MEDICAL DEVICE IMPORT AGREEMENT

BETWEEN

XXXXX

And

XXXXX

AGR-003 Rev A

(Information box – To be removed)

DISCLOSURE

This Agreement is providing general information about the collaboration between a Manufacturer and Importer.

Importers are required for Medical Device Manufacturers located outside of the European Union and that want to place their product on the EU market.

This should not be considered as a finished document and still require the review by a lawyer to satisfy your personal situation. Any changes may be done to satisfy your requirements.

All what is related to business activities can be changed.

Requirements to EU MDR 2017/745 and IVDR 2017/746 were included.

1/16/2020

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THIS AGREEMENT is made on

Between:

(1) XXXXX (Hereinafter referred to as ''Manufacturer'')

(2) XXXXX (Hereinafter referred to as ''Importer'')

BACKGROUND:

(A) Importer is experienced in the promotion, import, and sale of products similar to the Products in the territory of XXXXX.

(B) Manufacturer is engaged in the business of developing, manufacturing, selling and distributing Medical Devices.

(C) Manufacturer wishes to appoint **Importer** as its exclusive importer to promote, and sell the Products within the Territory, in accordance with the terms and conditions of this Agreement.

(D) Importer wishes to accept the appointment to promote and sell the Products within the Territory in accordance with the terms and conditions of the Agreement.

(E) Manufacturer and **Importer** desire to enter into a business relationship and establish terms and conditions upon which the **Manufacturer** shall provide the Product as described in Annex I according to the terms of this Agreement.

THE PARTIES AGREE as follow:

1. INTERPRETATION

1.1. Definitions

In addition to other terms which may be defined herein, the following terms, whether in singular or plural form, as appropriate, shall have the following meanings:

Acceptance Test: a process used to determine whether Deliverables submitted under this Agreement satisfies defined criteria.

Agreement: means this present Agreement as amended and includes all Annexes thereto.

Applicable Law(s): means all laws, ordinances, rules, and regulations of any governmental or regulatory authority that apply to the parties under this Agreement, including without limitation of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 (Or REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017).

Applicable Standard(s): ISO 13485:2016 or ISO 9001:2015 [You may write here the standard that you estimate valid for your industry].

Business Day(s): any day other than a Saturday and Sunday.

Commencement Date: the date of this Agreement.

Confidential Information: information in whatever form (including in written, oral, visual or electronic form or on any magnetic or optical disk or memory and wherever located) relating to the business, customers, products, affairs and finances of **Manufacturer** for the time being confidential to **Manufacturer** and trade secrets including technical data and know-how relating to **Manufacturer** Business or any of its products, suppliers, customers, agents, importers, shareholders, management or business contacts, and including information that **Importer** creates, develops, receives or obtains in connection with this Engagement, whether or not such information (if in anything other than oral form) is marked confidential, and including the following:

(a) Any information relating to the trading position of **Manufacturer** or its customers and suppliers, including in particular names and contact details of suppliers, partners, clients or customers;

(b) Any information relating to the business, products, affairs and finances of **Manufacturer** and its customers;

(c) Any information or data relating to the design, specification or performance of **Manufacturer**`s products and tools;

(d) Any information relating to the development of products or Inventions of **Manufacturer** or any employee of **Manufacturer**;

(e) Any medical or personal information about patients or users of the products of **Manufacturer**;

(f) Any information relating to the marketing plans, business development or structure of **Manufacturer** and its customers; and

(g) Any document or item marked as confidential.

Delivery Date(s): means the Products to be delivered to the Delivery Location as specified by this Agreement.

Deliverables: all documents, materials, and Product(s) provided by **Importer** under this Agreement (including drafts and any modifications to such items).

Delivery Location: means the location to which the Products must be delivered as specified by this Agreement.

Engagement: the engagement of **Importer** by **Manufacturer** on the terms of this Agreement.

EU: European Union.

Importer: means any natural or legal person established within the European Union that places a device from a third country on the Union Market.

Intellectual Property: means patents, rights to apply for patents, trademarks, trade names, service marks, domain names, copyrights and all applications and registration of such worldwide, schematics, industrial models, inventions, know-how, trade secrets, computer software programs, and other intangible proprietary information.

Loss or Losses: shall mean any and all liabilities, damages, losses, costs, fines, penalties, expenses or the like (including reasonable legal and attorneys' fees).

Manufacturer Business: the production, development and/or sale of Medical Device products.

Medical Device: shall have the meaning as defined by the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017, ARTICLE 2 (and/or REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017, ARTICLE 2,) as applicable in each particular case.

Notified Body: means a conformity assessment body designated in accordance with Applicable Law.

