MAXTEC LLC, DISTRIBUTOR REGULATORY AGREEMENT

This Distributor Regulatory Agreement (the "Agreement") by and between **Maxtec, LLC, a Utah limited liability** company, having offices at 2305 South 1070 West, Salt Lake City, Utah, 84119, USA ("Manufacturer"), and **Viamed Ltd.** a United Kingdom Limited company, having offices at 15 Station Road, Cross Hills, Keighley, West Yorkshire BD20 7DT, United Kingdom ("Distributor"). Manufacturer and Distributor are sometimes referred to herein individually as, a "Party" and together as, the "Parties."

The agreement Effective Date is the latest date of signature of both parties in the signature section of this agreement.

1. RECITALS

1.1. The purpose of this Agreement is to outline and show Distributor acceptance of the regulatory responsibilities of a Distributor of Maxtec (Manufacturer) products.

1.2. This agreement is **NOT** intended to grant authority to license Maxtec (Manufacturer) products, nor is it intended to act as a contract for Distribution Rights (exclusive or non-inclusive) or outline pricing structures, terms or warranties. Separate agreements such as a Distributor Agreement or Letter of Authorization shall be drawn up for these purposes.

1.3. This agreement shall stay in effect for the duration of the Manufacturer and Distributor relationship and be applicable for the extent that distributed products stay on the market.

1.4. Amendments or updates that partially or fully this supersede agreement shall be clearly identified as such.

2. DEFINITIONS

2.1. Unless the context otherwise requires, the following terms as used in this Agreement shall have the following meanings (such meanings to be equally applicable in the singular and plural forms of the terms defined):

"Adverse Events" means any undesirable experience associated with the use of a medical product in a patient. Undesirable experiences include, but not limited to, patient death, hospitalization, disability or permanent damage, serious injury, and any potential patient harm if the event were to occur.

"*Applicable Laws*" means all laws, rules, regulations, and guidelines that may apply to the development, licensing, marketing or sale of the Products or the performance of Representative's obligations under this Agreement including, without limitation, laws, regulations and guidelines governing the import, export, development, marketing, distribution and sale of the Products and including all standards or guidelines promulgated by any applicable Regulatory Authority.

"Confidential Information" means all non-public information disclosed by a party (Discloser) to the other party (Recipient), whether orally, electronically, or in writing and in any form, that is designated as confidential or that reasonably should be understood to be confidential given the nature of the information and the circumstances of disclosure (Confidential Information)

"Importer" The importer is defined as any natural or legal person established within the region that first places a device from a foreign country on the region's market.

"Distributor" means *any natural or legal person in the supply chain, other than the manufacturer or the importer that make a device available on the market, up until the point of putting into service. Note : Based on the supply chain manufacturer or the distributor may also be the importer.*

"Manufacturer" means any natural or legal person who manufactures a product or has a product designed or manufactured and markets the product under its name or trademark.

"*Products*" means those products that Manufacturer may grant or has granted Representative the right to sell, distribute, and/or market.

"*Region*" means the geographic area where products or sold, distributed, and/or marketed.

"*Regulatory Authority*" means all authorities, notified bodies, and any other national, multinational, federal, state, provincial or local regulatory agency, department, bureau or other manufacturing or governmental entity that has regulatory authority over Manufacturer, Representative and/or the Products or their chemical ingredients, materials, or components in the Region.

3. DISTRIBUTOR REPRESENTATIVE

3.1. The Distributor (Viamed Ltd.) hereby represents and warrants to Manufacturer that Distributor has the training, knowledge, expertise, authority, and qualifications necessary to perform all its obligations as set forth in this Agreement.

4. VIGILANCE

4.1. Distributor shall be responsible for reporting all product-related incidents to Manufacturer within the timeframes outlined in this agreement. Vigilance identification includes the reporting serious incidents, safety related corrective actions and product failures.

5. GENERAL MANUFACTURER RESPONSIBILITIES

5.1. Manufacturer shall be responsible for ensuring essential requirements, technical file documentation, Eudamed registration and labeling are compliant with EU MDR 2017/745 by the outlined transition implementation date(s) from EU MDD 93/42/EEC based on the class of devices supplied.

5.2. Manufacturer shall be responsible for ensuring that the product is labeled and listed in the US FDA's GUDID database in accordance with Unique Device Identification requirements as outlined in 21 CFR part 830.

5.3. Manufacturer shall be responsible for ensuring that products are designed, manufactured and labeled under the governance of a certified ISO 13485, Quality Management System.

5.4. Manufacturer shall be responsible for ensuring that the applicable Medical Device Product Approvals, Declarations of Conformity, details of Authorized Representatives, In Country Sponsors are made available to the Distributor and or on the product labeling as applicable.

