Correct Medical Malpractice in the Sale of Drugs and the Process of Providing Medical Services in 2016 (2016年糾正醫藥購銷和醫療服務中不正之風專項治理工作要點), which stipulates that the provinces (regions and municipalities) for pilot comprehensive medical reform and the cities for pilot public

hospital reform shall implement the "Two-Invoice System" in procurement of medical consumables. Some provincial governmental authorities also issued local regulations to require public medical institutions in their respective administrative regions to implement the "Two-Invoice System" in the procurement process of medical consumables, such as Two-invoice System Implementation Opinions on the Procurement of Medical Consumables in Public Medical Institutions in Anhui Province (Trial) (安徽省公立醫療機構醫用耗材採購"兩票制"實施意見(試行)) promulgated on November 20, 2017 and the Notice on Further Promoting the "Two Invoice System" for Medicines and Medical Consumables (關於進一步推進藥品和醫用耗材"兩票制"的通知) in Shaanxi promulgated on July 23, 2018, according to which, if the manufacturers or distributors of medical consumables fail to implement the "Two-Invoice System", they may lose the qualification to bid for, win a bid of or distribute medical consumables and they may also be included in the bad credit record for medical consumables procurement.

Advertisements of Medical Devices

SAMR promulgated on December 24, 2019 the Interim Measures for the Review and Administration of Advertisements for Pharmaceuticals, Medical Devices, Health Foods, and Formulas 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) effective from March 1, 2020 (the "**Interim Measures for Advertisements**"), according to which the provincial market supervision and regulation authorities and medical product regulatory authorities are responsible for the review of advertisements for medical devices. No advertisements for medical devices may be published without approval and the approval number shall be conspicuously indicated on the advertisements.

The contents of an advertisement on a medical device shall be subject to the contents of the registration certificate or the registered product instructions approved by the medical product regulatory authorities. The validity term of the approval number of advertisement conforms to the earliest expiry date of the registration certificates or production licenses for the relevant medical devices. If no validity term specified in the above documents, the validity term of approval number would be two years.

As of the Latest Practicable Date, ONM Shenzhen had obtained approvals for publishing advertisements for certain medical devices from Guangdong Medical Products Administration, and the approvals of the advertisements that were material to our current business operation were all within the valid period.

Foreign Exchange

Under the Foreign Exchange Administration Regulations of the PRC (中華人民共和國外匯管理條例), promulgated on January 29, 1996 and latest amended on August 5, 2008 by the State Council, from the perspective of administration on the foreign exchange, the international receipts and payments shall be classified into current account items and capital account items. The current account item refers to a transaction involving goods, services, gains or frequent

transfers in the international receipts and payments. The capital account item refers to a transaction which causes the changes in external assets and liabilities in international receipts and payments, including capital transfers, direct investments, investments in securities, derivatives and loans, etc.. No prior approval from or registration with SAFE is required for the international receipts and payments under current account items, however, certain procedural requirements should be followed and the handling banks in the PRC should verify whether the international receipts and payments are based on true and legal transactions. Compared to the current account items, the international receipts and payments under capital account items are subject to a deeper supervision by SAFE and it is normally required to register with SAFE or its local counterparts before such international receipts and payments are made.

As the cross-border capital flows are common to us based on our business model, the PRC laws and regulations in relation to the foreign exchange are material to our Group's business.

Environmental Protection

Environmental Impact Assessment

According to the Environmental Impact Assessment Law of the PRC (中華人民共和國環境影響評價法) which was passed by the SCNPC on October 28, 2002 and latest amended on December 29, 2018, and 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 on November 29, 1998 and latest amended on July 16, 2017 by the State Council, the PRC implements an environmental impact assessment system for construction projects and the administration of construction projects are classified into three types in accordance with the degree of their respective environmental impact. On December 28, 2020, Shenzhen Ecology and Environment Bureau promulgated the Environment Assessment Approval and Filing Administration Catalog of Construction Projects in Shenzhen (2021 Version) (深圳市建設項目環境影響評價審批和備案管理名錄(2021年版)) to further clarify the classified administration of the environment impact assessment on the construction projects in Shenzhen, according to which, a medical devices manufacturing project equipped with pollution prevention and control facilities for waste water and gas should be administrated by means of the environmental impact form (環境報告表), which means, according to the Environmental Impact Assessment Law of the PRC, the environmental impact of the construction project is mild and the construction enterprise should submit an environmental impact form containing the analysis or a specialized assessment on its environmental impact to the competent environmental authority and obtain the approval from the same.