Product(s): means the item, portion and/or component parts manufactured or sourced by **Manufacturer** further set forth in the Annex I. For the avoidance of doubt, the item, portions and/or components of a Product that is not being manufactured or sourced independently by **Importer** shall not be considered as Product.

Quality Management System: A formalized system that documents the structure, responsibilities and procedures required to achieve effective quality management. It is based on the requirements detailed in ISO-13485:2016 with additional enhancements.

Territory: XXXXX

Unique Device Identifier ('UDI'): means a series of numeric or alphanumeric characters that are created through internationally accepted Product identification and coding standards and that allow unambiguous identification of specific Products on the Territory.

1.2. In this Agreement, a reference to one gender shall include reference to every gender; words denoting a singular number include the plural and vice versa; references to persons shall include firms, companies, and other organizations; a reference to a statutory provision includes a reference to the same as modified, re-enacted or replaced from time to time and any subordinate legislation made under it; a reference to a legal or regulatory body includes a reference to any successor body or bodies to it; and a reference to this Agreement shall include its Annexes.

2. TERM

2.1. This Agreement shall commence on the Commencement Date and, subject to earlier termination in accordance with its provisions, it will continue thereafter unless or until the execution of this Agreement.

3. MANUFACTURER'S RIGHTS AND OBLIGATIONS

3.1. **Manufacturer** reserves the right to supply the Products directly to customers in the Territory.

3.2. **Manufacturer** is obliged, to pack all Products its expense, in accordance with its standard packing procedure, which must be suitable to permit shipment of the Products to the Territory; provided, however, that if **Importer** requests a modification of those procedures, **Manufacturer** must make the requested modification and **Importer** will bear any reasonable expenses incurred by **Manufacturer** in complying with such modified procedures which are in excess of the expenses which **Manufacturer** would have incurred in following its standard procedures.

3.3. **Manufacturer** will procure that the packaging of the Product contains all warnings and instructions regarding the safe use, transportation and storage of the Product as may be adequate or, as the case may be, compulsory in the Territory. **Manufacturer** procures that it is fully informed about any specific requirements in that respect and any changes thereof in the Territory.

3.4. **Manufacturer** who consider or have reason to believe that a Product which it have placed on the market or put into service is not in conformity with Applicable Law is obliged to immediately take the necessary corrective action to bring that Product into conformity, to withdraw it or to recall it, as appropriate.

3.5. **Manufacturer** is obliged to assign and maintain unique UDIs for its Product following the relevant coding standard.

3.6. Only the **Manufacturer** may place the UDI on the Product or its packaging (**Manufacturers** that repackage and/or reliable Product, with their own label is obliged retain a record of the original Product **Manufacturer's** UDI).

4. IMPORTER'S RIGHTS AND OBLIGATIONS

4.1. **Importer** is obliged to co-operate with **Manufacturer** to achieve an appropriate level of traceability of Product.

4.2. **Importer** shall be registered in the Electronic Database EUDAMED per EU MDR 2017/745 [EU IVDR 2017/746] requirement, when available.

4.3. In order to place a Product on the Territory, **Importer** shall verify that: (a) The Product has been CE marked and that the EU declaration of conformity of the Product has been drawn up; (b) The product identified the **Manufacturer** and **Manufacturer's** authorized representative; (c) The Product is suitably labeled and accompanied by the required instructions for use; (d) Where applicable, a UDI has been assigned by the **Manufacturer**; (e) the product is registered in the electronic system EUDAMED (when available).

4.4. Where **Importer** considers or has reason to believe that a Product is not in conformity with the requirements of Applicable Law, it must not place the Product on the Territory until it has been brought into conformity and inform **Manufacturer**.

4.5. Where **Importer** considers or has reason to believe that the Product presents a serious risk or is a falsified Product, it is obliged to inform the competent authority of the Member State in which **Importer** is established.

4.6. **Importer** must indicate on the Product or on its packaging or in a document accompanying the Product their name, registered trade name or registered trademark, their registered place of business and the address at which they can be contacted so that their location can be established.

4.7. **Importer** must ensure that any additional label does not obscure any information on the label provided by **Manufacturer**.

4.8. **Importer** must ensure that, while a Product is under their responsibility, storage or transport conditions do not jeopardize its compliance with the general safety and performance requirements.

4.9. **Importer** must keep a register of complaints, of non-conforming Products and of recalls and withdrawals, and provide **Manufacturer** with any information requested by them, in order to allow them to investigate complaints.

4.10. **Importer** who considers or have reason to believe that a Product which they have placed on the Territory is not in conformity with Applicable Law must immediately inform the **Manufacturer**.

4.11. **Importer** need to co-operate with **Manufacturer** to ensure that the necessary corrective action to bring that Product into conformity, to withdraw or recall it is taken. Where the Product presents a serious risk, they are obliged to immediately inform the competent authorities of the Member States in which they made the Product available and, if applicable, the notified body that issued a certificate for the Product in question, giving details, in particular, of the non-compliance and of any corrective action taken.

