TECHNICAL QUALITY AGREEMENT

BETWEEN "THE PARTIES",

(CONTRACT GIVER) here after referred to as "DISTRIBUTOR"
ARRABON DISTRIBUTION (PTY) LTD
And ARRABON TRADING CC
Unit 12 Imperium Business Park, 16 Venturi Crescent, Hennopspark, South Africa, 0157
Authorised Representative: S.J. Muller
Tel: +27126532086
E-mail: fmuller@arrabon.biz

(CONTRACT ACCEPTOR) Hereafter referred to as the "SUPPLIER"

Supplier Company Name:

Supplier Address

Authorised Representative Name and Surname:

Tel:

E-mail

"Supply" is the quality receipt, control, storage, warehousing, distribution and transport of Finished "PRODUCT" as in Annex "B

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This agreement relates specifically to the technical aspects of the relationship and is distinct from any commercial arrangement made between the parties.; where the “DISTRIBUTOR” provides medical devices to the Southern African market and the “SUPPLIER” provides medical devices in compliance to regulatory requirements.

The above-mentioned parties (“DISTRIBUTOR” and “SUPPLIER”) hereby agree to the defined responsibilities for SERVICE of the agreed “PRODUCTS”, hereinafter referred to as “PRODUCT or in multiple “PRODUCTS”. In the absence of any specific article or articles to the contrary, the regulatory requirements, and their updates from time to time, will be respected, observed and fulfilled; as appropriate.

This agreement does not cover commercial matters, but should, save for where justifiable and in the interest of “PRODUCT” safety, quality and efficacy, not be construed in a manner that it detracts from the commercial contract or agreement in place between the “DISTRIBUTOR” and “SUPPLIER”.

1. GENERAL REQUIREMENTS

1.1 The “SUPPLIER” undertakes not to vary anything explicit or implied in this Agreement other than by consultation with the “DISTRIBUTOR” and will give reasonable consideration to adopting any new standards, specifications and procedures at the written request of the “DISTRIBUTOR”, where requests relate to the obligations placed on the parties by explicit provisions contained in the Medicines Act 101 of South Africa or the Guidelines thereto.

1.2 The “DISTRIBUTOR” undertakes to conduct all warehousing and Distribution operations of the “SUPPLIER”s “PRODUCTS” in accordance with the requirements of any current, relevant health and safety legislation, and in accordance with any statutory or other requirements relating to the “PRODUCTS”.

1.3 The “DISTRIBUTOR” and “SUPPLIER” are responsible at all times for performing the different steps involved in controlling the “PRODUCTS” as specified in this agreement and as summarized in Annexure “**B**”.

2. SECURITY

The “DISTRIBUTOR” will store and distribute all “PRODUCTS” under secure conditions. When a “PRODUCT” requires special storage or distribution conditions, it is the responsibility of the “SUPPLIER” to inform the “DISTRIBUTOR” of such special conditions and recordkeeping where applicable.

3. PERSONNEL

3.1 The parties shall maintain an organisation chart showing reporting lines and levels of responsibility with names. The parties will ensure that the key personnel involved in supply of the “PRODUCTS” have appropriate ability and experience for the proper handling of “PRODUCTS”. The parties will ensure that its personnel are trained in relation to the duties assigned to them and that training records are maintained

3.2 Product training and training material regarding the use, handling, storage, transportation, distribution, Installation & commissioning, repair, maintenance and all relevant technical aspects of the “PRODUCTS” will be available from the “SUPPLIER”, to the staff of the “DISTRIBUTOR” at no extra cost. The “DISTRIBUTOR” will be allowed to request such training at reasonable intervals. Should new training or training material be available on products distributed by the “DISTRIBUTOR” it will be the responsibility of the “SUPPLIER” to inform the “DISTRIBUTOR” about such training being available.

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4. SERVICE OF PRODUCTS

4.1 The “SUPPLIER” will bear the responsibility of ensuring adequate and correct procedures for supply of the “PRODUCTS”, following applicable GMP (Good manufacturing practices” and GWP (good warehousing practices), as relevant, and any applicable regulatory requirements.

4.2 The “SUPPLIER” will bear the responsibility to enable the “DISTRIBUTOR” to fulfil all valid factory warranties arising from products failing under the “SUPPLIER”s warranty by supplying the necessary technical information and assistance required as well as making a replacement product available or by making the necessary spare parts available to enable the “DISTRIBUTOR” to restore the “PRODUCT” in question to a factory working condition.