Our Shenzhen production facility was administrated by means of the environmental impact form. ONM Shenzhen had submitted the environmental impact form regarding our Shenzhen facility to the competent environmental authorities and obtained the relevant environmental impact approval.

Pollutant Discharge

According to the Regulation on the Administration of Permitting of Pollutant Discharges (排污許可管理條例) which was promulgated by the State Council on January 24, 2021 and came effective on March 1, 2021 and Measures for Pollutant Discharge Permitting Administration (Trial)(排污許可管理辦法(試行) promulgated by the Ministry of Ecology and Environment of the PRC on January 10, 2018 and amended on August 22, 2019, the PRC implements the classified administration on pollutant discharges of enterprises in line with the amount of pollutants produced, emissions, the environmental impact and other factors, which means (i) a pollutant discharger who generates large amount of pollutants or emissions or has material impact on the environment should be under the key administration of pollutant discharge permit, (ii) a pollutant discharger who generates relatively small amount of pollutants and emissions and has mild impact on the environment should be under the simplified administration of pollutant discharge permit, and (iii) a pollutant discharger who generates very small amount of pollutants and emissions and has very small impact on the environment should be under the administration of pollutant registration.

ONM Shenzhen has been included the scope of simplified administration of pollutant discharge permit since November 9, 2021 and it obtained the relevant pollutant discharge permit on the same day with the validity period of 5 years. Prior to that, ONM Shenzhen was under the administration of pollutant registration and it completed the submission of the relevant pollutant discharge registration form on the national pollutant discharge permit administration information platform.

Employment

Labor Law

The Labor Law of the PRC (中華人民共和國勞動法), which was passed by the SCNPC on July 5, 1994 and was latest amended December 29, 2018, provides that employees are entitled to equal opportunities in employment, selection of occupations, receiving labor remuneration, rest days and holidays, protection of occupational safety and healthcare, social insurance and welfare, etc.. Employers must establish and improve the system for occupational safety and healthcare, provide training on occupational safety and healthcare to employees, comply with national local regulations on occupational safety and healthcare, and provide necessary labor protective supplies to employees.

Labor Contract Law

The Labor Contract Law of the PRC (中華人民共和國勞動合同法) (the "**Labor Contract Law**") which was passed by the SCNPC on June 29, 2007, came into effect on January 1, 2008, and was amended on December 28, 2012, and the Implementation Regulations on the Labor Contract Law (勞動合同法實施條例) which was promulgated by the State Council on September 18, 2008, and came into effect on the same day, provide that the labor contracts must be executed in order to establish the labor relationship between employers and

employees. The Labor Contract Law stipulates that an employer shall inform the employees truthfully the scope of work, working conditions, workplace, occupational hazards, production safety conditions, labor remuneration and other information requested by the employees. The Labor Contract Law also stipulates that employer and employee shall fully perform their respective obligations in accordance with the terms set forth in the labor contract. In addition, employer shall pay employees the labor remuneration timely and in full amount in accordance with terms in the labor contract. The Labor Contract Law also provides for the scenario of rescission and termination, except the situation explicitly stipulated in the Labor Contract Law which will not subject to economic compensation, the economic compensation shall be paid to the employees by the employer for the illegally rescission or termination of the labor contract.

Social Insurance and Housing Provident Funds

Under the Social Insurance Law of the PRC (中華人民共和國社會保險法), promulgated by the SCNPC on October 28, 2010 and amended on December 29, 2018, the Regulations on Work-Related Injury Insurance (工傷保險條例), promulgated by the State Council on April 27, 2003 and amended on December 20, 2010, the Regulations on Unemployment Insurance (失業保險條例), promulgated by the State Council on January 22, 1999, and took effective on the same day, the Provisional Measures on Maternity Insurance of Employees (企業職工生育保險試行辦法), promulgated on December 14, 1994 and came into effective on January 1, 1995, and the Interim Regulations on Collection of Social Insurance Premiums (社會保險費徵繳暫行條例), promulgated by the State Council on January 22, 1999 and amended on March 24, 2019, an employer is required to make contributions to social insurance schemes for its employees, including basic pension insurance, basic medical insurance, unemployment insurance, maternity insurance and work-related injury insurance. Employers are also required to withhold and remit to the social insurance schemes the social insurance premiums payable by the employees. If the employer fails to make social insurance contributions in full and on time, the social insurance authorities may demand the employer to make payments or supplementary payments for the unpaid social insurance within a specified period together with a 0.05% per day surcharge of the unpaid social insurance from the date on which the payment is due. If the employer fails to settle the overdue payment within a specified period, the relevant regulatory authorities may impose on such employer a fine equivalent to one to three times of the amount of the overdue payment.