4.12. **Importer** who has received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a Product which they have placed on the Territory must immediately forward this information to the **Manufacturer**.

4.13. **Importer** is obliged, to keep a copy of the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and

supplements. At least 15 years for implantable products and 10 years for other products.

4.14. **Importer** must cooperate with competent authorities, at the letters' request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by Product which they have placed on the Territory. **Importer**, upon request by a competent authority of the Member State in which the **Importer** has its registered place of business, will provide samples of the Product free of charge or, where that is impracticable, grant access to the Product.

4.15. **Importer** warrants that any and all warnings and instructions printed on, attached to or accompanying the Product will remain legible and will not be changed, covered or removed, in whole or in part, or in any other way may illegible.

5. SUPPLY OF PRODUCT

5.1. **Manufacturer** will manufacture and supply to **Importer** materially and legitimately flawless Product together with all documents *(The Manufacturer will provide Instructions for Use and product labeling in English for each of the Products. Where local language Instructions for Use and product labeling are required the Manufacturer will undertake to provide the appropriate translations. The Manufacturer must pre-approve any promotional material that is developed by the Importer and contains references to the Manufacturer before this material enters the local marketplace)* related to the Product in accordance with the specifications contained in the Annex I. **Manufacturer** will make all reasonable efforts to provide clear instructions, documentation, and Product specifications to the **Importer**.

6. QUALIFICATION OF IMPORTER PERSONNEL

6.1. The **Importer's** employees who are in connection with this Agreement may only be replaced or substituted by the **Importer** if they cease to be an employee of the **Importer** or are absent from their employment due to maternity leave, paternity leave or ill health. In such circumstances, **Importer** shall give **Manufacturer** reasonable notice of the need for replacement or substitution and without undue delay assign an employee of at least equal status and experience who are acceptable to **Manufacturer**.

6.2. In case of replacement or substitute employees are to be provided **Importer** shall ensure that such employees are fully briefed in respect of their obligations under this Agreement.

6.3. **Importer** shall ensure the competency of its employees who are in connection with this Agreement.

6.4. **Importer** employees shall be trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

6.5. At all times, **Importer** shall ensure that each of **Importer's** or its subcontractors' employees is suitably qualified, adequately trained and competent in the relevant field in respect of which they are engaged.

6.6. **Importer** shall indemnify and keep fully and effectively indemnified on demand **Manufacturer** (and any Replacement **Importer**) against any claims, demands, actions, proceedings, settlement and all Losses, costs, charges, penalties, awards, expenses, and liabilities suffered or incurred by such indemnified (whether on, before or after the expiry or termination of this Agreement, whether in whole or in part) which arise out of or in connection with the employment and/or termination of employment of any employees or former employees of **Importer** or its agents or sub-contractors engaged in activities under this Agreement, including in respect of any failure to inform and consult.

7. CONTRACT MANAGEMENT

7.1. The parties shall appoint a primary contact representative in relation to the provision of this Agreement, who will facilitate and coordinate any action required of each party, their name and contact details being provided in Annex I.

8. SUB-CONTRACTING

8.1. **Importer** may not sub-contract its obligations under this Agreement without **Manufacturer's** prior written consent. **Importer** is solely responsible for the management of its subcontractors and shall at all times remain fully responsible for the performance of the obligations under this Agreement and shall be liable for the acts and omissions of any sub-contractors as they were its own.

9. INSURANCE

9.1. **Importer** shall, at its own expense, at all times during the Term of this Agreement and after its termination, provide and maintain in effect those insurance policies and minimum limits of coverage as designated below together with any other insurance required by law in any jurisdiction where **Importer** sells the Products under this Agreement. Such policies shall be issued by insurance companies authorized to do business in the jurisdiction where **Importer's** obligations are to be performed and are reasonably acceptable to **Manufacturer**. In no way do these minimum requirements limit the liability assumed elsewhere in this Agreement.

9.2. **Importer** is obliged to obtain and keep in force all-risk property and cargo insurance with limits at least equal to the value of Products purchased until payment is received in full by Seller.

9.3. During the term of this Agreement and for four (4) years thereafter, **Importer** shall maintain an insurance policy issued by a reputable insurance company, which policy shall insure against any and all claims, liabilities, costs or expenses resulting from or caused by (or claimed to be resulting from or caused by) any use or operation of any Products sold by **Importer** in the amount of at least $5 million per claim.

10. ACCEPTANCE

10.1. **Importer** must inspect delivered Products and report claims for defects, damages, shortages or receipt of wrong Products which are discoverable on a visual inspection within 72 hours of delivery or the Products will be deemed irrevocably accepted and such claims will be deemed waived. However, shipping damage claims must be made by **Importer** directly with the shipping company in accordance with such company's policies.

