Interface Agreement

for the purpose of defining the scope of responsibility for compliance with legal requirements of medical products and quality assurance between the

Buyer: **Viamed Ltd.**
15 Station Road
Keighley
West Yorkshire BD20 7DT
United Kingdom

(hereinafter referred to as Buyer) and the

Manufacturer: **EnviteC-Wismar GmbH**
Alter Holzhafen 18
23966 Wismar
Germany

(hereinafter referred to as Manufacturer).

0. Preamble

The Products manufactured by Manufacturer (including, for example, materials, packaging, instruction for use and labelling) shall be marketed by Buyer on Buyer's own responsibility and in Buyer's own name.

1. Term and termination of the agreement

The agreement shall come into effect as of 1st November 2015 and shall be valid for an indefinite period. It may be terminated by either party by giving six months' notice prior to the end of the month. The agreement shall be terminated by registered letter.

This contract terminates automatically without further notice on the effective date of any termination or expiry of the sales agreement for the Products manufactured by the Manufacturer.

In case of termination of expiry or succession or novation all relevant information to guarantee, in particular, the duty to observe and report shall be handed over to the other party.

The obligation to keep documentation and records in accordance with sections 4 to 6 of the agreement shall remain in force for a period of ten years after the last Product has been sold.

In the event of a conflict between the terms and conditions of this Agreement and the sales agreement, the terms and conditions of the sales agreement will govern with respect to the commercial terms (e.g. pricing, cost and expenses, delivery terms) and this Quality Agreement will govern with respect to the quality terms between the parties.

2. Basis of the agreement

The basis of the agreement is the European Law on Technology, expressed as Council guidelines, as amended, and the national legal provisions derived therefrom.

Non-exhaustive list of the legal provisions:

Medical Devices Directive 93/42 EEC

3. Products

See Appendix 1

Sales territory: Worldwide

4. Obligations of Manufacturer

Manufacturer undertakes to meet the basic requirements of the legal provisions pursuant to section 2. This obligation enables Buyer to refer to the manufacture, quality assurance and final inspection of Manufacturer for which Manufacturer is responsible.

Manufacturer shall maintain a reasonable amount of information that allows traceability of the Product for Buyer (based on the serial number/batch).

In order to market the Products listed in Appendix 1, the following information shall be made available to Buyer:

- ☐ General description, variants and purpose (indication, contraindication), *as already exchanged*
- ☐ List of accessories, adapters, intended combinations of device, *our cross-reference list refers*
- ☐ Classifications, *as already exchanged*
- ☐ Markings, warning notices, labelling, instructions for use etc., *as already exchanged*
- ☐ Used (harmonised) standards, *as already exchanged*
- ☐ Declaration of conformity, *as already exchanged*

Manufacturer shall furnish Buyer with information about all substantial changes in the manufacturing process, in the case of product modifications and changes in the materials used for the Products that have an impact on product quality and safety. This applies, in particular, to the observation of the requirements of the legal provisions in accordance with section 2 of this agreement.

If any material changes arise in the course of the certification of the Products or Manufacturer, Buyer shall be informed as soon as reasonably possible.

Manufacturer shall document, implement, and maintain a process for initiating corrective action to address non-conforming products. Upon request from Buyer, the Manufacturer shall provide documented corrective action plans within 30 days from receiving a corrective action request from Buyer; such corrective action plan is subject to Buyer's written approval, not unreasonably withheld.

If the Manufacturer intends to make any modifications that may change the character or appearance of an item, or if the specifications cannot be met, Buyer shall be notified. No such changes may be implemented by Manufacturer without receiving Buyer's prior written approval, not unreasonably withheld. Those changes in the production process which usually occur between various production series or which lie within the scope of process qualification shall not be considered applicable to what was stated in the preceding paragraph.

5. Requirements of the quality assurance system and of certification

Manufacturer has successfully completed an approved conformity assessment procedure for the Products listed in Appendix 1 of this agreement in accordance with section 2.

Buyer shall, in the case of use of Buyer's own label (own brand label), assume the liability of the manufacturer pursuant to these statutory provisions. Buyer, in turn, must furnish proof of a conformity assessment procedure that complies with the statutory provisions listed in section 2.