Under the Administrative Regulations on Housing Provident Funds (住房公積金管理條例), which was promulgated by the State Council on April 3, 1999 and latest amended on March 24, 2019, employers are required to make contribution to housing provident funds for their employees. Employers are also required to withhold and remit the contributions payable by the employees to the housing provident funds. Where an employer fails to pay up housing provident funds due in full within the prescribed time limit, the housing fund administration center shall order it to make payment within a specified period. If the employer still fails to do so, the housing fund administration center may apply to the court for enforcement of the unpaid amount.

Intellectual Property

Trademark Law

The Trademark Law of the People's Republic of China (中華人民共和國商標法), which was promulgated by the SCNPC on August 23, 1982 and latest amended on April 23, 2019, and the Regulations for the Implementation 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), which was promulgated by the State Council on August 3, 2002 and latest amended on April 29, 2014, provides for the application, review and approval, renewal, alteration, transfer, use, and invalidity cases of trademark registration, and protects the trademark registrant's right to exclusive use of trademark. According to the above-mentioned laws and regulations, the validity period of a registered trademark is 10 years, starting on the day when the registration is approved. If the valid period of a registered trademark has expired and further use is required, the renewal procedures must be completed in accordance with the regulations within 12 months before the expiration date. If the procedures cannot be completed within the time limit, it can be extended further for six months. The validity period of each renewal of registration is 10 years, starting from the day after the expiration date of the previous validity period of the trademark. A trademark registrant can authorize others to use his or her registered trademark by entering into a trademark license contract.

Our Group has registered certain trademarks in the PRC which are protected and regulated by the Trademark Law of the PRC and its implementation rules above.

Patent Law

According to the Patent Law of the People's Republic of China (中華人民共和國專利法), which was promulgated by the SCNPC on March 12, 1984 and last amended on October 17, 2020, and the Regulations for the Implementation 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), which was promulgated by the State Council on June 15, 2001 and latest amended by the State Council on January 9, 2010, invention-creations refer to inventions, utility models and designs. Inventions refer to new technical solutions proposed for products, methods or improvements. Utility model refers to a new technical solution suitable for practical use proposed for the shape, structure or combination of the product. Design patents refer to a new design that is esthetically pleasing and suitable for industrial applications based on the overall or partial shape, pattern, or combination of the product, as well as the combination of color, shape, and pattern. The term of patent right for inventions is 20 years, the term of patent right for utility models is 10 years, and the term of patent right for designs is 15 years. All the terms of patent right start on the date of filing.

Our Group has been granted, by the PRC patent regulatory authority, certain invention patents and utility model patents which are protected and regulated by the Patent Law of the PRC and its implementation rules above.

Property

The Land Administration Law of the PRC (中華人民共和國土地管理法), which was promulgated by the SCNPC on June 25, 1986 with effect from January 1, 1987 and latest amended on August 26, 2019, and the Implementation Regulations of the Land Administration Law of the PRC (中華人民共和國土地管理法實施條例), which was promulgated by the State Council on January 4, 1991 and latest amended on July 2, 2021 and took effective on September 1, 2021, provide that the land-use regulation system and the land registration and certification system are implemented in the PRC. Enterprises or individuals must use land in strict accordance with the purposes of land use as specified in the overall land utilization plan. Any change to the ownership and/or the use of the land requires the relevant approvals to be obtained from and the relevant registrations to be made with the competent governmental authorities according to the relevant laws and regulations. Under the Civil Code of the PRC (中華人民共和國民法典), the creation, alteration, transfer or termination of the title of an immovable property shall be subject to registration in accordance with the PRC laws.

Our Group has self-owned properties located in Shenzhen, the PRC, which are protected and regulated by the PRC laws in relation to the properties.

