OEM Contract

for the purpose of defining the scope of responsibility and quality assurance between the

Marketing party:

VIAMED Ltd.
15 Station Road, Cross Hills,
Keighley, West Yorkshire,
BD2O 7DT. United Kingdom

(hereinafter referred to as Marketing Party) and the

Manufacturer

X
X
X

(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 Marketing Party on Marketing Party 痴 own responsibility and in Marketing Party 痴 own name.

1. Term and termination of the agreement

The agreement shall come into effect as of 01/06/07 and is concluded for an indefinite period; it may be terminated by either party by giving six monthsnotice prior to the end of the month. The agreement shall be terminated by registered letter.
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.

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.
List of the legal provisions as required:

XXX	CE	Annexe II of the Medical Devices Directive 93/42/EEC
XXX	ISO	ISO 13485:2003
Viamed	XXX	Agreement

3. Products

XXXXX
XXXXX

4. Obligations of Manufacturer

Manufacturer undertakes to meet the fundamental requirements of the legal provisions pursuant to section 2. This obligation enables Marketing Party to refer to the manufacture, quality assurance and final inspection of Manufacturer for which Manufacturer is responsible.
Manufacturer shall hold all information ready that guarantees the re-traceability of the product for Marketing Party (based on the serial number/batch).
In order to market the above-mentioned products, the following information shall be made available to Marketing Party:

- General description, variants and purpose (indication, contraindication)
- List of accessories, adapters, intended combinations of devices
- Classifications
- Markings, warning notices, labelling, instructions for use etc.
- Used (harmonised) standards
- Declaration of conformity

- Certificates, inspection documents etc. of Manufacturer or for the products listed in section 3

Manufacturer has a duty to furnish Marketing Party with information about all changes in the manufacturing process, in the case of product modifications and changes in the materials used for the products that may 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 changes arise in the course of the certification of the products or Manufacturer, Marketing Party shall be informed immediately.

5. Requirements of the quality assurance system and of certification

Manufacturer has successfully completed an approved conformity assessment procedure for the above-mentioned products pursuant to the basis of the agreement in accordance with section 2.
Marketing Party shall, in the case of Marketing Party 痴 own label (private label), assume product
liability pursuant to these statutory provisions. Marketing Party, 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 and documentation on the quality assurance system in accordance with Manufacturer 痴 conformity assessment procedure pursuant to the aforementioned statutory provisions is available and that it is continuously kept up to date.
In the event of a product liability case, Manufacturer shall grant the body specified by Marketing Party or the competent authorities the right to inspect all documentation regarding the product.

7. Quality audits

Notified bodies and authorities of Marketing Party are entitled at any time after prior arrangement of an appointment during normal office hours to conduct quality audits at

Manufacturer 痴 company.
In special cases (e.g. complaints or complaints in accordance with section 8), Marketing Party shall be permitted to inspect the QM system after consultation with Manufacturer.

8. Obligations of Marketing Party

Marketing Party shall keep available Marketing Party 痴 technical documentation on the products in section 3, any accompanying information and safety instructions, as well as the declaration of conformity.
Marketing Party undertakes to set up a system for batch re-traceability.

9. Reporting of incidents/product observation/corrective action/post market surveillance

Both parties to the agreement shall inform each other immediately of all product risks/malfunctions regarding the aforementioned products 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 is obligated to initiate appropriate corrective action in order to minimise damage and prevent damage in case of product risks. Each party is responsible for reporting to their own governing / notified bodies if appropriate.

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 Marketing Party and Manufacturer.

11. Final provision

This agreement is not transferable to third parties without the consent of the parties to the agreement. In the event that one of the parties to the agreement withdraws therefrom, the obligations arising from this agreement will pass to the legal successor or all relevant information to guarantee, in particular, the duty to observe and report shall be transferred to the other party to the agreement.

Marketing Party Viamed Ltd	**Manufacture**
Place/date.....	Place/date.....
Stamp / signature	Stamp / signature
Print Name:	Print Name: .....