10.2. If delivered Product does not meet the requirements under this Agreement, **Importer** shall return back this Product and require **Manufacturer** to re-deliver rectified Product. The cost of return back, rectifying and re-delivered Products that fail Acceptance Test shall be borne by the **Manufacturer** without any further charge to **Manufacturer** which must be paid in 5 Business Days after **Importer's** request.

10.3. If rectified Deliverable Product fails to pass Acceptance Test, **Importer** may, without prejudice to its other rights and remedies, choose at its sole discretion:

10.3.1. Require the **Manufacturer** to perform a further attempt at rectification and Acceptance Test on the same terms and conditions; or

10.3.2. Revise the specifications for the affected Deliverables; or

10.3.3. Reject the Deliverables as not being in conformity with the relevant Specifications.

10.4. In the case where Deliverables are rejected, the **Importer** may terminate this Agreement immediately upon written notice with no charge being payable for Deliverables that have been rejected.

11. CHARGES AND PAYMENT

11.1. The **Manufacturer** will be paid by the **Importer** with the amount of XX.00 USD totally (Including VAT and excluding all taxes). Payment shall be made within 10 days from the invoice submission.

11.2. **Importer** shall be entitled to deduct from the fees (and any other sums) due to the **Manufacturer** any sum that the **Manufacturer** may owe to **Importer** at any time.

11.3. All amounts payable by **Importer** hereunder will be made in United States Dollars.

12. PENALTY

12.1. If the **Manufacturer** does not deliver the Product to the **Importer** at a Delivery Date, the **Manufacturer** will be liable to pay a penalty of 0.1% of the value of this Agreement for each overdue day within 5 Business Days after **Importer's** request.

13. AUDIT

13.1. **Importer** shall allow **Manufacturer** and any third party auditors (Notified Bodies, Certification Bodies, National Health Authorities of local or foreign countries) or representatives of, or other advisers to, **Manufacturer** to access any of the **Importer's** premises, personnel, and relevant records as may be required by **Manufacturer**.

13.2. The **Importer** shall allow unannounced audit of the facility by the **Manufacturer** in case of major issue identified or by the **Manufacturer's** Notified Body as required by Applicable Law.

13.3. **Importer** will ensure that the **Manufacturer** has the same rights of access with prior notice to any subcontractors of **Importers** to carry out an audit.

13.4. The **Manufacturer** shall use its reasonable endeavors to ensure that the conduct of each audit does not unreasonably disrupt the **Importer** or delay the provision of this Agreement by the **Importer**.

13.5. **Importer** shall provide written responses and summaries of actions as a result of audits, corrective action requests, and/or escalations raised by the **Manufacturer**.

13.6. **Importer** shall promptly notify the **Manufacturer** of the performance and results of any inspections, audits, formal visits, etc. of any regulator, notified body, or other certification body acting in a formal capacity.

13.7. **Importer** shall promptly notify the **Manufacturer** of any inspection or audit findings that impact the safety, effectiveness, conformity, availability, or quality of any Product that the **Manufacturer** provides to the **Importer**.

13.8. **Manufacturer** shall provide at least five Business Days' notice of its intention to conduct an audit of its own. If the purpose of an audit is to investigate suspected fraud or to support investigations related to a safety issue, a customer complaint or a suspected non-conformity, no notice shall be required.

13.9. **Importer** shall allow and support unannounced audits by **Manufacturer's** and/or other regulatory agencies.

13.10. The parties shall bear their own costs and expenses incurred in respect of compliance with their obligations under this clause.

13.11. Any significant organizational changes to **Importer** shall be communicated to the **Manufacturer** immediately.

13.12. Upon **Manufacturers'** request and as applicable, **Importer** shall provide all appropriate Product certifications including all applicable safety, regulatory, and operating systems certifications at **Importer's** sole cost and expense.

13.13. Keep **Manufacturer** advised and informed regularly, and as the need arises, of the sale, importing, marketing and promotional activities of any companies

manufacturing, selling, importing or promoting any products which compete or may compete with the Products and also of any significant information which is likely to be of benefit to **Manufacturer** in the marketing of the Products and any event affecting the sale or servicing of the Products in the Territory.

13.14. **Importer** shall mail to **Manufacturer**, during this Agreement and any extension thereof, prompt written notice of the address of each location at which products are stored, and the address of each facility established by **Importer** to sell and service the Products.

13.15. Forward to **Manufacturer** all inquiries that **Importer** receives regarding the purchase of Products from interested parties outside of the Territory.

13.16. **Importer** should immediately forward to the **Manufacturer** complaints or reports from end-users about suspected incidents with the relevant Product.