Customs

Pursuant to the Customs Law of the PRC (中華人民共和國海關法), which was adopted by the SCNPC on January 22, 1987 and latest amended on April 29, 2021, all conveyance, goods and articles entering or leaving the territory shall be subject to customs control, including declaration, examination and supervision. Duties shall be levied accordingly. Unless otherwise exempted or reduced by the laws or regulations, the consignee of import goods, the consignor of export goods and the owner of inward and outward articles shall be the obligatory customs duty payer. A fine may be imposed for acts which violate the regulations on customs control prescribed in the Customs Law of the PRC, such as, the failure to make accurate declaration of the import or export goods to the PRC customs authority, the failure to accept, in accordance with relevant regulations, the checking and examination by the PRC customs authority of the conveyance, goods or articles entering or leaving the territory, and to open or break seals affixed by the PRC customs authority without authorization.

The State Council promulgated the Regulations on the Customs Supervision in Bonded Areas (保稅區海關監管辦法) on January 8, 2011 which took effect on the same day. According to the regulations, the bonded areas within the territory of the PRC are special areas under the supervision of the PRC customs authorities and the flow of goods between the bonded areas and abroad is subject to the administration and supervision with simple, convenient and effective principle. The enterprise incorporated and located in the bonded areas shall set account book and make statements and accounting based on the valid proof and shall record the storage, transfer, relocation, sales, processing, use and loss of the goods and articles into and out of the bonded areas. The goods brought from abroad into the bonded areas can be bonded if they are raw materials, spare parts, primary components or packing materials. When the finished product or the leftover materials produced by the processing enterprise in bonded

areas are transported abroad, such enterprise shall complete the relevant customs procedures and, unless otherwise provided by the laws and regulations, the export duties will be exempted. The import procedures shall be completed when the goods brought from the bonded areas into non-bonded areas in the PRC. When the finished products or the leftover materials produced by the processing enterprise in bonded areas are transported into the non-bonded areas in the PRC, such enterprise shall complete the import procedures and pay the tax in accordance with laws.

Our Shenzhen factory is located in Futian Bonded Area and the flows of raw materials and products of ONM Shenzhen between Futian Bonded Area and abroad or non-bonded areas in the PRC shall be subject to the special customs rules under the Regulations on the Customs Supervision in Bonded Areas and the related PRC regulations.

Transfer Pricing

According to the Enterprise Income Tax Law of the PRC (中華人民共和國企業所得税法) which was promulgated on March 16, 2007 and most recently amended on December 29, 2018, the Implementation Regulations of the Enterprise Income Tax Law of the PRC (中華人民共和國企業所得税法實施條例), which was promulgated on December 6, 2007 and amended on April 23, 2019 and the Law on the Administration of Tax Collection of the PRC (中華人民共和國税收徵收管理法), which was promulgated on September 4, 1992 and amended on April 24, 2015, (i) the related party transactions shall comply with the arm's length principle (獨立交易原則) and if the related party transactions fail to comply with the arm's length principle which results in the reduction of the enterprise's taxable income, the PRC tax authority has the power to make adjustments with reasonable methods within 10 years from the taxable year when such related party transaction occurred; (ii) an enterprise shall fill in and submit an annual related party transactions form (年度關聯業務往來報告表) along with its submission of the annual enterprise income tax returns to its competent tax authority; and (iii) an enterprise which has related party transactions shall prepare the contemporaneous documentation (同期資料) (such as the standards, calculation methods and explanation of the pricing and expenses in respect of the related party transactions) and submit to the PRC tax authority if requested. According to the Announcement on Promulgating the Administrative Measures for Special Tax Investigation Adjustments and Mutual Agreement Procedures (關於發佈《特別納税調查調整及相互協商程序管理辦法》的公告), which was issued by the State Taxation Administration (the "SAT") on March 17, 2017 and became effective on May 1, 2017, if an enterprise receives a special tax adjustment risk warning from tax authorities or detects in itself any special tax adjustment risk, it may carry out voluntary adjustments regarding tax payment matters and the relevant tax authority may still proceed with special tax investigation adjustment procedures according to the relevant provisions. In the event that the tax authority determines to implement the special tax adjustment after investigations, the relevant enterprise may be required to pay up the relevant tax. Besides, pursuant to the tax treaties signed by the PRC with other jurisdictions, the SAT may activate mutual consultation procedures either upon application by an enterprise or upon request by the competent tax authority of the contracting counterparty of a tax treaty to consult and negotiate with the latter, so as to avoid or eliminate international double taxation triggered by special tax adjustment.