Supply Agreement

Viamed Ltd.
15 Station Road
Cross Hills
Keighley
West Yorkshire
BD20 7DT
United Kingdom

- referred to as the Supplier -

&

Sedana Medical AB (publ)
Vendevägen 89
182 32 Danderyd
Sweden
(Sedana Medical Limited, is wholly owned by Sedana Medical AB)

- referred to as the Buyer -

May 2023

Whereas:

- the Supplier carries on the business of supplying medical products such as Gas Sampling Lines and other devices.

- the Buyer carries on the business of selling and developing of medical products.

General terms

(1) Viamed is the supplier Bluepoint Medical is the legal manufacturer and will designate an authorized representative.

(2) Viamed/Bluepoint Medical will apply for Free Sales Certificates (CFS) where needed.

(3) The Supplier will manage translations to required languages, the cost will be borne by the buyer.

(4) The Buyer is the importer.

(5) The Buyer will distribute products both within EU and outside EU (globally)

Contractual Products

1. Contractual products:

Article Nr	description (as printed on invoice/ delivery note)	Short_description
REF: 8090121313V (4421517)	Gas Sampling Line - H Type	N/a

2. The Supplier shall be required to Supply the contractual products according to the agreed specifications. (Available on request)
3. The Supplier is obliged to inform the Buyer of all intended significant deviations in the manufacturing process that may have an adverse impact on the quality of products provided or the Buyers regulatory filings. These include but are not limited to changes in component material, material supplier or manufacturing process which have the potential to affect the fit, form or function of the finished product, or a change to the manufacturing site location or senior management.

Placement of order

1. The Buyer shall be required to place all orders in advance, there is no minimum or maximum order quantity.
2. The buyer will endeavor to provide a yearly forecast with can be edited 3 months in advance.

3. Contact persons Supplier:

Article	Article Nr	Contact Person	Email
Gas Sampling Line - H Type 2,5m	REF: 8090121313V (4421517)	Ryan Swaine International Sales Manager	ryan.swaine@viamed.co.uk

Lead time

1. The product provided by Viamed is a niche product and therefore it is not possible for Viamed to commit to lead times, orders can be placed and then Viamed will confirm delivery schedule.
2. Approximate production times (working days) from receipt of order and payment:
   - 10 boxes, 250 lines – 2 weeks
   - 40 boxes, 1000 lines – 3 weeks
   - 400 boxes, 10000 lines -12 weeks
   - 2000 boxes, 50000 lines - 48 weeks
   - 4000 boxes, 100000 lines - 98 weeks.

   Increased quantities will require tubing to be produced specifically for the order, tubing production typically takes 8 weeks.

Third Party Integration (TPI) Quality Requirements

Supplied information:

Supplier will ensure that the device will be supplied with information according to article 10 in MDR 2017/745 in an official Union language determined by the Member State in which the device is made available to the Buyer.

The buyer shall be responsible for coordinating requests for revisions to the Supplier labeling to meet the requirements for the region being distributed. In the case that the request is deemed not feasible for the Supplier the Buyer is ultimately responsible for ensuring that regional requirements are met prior to distribution into the market.

CoC/Doc:

Supplier will supply the Buyer with Product Certificates of Compliance/ Certificates of Conformance (CoC) and Product Declaration of Conformity (DoC)

Significant Change Notification and Management:

Supplier will notify the Buyers QA Department in writing of planned significant design or manufacturing changes to Product in a timely manner prior to implementation to allow the Buyer to conduct an appropriate assessment of the planned change.

EU MDR:

Supplier is responsible for ensuring general safety and performance requirements checklists, 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 classification of devices supplied.

Regulatory Approval in new Territories:

Supplier will make available to the Buyer a listing of existing product approvals by territory or regions as requested. For new territory approvals Buyer shall contact Supplier for the necessary documentation to process an application for market approval. The Supplier shall make the decision whether to make the application for market approval in the new territory directly, or whether to approve the Buyer to process this application on their behalf. Buyer will be informed of the outcome of this decision within 10 business days. Where the Buyer is authorized to process and application for market approval Supplier agrees to process all requests for information within 10 business days.

Vigilance and PMS:

If Sedana considers that a device is not compliant with the Regulations, the device shall not be placed on the market and the Sedana shall inform the supplier and the authorized representative. Sedana should also inform the authorities if they suspect that a device has been falsified or that there is a serious risk to health.

Sedana shall inform the supplier in the event of complaints or adverse events. They should also keep a register of complaints, non-conforming devices, recalls and withdrawals, and escalate non-compliance to authorities if they suspect that a device has been falsified or that there is a serious risk to health.

Sedana shall cooperate with authorities and provide samples or grant access to the devices.

The supplier shall conduct any complaint investigations and make results available to Sedana.

The supplier shall coordinate any recall activities and or adverse event reporting via interaction with the applicable Notified Body or authority, the supplier's appointed Authorized Representative and the buyer.

Price

(1) See Appendix 1

(2) All levies, dues, taxes, duties and other charges shall be borne by the Buyer.

Payment

(1) The Buyer shall pay the price of the goods (less any discount to which the Buyer is entitled, but without any other deduction) payment terms are advance prepayment of the Supplier's Proforma invoice.

Term of Agreement

(1) This agreement shall run for an indefinite period of time; it shall come into force and effect upon its execution.

(2) Each party hereto may terminate the agreement by ordinary written notice of termination that shall take effect at the expiry of three months.

Appendix

1) Prices

2) QARA contacts

Supplier: Viamed Ltd.	**Sedana Medical AB (publ)**
Place, Date: **Viamed – Keighley** **22nd May 2023**	*Place, Date:*
Signature:	*Signature:*
Name: ***Steve Nixon***	*Name:* Johannes Doll

Appendix 1 Prices

1. No firm prices have been agreed because of current market conditions. For illustrations purposes the price of 1 SKU is set at €87.50.
2. The volume discounts stated in the table below will be applied at the agreed prices.
3. As the sampling line is an OEM bespoke product for Sedana Medical, then payment is required in advance when the official purchase order is submitted by Sedana.

Article Nr.	Article Name	Volume SKU	Volume Base Units	% Discount
REF: 8090121313V (4421517)	Gas Sampling Line - H Type	1 Box	25	0%
REF: 8090121313V (4421517)	Gas Sampling Line - H Type	40 Boxes	1000	2.58%
REF: 8090121313V (4421517)	Gas Sampling Line - H Type	400 Boxes	10000	5.15%
REF: 8090121313V (4421517)	Gas Sampling Line - H Type	2000 Boxes	50000	7.43%
REF: 8090121313V (4421517)	Gas Sampling Line - H Type	4000 Boxes	100000	14.58%

Appendix 2 QARA Contacts

Supplier: Viamed Ltd.	**Sedana Medical AB (publ)**
Name: ***Derek Lamb***	*Name:* Morgan Nilsson
Title: **Managing Director**	*Title:* QA Manager
Phone and e-mail: ***+44 1535 634542*** ***derek.lamb@viamed.co.uk***	*Phone and e-mail:* *+46 (0)707 60 84 08* *morgan.nilsson@sedanamedical.com*