13.17. **Importer** shall provide the **Manufacturer** with all details requested, including without limitation, the customer name, address and contact details, including the batch or lot numbers, including quantities sold to facilitate traceability to the end-user.

14. CONFIDENTIAL INFORMATION

14.1. **Importer** shall not (except in the proper course of its duties), either during the Engagement or at any time after the Termination Data, use for its own benefit or the benefit of others, divulge or communicate to any person, firm or organization, any of the trade secrets or other Confidential Information, technical or commercial information of **Manufacturer** related to business, organization, accounts, analysis or other affairs of **Manufacturer** or its customers which it may have received or obtained during the Engagement.

14.2. In particular, **Importer** shall not (except in the proper course of its duties) without the prior written consent of **Manufacturer**, permit any Confidential Information:

14.2.1. To be disclosed, whether directly or indirectly, to any party within its own organization who does not need to know such information in furtherance of the **Importer's** obligation under this Agreement; or

14.2.2. To be disclosed, whether directly or indirectly, to any third party, except to those authorized by **Manufacturer** to know or as required by Applicable Law; or

14.2.3. To be copied or reproduced in any form or to be commercially exploited in any way other than in the usual course of the Engagement; or

14.2.4. To be used for its own purposes or for any purposes other than those of **Manufacturer** or to be used or published by any other person; or

14.2.5. To pass outside of its control.

14.3. **Importer** may disclose Confidential Information to its representatives, provided that:

14.3.1. Such disclosure is necessary to allow them to perform work undertaken for **Manufacturer**;

14.3.2. It informs its representatives of the confidential nature of the Confidential Information before disclosure;

14.3.3. It procures that its representatives shall, in relation to any Confidential Information disclosed to them, comply with this Agreement as if they were the recipient and, if **Manufacturer** so requests, procure that any relevant representative enters into a confidentiality agreement with **Manufacturer** on terms equivalent to those contained in this Agreement; and

14.3.4. It keeps a written record of these representatives, and it shall at all times be liable for the failure of any representative to comply with the term of this Agreement.

14.4. The restrictions set out in this clause will continue to apply after the termination of the Engagement but will cease to apply to any information which may come into the public domain other than through unauthorized disclosure.

14.5. The restriction set out in this clause does not apply to:

14.5.1. Any use or disclosure authorized by **Manufacturer** or required by Applicable Law; or

14.5.2. Any information which is already in, or comes into, the public domain otherwise than through the **Importer's** unauthorized disclosure.

14.6. In the event that the **Importer** becomes legally compelled to disclose all or any portion of the Confidential Information, the **Importer** will provide a **Manufacturer** with prompt notice thereof, so that the **Manufacturer** may seek a protective order or other appropriate remedies. In the event that such protective order or other remedy is not obtained, **Importer** or its representative will furnish only that portion of the Confidential Information that is legally required to be disclosed and **Importer** will exercise reasonable efforts to obtain reliable assurances that confidential treatment will be afforded to such information.

14.7. **Importer** shall not, without **Manufacturer's** prior written consent, make any public announcement concerning the existence of a formal relationship with **Manufacturer** and/or the execution or performance of this Agreement.

15. INTELLECTUAL PROPETY

15.1. **Importer** agrees that: (i) **Manufacturer** is the sole and exclusive owner of all trademarks, trade names, service marks, service names, logos, patents and other similar proprietary rights to the Products.

15.2. **Importer** acknowledges that **Manufacturer** is the owner of the Intellectual Property and all rights not expressly granted to **Importer** in this Agreement are reserved by **Manufacturer**. Any goodwill derived from the use by **Importer** of the Trademarks will inure to the benefit of **Manufacturer**. If **Importer** acquires any rights in the Trademarks or Intellectual Property, by operation of law, or otherwise, such rights will be deemed and are hereby irrevocably assigned to **Manufacturer** without further action by any of the parties.

15.3. During the term of this Agreement, **Importer** is authorized to use the Intellectual Property in the Territory on a non-exclusive basis solely in connection with **Importer's** sale, advertisement and promotion of Products in the Territory. **Importer** will cease to use any of such Trademarks within five (5) Business Days following the effective date of termination of this Agreement. **Importer** will promptly notify **Manufacturer** in writing of any possible infringement of the Trademarks or of any claim or allegation that the Trademarks infringe the rights of any third party, and **Manufacturer** will have exclusive control over, and conduct of, all claims and

proceedings. The **Manufacturer** will bear the cost of any proceedings and will be entitled to retain all sums recovered in any action for its own account. **Importer** will provide **Manufacturer** with all assistance that **Manufacturer** may reasonably require in the conduct of any claims or proceedings.

15.4. Apart from the Trademarks, no other trademark or logo may be affixed to, or used in connection with, the Products except with the prior written consent of **Manufacturer**.