5.5. Manufacturer shall be responsible for providing documentation, as requested, of manufacturer held licensing, registrations and product approvals.

6. GENERAL DISTRIBUTOR RESPONSIBILITIES

6.1. The Distributor shall be responsible for complying to the applicable laws of the geographical region (including state and federal laws) for which the products are being distributed to and from. Products shall not be distributed into a region where the Distributor and or Manufacturer (as appropriate per regulations) does not hold a required license or registration or other required medical device approval.

6.2. The Distributor shall verify that products have the appropriate marking for the distribution regions prior to distribution such as, but not limited to, a CE Mark.

6.3. The Distributor shall ensure that an EU Declaration of Conformity (DoC) is documented and made available by the Manufacturer for any products shipped into the European Union or other region that recognizes the CE Mark.

6.4. The Distributor shall ensure that the labels and instructions for use are provided in the official languages of the member states (or in languages accepted by said state) in which the device is made available, if applicable.

6.5. The Distributor shall verify that the importers name is indicated on each device or in the accompanying documentation, and that the device bears a UDI at all relevant packaging levels.

6.6. The Distributor shall ensure that storage and transports conditions, when under their responsibility, are appropriate and in line with recommendations of the manufacturer.

6.7. If the Distributor considers that a device is not compliant with applicable regulations, the device shall not be placed on the market and the Distributor shall inform Manufacturer and, if applicable, Manufacturer's EU authorized representative. The Distributor should

also inform Manufacturer and cooperate with the applicable authorities if they suspect that a device has been falsified or that there is a serious risk to health.

7. RECORD RETENTION

7.1. The Distributor shall maintain and keep on file, in a readable and retrievable format, complete and systematic records relating to the Products, including without limitation, applications, filings, notices, correspondence, customer complaints, lot and batch numbers, Product traceability documentation, and shipping logs.

7.2. The Distributor shall make all records and documentation maintained in accordance with this available to Manufacturer and any applicable Regulatory Authorities, upon request.

7.3. The Distributor shall preserve and maintain all records and documentation for a minimum period of (15) years from the date of distribution.

8. RECALLS

8.5. The Distributor shall establish a recall procedure that complies with the Applicable Laws.

8.6. Manufacturer shall notify the Distributor, in writing, of any product recalls or withdrawals (voluntary or involuntary) for products which have been released by Manufacturer to the Distributor.

8.7. Distributor shall notify Manufacturer within (1) day of any recall decision that is not initiated by Manufacturer.

8.8. The Distributor shall perform and carry-out, in cooperation with, and on behalf of Manufacturer, any applicable recall strategy relating to the Products in the Region(s) they have distributed.

8.9. The Distributor shall report Product-related documentation, in cooperation with, and on behalf of, Manufacturer, to the applicable Regulatory Authorities in accordance with the Applicable Laws and required reporting timeframes based for the region products have been distributed.

9. ADVERSE EVENTS

9.1. The Distributor shall notify Manufacturer, in writing, within (2) days of any information of which it becomes aware concerning any adverse experiences or complaints in connection with the use of the Products, including the incidence and the severity thereof.

9.2. Manufacturer shall be responsible for the reporting of Adverse Events, as the manufacturer, to the applicable authorities for which the product has been distributed. The Distributor shall be responsible for understanding and executing any additional

reporting requirements of the distributor as required by the applicable laws of the region that the products were distributed.

10. COMPLAINTS

10.1. Distributor shall be responsible for reporting all product-related complaints to Manufacturer, in writing, within (3) days of the incident occurring.

11. ACCESS

11.1. The Distributor shall grant access to Manufacturer and any Regulatory Authorities to obtain information to ensure safety, efficacy and regulatory compliance for the Products.

12. CONFIDENTIAL INFORMATION

12.1. Each party agrees to protect Confidential Information received from the other party; and each party further agrees that it will limit its use of the Confidential Information received under this Agreement and will disclose such information only to those of its employees who have a need to know such Confidential Information for the purpose described above. With respect to such Confidential Information disclosed in writing or some other tangible form, each party agrees that it will not duplicate such Confidential Information in any manner unless authorized to do so and that it will return such Confidential Information to the disclosing party upon request together with any copies or will provide written certification of the destruction thereof. This obligations under this Section shall survive the expiration or earlier termination of this Agreement

13. SIGNATURES

The Parties, through their duly authorized representatives, have executed this Agreement to be effective as from the Effective Date.

Maxtec	***Name of Distributor:***
Name:_____	Name: Steve Nixon
Signature:_____	Signature: 
Title: VP of QARA	Title: Director
Contact Info: shankins@maxtec.com	Contact Info: steve.nixon@viamed.co.uk
Date: _____	Date: 7th December 2021