4.3 The batch numbering or serial number system of “SUPPLIER” will be used.

4.4 Any deviations from the above agreed conditions will be reported to the “DISTRIBUTOR” by the “SUPPLIER”.

4.5 Any related quality control documents will be kept by the “SUPPLIER”. On request copies of such quality control documents will be submitted to the “DISTRIBUTOR” within a reasonable time frame.

5. ASSIGNMENT OF THE AGREEMENT

The Parties shall not be allowed to assign any rights and/or responsibilities given by this Agreement to a third party, without prior written consent of the other Party, unless such assignment has been disclosed as part of this agreement.

6. ENQUIRIES AND COMPLAINTS

6.1 The “SUPPLIER” will ensure that all types of complaints are recorded and handled in line with their current SOPs for technical complaints handling, and adverse events reporting. The “DISTRIBUTOR” must be informed of adverse events.

6.2 All complaints will be dealt with by the “SUPPLIER” in accordance with the instructions provided by the “DISTRIBUTOR” in line with Guidelines issued under Legislation in line with practice and guidelines issued from time to time by regulatory authorities.

6.2 The “Distributor”, with the co-operation of the “SUPPLIER” (when applicable) will investigate all complaints promptly, take appropriate action, including but not limited to, reporting to the relevant health authority, if required by legislation, record the outcomes of such action and provide the parties with a final or interim written report within 5 working days (when applicable). Where required and in line with legislation, the “DISTRIBUTOR” may require of the “SUPPLIER” to take corrective steps to remedy any aspect within their control that have been causally proven to relate to their actions or duties relating to the “PRODUCT”.

6.3 All adverse events must be communicated to the “DISTRIBUTOR” immediately or as soon as practically possible by the “SUPPLIER”. In the case of a potentially serious complaint, the “DISTRIBUTOR” will indicate the proposed actions to be taken and the timelines on the same day or as soon as practically possible. It is accepted that completion of a full investigation may take longer than a day and may involve investigations and/or co-operation by the “SUPPLIER”.

6.4 The “DISTRIBUTOR”, or where appropriate in conjunction with the “SUPPLIER”, as the case may be, will be responsible for communication with the complainant or person that has brought the technical complaint or adverse reaction to the attention of any of the parties.

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7. DOCUMENTATION

7.1 "SUPPLIER" will have written and approved SOP's in place to ensure that a good standard of Quality Management is maintained, and to serve as a reference for instructions for performing operations. These SOP's must be reviewed on a regular basis.

7.2 Transactions/invoices shall be retained by the "DISTRIBUTOR", and the "SUPPLIER" and shall be processed in such a way that batch traceability is always possible. The authority and final decision of a batch recall lies with the "DISTRIBUTOR", and the costs involved are borne by the "DISTRIBUTOR", unless the recall is as a result of negligence on the part of the "SUPPLIER".

8. FINISHED "PRODUCT" POST MARKETING SURVEILLANCE

8.1 Where applicable, this will be the primary responsibility of the "DISTRIBUTOR", but may be brought to the attention of the "DISTRIBUTOR", by the "SUPPLIER" in accordance with the complaints processes, relevant SOP and requirements set by the legislation in this regard.

8.2 The "SUPPLIER" will provide supporting documentation, records and reports to enable the "DISTRIBUTOR", to conclude a post-market surveillance and/or Annual "PRODUCT" Review.

9. QUALITY AUDITS AND INSPECTION VISITS / AUDITS

9.1 In order to enable the "DISTRIBUTOR", to satisfy himself that the terms and conditions and responsibilities laid down herein are being carried out as detailed, and that the "SUPPLIER" has adequate premises, equipment and staff with sufficient knowledge and experience to carry out all operations relating to the "PRODUCTS", the "DISTRIBUTOR", may visit and/or audit the "SUPPLIER" facilities during business hours and upon prior written notice to the "SUPPLIER".

9.2 The "DISTRIBUTOR", reserves the right to inspect, during business hours and with prior written notice, the premises and any documentation relevant to the "PRODUCTS". The information gained from these inspections will be treated with strict confidentiality.

9.3 The "SUPPLIER" shall take a course of action and resolution acceptable to the "DISTRIBUTOR", in the event that the "DISTRIBUTOR", finds any contractual, QMS or regulatory deficiencies during such audit.