15.5. **Importer** agrees that it will not, during the Term or thereafter, directly or indirectly: (i) do, omit to do, or permit to be done, any act which will or may dilute the Trademarks or tarnish or bring into disrepute the reputation of or goodwill associated with the Trademarks or **Manufacturer** or which will or may invalidate or jeopardize any registration of the Trademarks.

15.6. During the Term and at any time thereafter, **Importer** shall not challenge or contest, directly or indirectly, the ownership and/or exclusive rights of **Manufacturer** with respect to the ownership and use of the Intellectual Property and shall execute such documents and instruments as **Manufacturer** may request to secure and preserve **Manufacturer**'s right, title and interest in and to the Intellectual Property, and will not use such marks or names, or any words that are confusingly similar, in any manner which might tend to defeat or diminish said Intellectual Property, except with the consent of **Manufacturer**.

15.7. **Importer** shall assist Manufacturer, whenever requested, in the protection of the Intellectual Property. **Manufacturer**, in its sole discretion, may commence and prosecute any claims or suits for infringement of all or any portion of the Intellectual Property in its own name, in the name of its licensor or designee, or in the name of **Importer**, and may join **Importer** as a party thereto. **Importer** agrees to notify **Manufacturer** if **Importer** learns that any other person, firm, or corporation is using a copyright, trade name, trademark, patent or design which is substantially or confusingly similar to those owned by or used pursuant to the authority of **Manufacturer**. **Importer** shall not institute any suit or take any action on account of any such infringement without obtaining **Manufacturer's** prior written consent. The **Manufacturer** may elect to retain counsel and prosecute any infringement or to

institute legal or other action to prevent or remedy the same, but shall not be obligated hereunder to do so.

16. ADVERTISEMENT

16.1. **Importer** shall be entitled, during the term of this Agreement and any extension thereof, to advertise and hold itself out as an authorized **Importer** of the Products. At all times during this Agreement and any extension thereof, **Importer** shall use the Trademarks in all advertisements and other activities conducted by **Importer** to promote the sale of the Products.

16.2. **Importer** shall submit examples of all proposed advertisements and other promotional materials for the Products to **Manufacturer** for inspection and **Importer** shall not use any such advertisements or promotional materials without having received the prior written consent of **Manufacturer** to do so.

16.3. **Importer** shall not, pursuant to this Agreement or otherwise, have or acquire any right, title or interest in or to **Manufacturer's** Trademarks.

16.4. **Importer** shall advertise the Products within the Territory at its own cost.

16.5. No promotional material, advertising, or notice to any third party (whether written or oral) concerning this Agreement shall be issued, given, or otherwise disseminated without the prior approval of **Manufacturer**.

17. REGULATORY COMPLIANCE

17.1. Parties in their field of activities shall comply with all Applicable Standard and Applicable Laws including any applicable anti-bribery and anti-collusion laws, statutes, and regulations.

18. OTHER ACTIVITIES

18.1. Nothing in this Agreement shall prevent the **Importer** from being engaged, concerned or having any financial interest in any other business, trade, profession or occupation during the Engagement provided that:

18.1.1. Such activity does not cause a breach of any of the **Importer's** obligations under this Agreement; and

18.1.2. **Importer** shall not engage in any such activity if it relates to a business which is similar to or in any way competitive with **Manufacturer** Business or **Manufacturer** Business opportunities without the prior written consent of **Manufacturer**. (The **Importer** hereby warrants to the **Manufacturer** that it does not currently represent or promote any lines or products that compete with the Products. During the Term, **Importer** shall not represent, promote, or otherwise try to sell in the Territory any lines or products that, in the **Manufacturer's** judgment, compete with the Products directly or indirectly. **Importer** shall provide the **Manufacturer** with a list of the companies and the products that it currently represents, and shall notify the **Manufacturer** in writing of any new companies or products at such time as its promotion of those new companies and products commences)

19. LIABILITY AND INDEMNITY

19.1. Either Party shall indemnify, defend, and hold harmless each-other and its officers, directors, employees, agents, successors and assigns from and against any and all Losses, liabilities, damages, and expenses, including reasonable professional fees and expenses, that they may suffer as a result of any claims, demands, actions or other proceedings made or instituted by any third party against any of them and arising out of or relating to the breach by the one Party of any term, representation or warranty set forth in this Agreement or the gross negligence or willful misconduct of the one Party in the performance of its obligations under this Agreement.

19.2. In no event will either party be liable for costs, expenses, or damages in connection with this Agreement in excess of actual costs, expenses, damages, or provable and actual lost revenue.

19.3. Nothing in this Agreement shall limit or exclude either party's liability for fraud or fraudulent misrepresentation.

20. TERMINATION

20.1. **Manufacturer** and **Importer** may at any time by mutual consent decide to terminate this Agreement pursuant to written and delivered notice to the other party.