6. Technical documentation / documentation on the quality assurance system

Manufacturer confirms that technical documentation according to NB-MED/2.5.1/Rec5, published by the Notified Bodies, and documentation on the quality assurance system in accordance with Manufacturer's conformity assessment procedure pursuant to the aforementioned statutory provisions is available and updated regularly.

In the event of a product liability case, Manufacturer shall grant the notified body of Buyer or the competent authorities the right to inspect documentation regarding the Product as set out in this agreement.

7. Quality audits

Buyer shall at scheduled times audit manufacturer to review compliance with this Agreement and in accordance with ISO 13485 standards. Both parties shall agree on the timing of the audit.

Manufacturer is responsible for attending to deviations reported during the audit within 30 calendar days. Manufacturer is responsible for investigating the root cause and implementing corrective actions with respect to the deviations reported during the audit. Manufacturer shall report both the root cause and implemented corrective actions to Buyer.

Manufacturer shall allow their facility, quality management system, specifications, instructions and batch documentation for the Product/s to be audited by the competent authority or Buyer´s certification body. Manufacturer is aware that the audits may be unannounced.

8. Obligations of Buyer

Buyer shall maintain and make available technical documentation on the Products listed in Appendix 1, any accompanying information and safety instructions as well as the declaration of conformity.

Buyer undertakes to set up a system for batch traceability.

9. Reporting of incidents/product observation/corrective action

Both parties to the agreement shall inform each other as soon as reasonably possible of all product risks/malfunctions regarding the Products, as listed in Appendix 1, that become known to them. This shall also apply to products or comparable products which have resulted or could have resulted in the death or a serious deterioration in the health of a patient or user or in a product call-back.

Manufacturer shall initiate appropriate corrective action in order to minimize damage and prevent damage in case of product risks as set out in the sales contract for the Products.

10. Duty to notify and report

Each party shall be individually responsible for performing the national duties to observe, notify and report incumbent upon them in their functions as Buyer and Manufacturer.

11. Final provision

The parties exclude all liability for all damages whatsoever and howsoever caused other than for intentional or grossly negligent actions. In case of a breach of a material obligation each party will be liable for its negligence but only to the extent of the contractually typical and foreseeable damages. Claims for loss of profit, savings, claims of third parties as well as other indirect and consequential mages are excluded. Neither party seeks to exclude or restrict its liability for: death or personal injury, fraud, specific quality guarantees or claims pursuant to the Product Liability Act.

This agreement is subject to German law and the parties submit to the exclusive jurisdiction of the courts in Schwerin. Any amendments to this agreement shall be made in writing. This agreement is not transferable to third parties, which are not affiliated companies in the sense of §§15 Aktiengesetz, without the consent of the parties to the agreement.

The obligations arising from this agreement will pass to the legal successor. If any provision of this agreement or part of a provision is determined by a court of competent jurisdiction to be illegal, invalid, or unenforceable, for any reason, then such provision or part or a provision shall be deemed stricken out for the purpose of the dispute in question, but only to the extent necessary to make the remaining portion of the provision legal, valid and enforceable, if possible, and all other provisions of this agreement shall remain in full force and effect.

Buyer VIAMED - KEIGHLEY

Place/date, 23/2/16

Stamp / signature

VIAMED
Company registered in England
Company Registration Number 01291765

Manufacturer

Place/date, ...

.....

Stamp / signature

Appendix 1 – Product

Product name	Product identification Manufacturer	Product identification Buyer	Classifi -cation
• Oxygen Sensor	OOM202-2S	R- 42V	IIa
• Oxygen Sensor	OOM112	R- 43V	IIa
• Oxygen Sensor	OOM113	R-48V	IIa
• Oxygen Sensor	OOM201	R- 23V	IIa
• Oxygen Sensor	OOM103	R-22MEDV	IIa
• Oxygen Sensor	OOM202-1	R- 41V	IIa
• Oxygen Sensor	OOM202	R-49V	IIa
• Oxygen Sensor	OOM202-2	R- 44V	IIa
• Oxygen Sensor	OOM106	R- 45V	IIa
• Oxygen Sensor	OOM204	R- 47V	IIa
• Oxygen Sensor	OOM110	R- 30V	IIa
• Oxygen Sensor	OOM111	R-75V	IIa