10. RECALL OF BATCHES

10.1 The decision to recall a batch rests with the "DISTRIBUTOR", The nature and urgency of a recall will be decided by the "DISTRIBUTOR", according to the recall SOP of the "DISTRIBUTOR".

10.2 Once the decision to recall a batch has been taken by the "DISTRIBUTOR", the recall will be initiated by the Authorised Representative of the "DISTRIBUTOR", or his/her delegate.

10.3 The "DISTRIBUTOR" will inform the "SUPPLIER" of any action required. The "SUPPLIER" is responsible for maintaining a "PRODUCT" Recall Procedure when it is necessary to recall a defective "PRODUCT" from the market.

10.4 In case of a recall the "SUPPLIER" will be expected to give priority to assisting the "DISTRIBUTOR", with required documentation, records and reports.

11. SERIOUS INCIDENTS

11.1 In the event a serious incident occurs relating to the "PRODUCTS" stored and transported for the "DISTRIBUTOR", the "SUPPLIER" will inform the "DISTRIBUTOR", within 24 hours of becoming aware of such incident.

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12. MISCELLANEOUS

12.1 The "DISTRIBUTOR", will market and carry the legal responsibility for the marketing of the "PRODUCTS", which includes ensuring that marketing and advertisement occur within the scope of products legislation and the Code of Marketing Practice applicable in South Africa.

13. DURATION OF THIS AGREEMENT

13.1 This agreement shall come into effect upon the date of signature of the last Party signing this agreement.

13.2 This agreement will remain in force as long as there are "PRODUCTS" and related records in the possession of the "SUPPLIER".

13.3 This agreement may be terminated upon satisfactory transfer by both Parties of the responsibility for the "PRODUCTS", as published from time to time.

14. DISCONTINUATION OF CONFORMANCE OR COMPLIENCE WITH REGARDS TO ISO 13485, FDA (USA FOOD AND DRUG ADMINISTRATION) OR CE (EUROPEAN) COMPLIENCE OR ANY OTHER "PRODUCT" RELATED COMPLIENCE

In the event where the "SUPPLIER" has furnished the "DISTRIBUTOR" with a certificate or confirmation of compliance for a specific "PRODUCT" or range of "PRODUCTS" and the "SUPPLIER" wishes to discontinue such compliance, the "SUPPLIER" undertakes to inform the "DISTRIBUTOR" of such discontinuation of compliance in writing at least 90 days before expiry or nullifying of such compliance.

15. CLOSING STATEMENTS

The revocation, alteration or extension of this agreement will take place in writing and with the consent of all parties. Invalid clauses contained in this agreement do not affect the validity of the other remaining requirements. Invalid clauses will be replaced by matching valid clauses.

In the event of any inconsistencies between the terms of this Agreement and the Annexures, the terms of the Agreement will take precedence.

Each party will inform the other of any change of the responsible persons or function as mentioned in Annexure "**A**" and of any change of address or contact or telephone numbers.

ANNEXURES ATTACHED HERETO:

Annexure "A" – List of Contact Persons and Premises

FOR THE "DISTRIBUTOR"

Company Name: ARRABON DISTRIBUTION (PTY) LTD
And ARRABON TRADING CC

ADDRESS: Unit 12 Imperium Business Park, 16 Venturi Crescent, Hennopspark, South Africa, 0157

Contact List:

Initialled / Company Stamp "SUPPLIER"	Initialled / Company Stamp "ARRABON"

Department: Management

Contact: Fanie Muller

Email: fmuller@arrabon.biz

Contact Number: +2712 653 2086

Department: Quality Management

Contact: Ms. Candice Robinson

Email: qc@arrabon.biz

Contact Number: +2712 653 2086

ARRABON Authorised Signatory:

Name: _____ **Surname:** _____

Signature_____ **Date:**_____

ANNEXURE "A" – List of Contact Persons and Premises,

FOR THE "SUPPLIER"

Company Name:

ADDRESS:

Contact List:

Department:

Contact

Email:

Contact Number:

Department: Quality Management

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Contact:

Email:

Contact Number:

Authorised Signatory:

Name: _____ **Surname:** _____

Signature_____ **Date:**_____

ANNEXURE "B" – List of "PRODUCTS" defined by product group supplied by the "SUPPLIER" to the **"DISTRIBUTOR"**

(List all products by family only ie Dopplers, Oxygen flow meters, Blood pressure equipment etc you would be able to supply us)

1.

2.

3.

4.

5.

6.

7.

8.

9.

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