The **Manufacturer** may terminate this present Agreement for any reason on 90 Business Days' written notice of termination. **Importer** retains the right at any time to terminate its obligations under this Agreement on 90 Business Days' written notice of termination. This Agreement also may be terminated automatically, without notice, (i) upon the institution by or against **Manufacturer** or **Importer** of any insolvency, receivership or bankruptcy proceedings or any other proceedings for the settlement of debts, (ii) upon **Manufacturer** or **Importer's** making an assignment for the benefit of creditors, or (iii) upon **Manufacturer** or **Importer's** dissolution.

21. CONSEQUENCES OF TERMINATION

21.1. Upon the termination of this Agreement, the rights and licenses granted to the **Importer** pursuant to this Agreement will automatically terminate. All payments owing from **Manufacturer** to **Importer**, or refunds due from **Importer**, will become immediately due and payable, and legally enforceable, upon termination. The **Importer** will not make or retain any copies or samples of any confidential items or information which may have been entrusted to it.

22. DEFAULT

22.1. If either party should fail to perform its respective obligations under the terms of this Agreement, the other party will notify of the party that it is presumed to be in default and give reasonable recourse to cure the stated issue. The defaulting party will have the opportunity to cure the default within 10 Business Days of notice by the other party. In the event of a failure to cure a breach or default within the stipulated time, the other parties will have the right to terminate this Agreement immediately.

23. FORCE MAJEURE

23.1. If the performance of this Agreement, or any obligation hereunder, is prevented, restricted or interfered with by any act or condition beyond the reasonable control of the party affected thereby, including fire or other casualty or accident; strikes or labor disputes; war, terrorist attacks or other violence; or any law, order, proclamation, regulation, ordinance, demand or requirement of any governmental or

intergovernmental agency or body (Event of Force Majeure), the party so affected shall be excused from such performance to the extent of such prevention, restriction or interference and for a while equal to the period for which the Event of Force Majeure continues to save that where the Event of Force Majeure continues for more than two weeks the party unaffected by the Event of Force Majeure may terminate this Agreement immediately on giving notice in writing.

24. DISPUTE

24.1. The parties shall use all reasonable efforts and negotiate to resolve any dispute, controversy, or claim arising out of or in connection with this Agreement. In the event of any dispute, the representatives of the parties shall meet and attempt in good faith to resolve the dispute. If within 10 Business Days of their first meeting the representatives are for any reason unable to resolve the dispute, parties can refer to the XXXXX court.

25. MISCELLANEOUS

25.1. **WARRANTY**

25.1.1. **Manufacturer** warrants that it will perform the rights and duties under this Agreement in a good, professional and workmanlike manner and **Manufacturer** will promptly notify **Importer** of any delay or defect in the manufacture and supply of the Products. **Manufacturer** warrants that the Products will be manufactured and supplied in compliance with Applicable Law and Applicable Standard. **Manufacturer** warrants that the Products will be free from substantive defects in workmanship for a period of XXXXX the date of shipment. The warranty does not apply to any Products that are damaged due to the misuse, abuse, alteration or negligence of any party other than **Manufacturer**. MANUFACATURER MAKES NO OTHER REPRESENTATIONS OR WARRANTIES, WHETHER EXPRESS OR IMPLIED AND EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

25.2. **INDEPENDENT CONTRACTORS**

25.2.1. The relationship between **Manufacturer** and **Importer** established by this Agreement is that of independent contractors. Nothing in this Agreement shall be construed to create any other relationship between **Manufacturer** and **Importer**. Neither Party shall have any right, power, or authority to assume, create, or incur any expense, liability, or obligation, express or implied, on behalf of the other.

25.3. **ASSIGNMENT**

25.3.1. This Agreement shall be binding and inure to the benefit of the parties and their respective representatives, heirs, administrators, executors, successors and permitted assigns.

25.3.2. The parties agree that their rights and obligations under this Agreement may not be transferred or assigned without the prior written consent of the other party.

25.3.3. If applicable the **Importer** hereby transfers and assigns to the **Manufacturer** such Intellectual Property rights as **Importer** has or in future may own on the Product.

25.3.4. If **Importer** enters into an assignment or transfers to any person who succeeds to substantially all of the assets and business of **Importer** to which this Agreement relates, **Manufacturer** shall at its sole discretion have the right to terminate this Agreement forthwith.

25.4. **INTERPRETATION**

25.4.1. Each party acknowledges that it participated in the negotiation and preparation of this Agreement and that it had the opportunity to consult with an attorney of its choice in connection therewith. Ambiguities, if any, in this Agreement shall not be construed against either party, irrespective of which party may be deemed to have drafted the Agreement or authorized the ambiguous provision.

25.5. **SEVERABILITY**

25.5.1. If any provision of this Agreement is held to be invalid, illegal or unenforceable in whole or in part, the remaining provisions shall not be affected and shall continue to be valid, legal and enforceable as though the invalid, illegal or unenforceable part had not been included in this Agreement.

25.6. **NO WAIVER**

25.6.1. No party shall be deemed to have waived any provision of this Agreement or the exercise of any rights held under this Agreement unless such waiver is made expressly and in writing. The waiver by any party of a breach or violation of any provision of this Agreement shall not constitute a waiver of any other subsequent breach or violation.

25.7. **NOTICES**

25.7.1. Any notice given to a party under or in connection with this contract shall be in writing and shall be:

(a) Delivered by hand or by pre-paid first-class post or other next working day delivery service at its registered office (if a company) or its principal place of business (in any other case); or

(b) Sent by e-mail to the relevant contact (or to the referred contact if out-of-office is applied).

25.7.2. Any notice shall be deemed to have been received:

(a) If delivered by hand, on the signature of a delivery receipt;

(b) If sent by pre-paid first-class post or other next working day delivery service, at 9.00 am on the second Business Day after posting or at the time recorded by the delivery service;

(c) If sent by e-mail, at 9.00 am on the next Business Day after transmission.

25.7.3. This clause does not apply to the service of any proceedings or other documents in any legal action or, where applicable, any arbitration or other methods of dispute resolution.

25.7.4. Addresses of the parties:

If **Manufacturer**:

If **Importer**:

25.8. **SHIPMENT**

25.8.1. The Products will be delivered by **Manufacturer** to **Importer** in accordance with the agreed-upon terms and Delivery Date in the Annex I. The Products will be suitably packaged in accordance with the Annex I specification. The **Manufacturer** will pay for all freight, insurance, and other shipping expenses.

Manufacturer will use commercially reasonable efforts to deliver the Products on the agreed-upon Delivery Dates and notify the **Manufacturer** of any anticipated delays.

25.9. **HEADING**

25.9.1. The section headings herein are for reference purposes only and shall not otherwise affect the meaning, construction or interpretation of any provision of this Agreement.

25.10. **ENTIRE AGREEMENT**

25.10.1. This Agreement and the exhibits hereto constitute and contain the entire understanding and Agreement between the parties with respect to the subject matter hereof and supersedes all prior negotiations, understandings, and Agreements.

25.11. **COUNTERPARTS**

25.11.1. A PDF or other reproduction of this Agreement may be executed by the Parties and shall be considered valid, binding and effective for all purposes. This Agreement may be signed in counterparts, each of which shall constitute an original, but all of which together shall constitute one and the same Agreement.

25.12. **AMENDMENT**

25.12.1. This Agreement may be modified only by a written document signed by an authorized representative of each party and which refers to this Agreement.

25.13. **VARIATION**

25.13.1. No variation of this Agreement shall be effective unless it is in writing and signed by the parties.

25.14. **LANGUAGE**

25.14.1. The parties confirm that it is their wish that this Agreement, as well as Annexes and other documents relating to this Agreement, including all notices, have been and will be drawn up in the English language only.

25.15. **JURISDICTION**

25.15.1. This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes

or claims) shall be governed by and construed in accordance with the law of XXXXX.

25.15.2. Each party irrevocably agrees that the courts of XXXXX shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with this Agreement or its subject matter or formation (including non- contractual disputes or claims).

EXECUTED by the parties on the date first mentioned above

Manufacturer	**IMPORTER**
Name and Function:	Name and Function:
Date:	Date:
Signature	Signature

ANNEX I

Product	Product Description	Product Specification	Special Instruction for Product	Delivery Date	Total Price
					XX.00 USD

1. **CHANGES**

   As applicable, the Supplier must notify **Manufacturer** for any changes in the Product before the implementation of any changes that affect the ability of the Product to meet specified requirements under this Agreement.

2. **CONTACT REPRESENTATIVES**

   In case of **Manufacturer**:

   In case of Supplier:

3. **Key Performance Indicator**

a. Major Delay:

- What is considered a major delay? [Provide your answer – Be specific to avoid any misunderstanding]

b. Trend:

- How many similar issues are considered as a trend? [Provide your answer – A reference to a procedure can help]

c. Notice for an announced Audit:

- How many days prior to the audit should you inform your Supplier? [Provide your answer for announced and unannounced audit]

d. Acceptance:

- What is the rate of unacceptable products that you may consider to re-evaluate the Supplier? Rate= unacceptable lots / number of lot received x 100 (Percentage)

[Provide your answer – A link to a procedure would also help to clarify the requirements]

EXECUTED by the parties on the date first mentioned above

Manufacturer	**IMPORTER**
Name and Function:	Name and Function:
Date:	Date:
Signature	Signature