QUALITY AGREEMENT

AN AGREEMENT is made the day of 2002

BETWEEN Viamed Limited whose registered office is situate at
15 Station Road, Crosshills, Keighley, West Yorkshire, BD20 7DT. United Kingdom.

AND XX
(XX) (2)

WHEREAS:

1. This Agreement ensures that development design manufacture testing packaging approval release and delivery are all in accordance with the quality assurance measures specified herein

2. This Agreement assumes the mutual Trust of each party hereto and neither party shall utilise information in any way which it receives by virtue of this Agreement unless specifically authorised to do so by the other party hereto This clause shall have effect both during the currency of this Agreement and after termination

3. This Agreement relates to all articles manufactured and supplied by XX as specified in the order from Viamed XX shall be responsible to Viamed for all sub-contractors on the same terms as pertain to XX under this Agreement notwithstanding that Viamed may have approved a sub-contractor and may have demanded that XX make make purchases from a specified sub-contractor

IT IS HEREBY AGREED AS FOLLOWS:

1. QUALITY CONTROL SYSTEM

XX must have an introduced efficient quality control system which complies with ISO 9001and EN 4600 and/or ISO 9000 2000, ISO13485 2003 which has been third party certified and approved by a certifying body notified in the EU or alternatively have already commenced a process to introduce ISO 9000 2000 ISO13485 2003 and has planned to comply within 12 months from the date hereof
Compliance with quality system requirements must exist each time an article is manufactured tested packaged and released.
ISO9001 EN4600 are in process of being superseded by ISO 13485 2003

2. DEVELOPMENT AND DESIGN

XX shall be responsible for and pursue development and design work so that only fault-free articles supplied according to written specifications and intended operating reliability must continue after delivery by XX
Design shall be verified against functional specifications and written documents must be prepared for this purpose and comprise both method and measurement results
Such documents are to be kept on file in accordance with paragraph 10 hereof

3. MANUFACTURING DOCUMENTATION

XX shall assess and prepare all documentation required for manufacture testing approval packaging and release
XX shall keep all submitted documentation on file in accordance with paragraph 10 hereof

4. MANUFACTURING MATERIALS AND MANUFACTURING COMPONENTS

Viamed shall be responsible for the purchase and arrival tests of those materials

and components supplied by

5. MANUFACTURING AND PROCESS VALIDATION

All manufacturing processes are to be validated and the methods and results are to be documented which documents must be kept on file in accordance with paragraph 10 hereof

For the assembly of parts of articles XX may only use those sub-contractors who have an introduced efficient quality control system which complies with the ISO 9000 or have already commenced a process to introduce ISO 9000 and who have planned to comply with such stipulations within 12 months from the date hereof

'Assembly' shall include pre-delivery assembly by sub-contractors of multiple components and manufacturing according to instruction by drawings

Manufacturing of pre-production samples must be in accordance with paragraph 9 hereof

Series production of new articles including when revisions have been made must be started in accordance with paragraph 6 hereof and parts of article must be made by the same sub-contractors who manufactured the same parts of the pre-production series

Only the specifications as approved by Viamed shall be used in respect of materials process measurement equipment tools or quality control as in accordance with paragraph 6 hereof

6. NEW ARTICLES AND REVISIONS

Before the manufacture of new articles commences pre-production samples will be manufactured and validated with processes in accordance with approved documents The pre-production series must be checked and approved in writing by Viamed

Where XX intends to make alterations to the agreed specifications in any manner Viamed must be informed in writing immediately

Such changes in written specification of any article must be approved in writing by Viamed and previously issued documents must be replaced before any revised production (altered as necessary) in validated processes

Pre-production samples must be checked and approved in writing by Viamed XX shall perform control measurements of pre-production samples and supply measurement protocols to Viamed showing measurement results confirming that submitted pre-production samples are in compliance with written specifications

Viamed reserves the right to waive the right to view such measurement protocols but where such waiver is invoked **XX** remains liable for the supply of articles which comply with written specifications

All aforementioned written information documentation prepared by XX including measurement protocols and written approvals by Viamed shall be kept on file in accordance with paragraph 10 hereof

7. TESTS

XX shall perform tests in accordance with paragraph 3 hereof and protocols shall be kept showing that processes and tests were performed by XX in accordance with the documentation referred to in paragraph 3 hereof XX must also assess quality control to identify defects and all defects must be eradicated immediately here defects are discovered in final inspection defective parts of any batch must be separated from the remainder of the batch immediately

8. DELIVERIES RELEASE AND CERTIFICATES

Prior to delivery XX must approve and release articles such release to be based upon the results of documented approved tests of materials and components and on tests performed during the manufacturing process up to final inspection and including pre-packaging with markings and contents and according to ISO 9000 2003 paragraph 8.2.3 and 8.2.4 " Monitoring and measurement of processes and product",

XX shall be responsible for ensuring that supplied articles comply with any written specifications and also that certificates accompanying deliveries are in accordance with paragraph 10 hereof

Certificate contents are specified in Appendix A1 hereto

9. TRACEABILITY

XX shall ensure traceability between received materials and components and Quality documents which lie on file in respect of articles delivered to Viamed

10. FILING QUALITY CONTROL DOCUMENTS

XX shall file all documents as detailed in this Agreement under paragraphs 2,3,5,6,7,8 and 12 and additionally in accordance with ISO 9000 paragraph 4.10.5 'Inspection and Test Records' and paragraph 4.16 'Control of Quality Records' or ISO13485 2003 paragraph 4.2 "Documentation requirements"
Should Viamed request any final test document which is held on file copies of such documentation must be supplied to Viamed within 7 days from the date of request All documents must be kept on file for 5 years after issue

11. AUDITS

Viamed hereby reserves the right to visit XX together with any sub-contractors which have not been third party certified and approved by a certifying body notified within the EU
Such visits are to enable Viamed to carry out a quality audit and check processes and documents which are on file
The right of access shall apply where Viamed is the subject of inspection by a public agency where such agency demands to inspect XX or a sub-contractor of XX
The right of access hereby reserved shall at all times be preceded by written notice of an intended visit such notice to be 7 working days minimum except when the inspection by a public agency requires shorter notice.

12. QUALITY INFORMATION

There must be a continuous exchange of quality information between XX and Viamed such information being the basis for the introduction of requisite improvements to ensure that safety risks operational and production disruptions never occur
XX must immediately advise Viamed in writing in respect of any technical problems and suspected defects in articles which XX has already delivered to Viamed
XX must in such cases ensure that sub-contractors provide supporting information
Viamed must immediately advise XX in writing of any discovery of defect
Defective articles in respect of which Viamed submits claims or returns will be processed as complaints and both Viamed and XX shall process complaints in accordance with ISO9001 paragraph 4.14.2 or ISO13485 2003 paragraph 8.5.2 " Corrective Action and 8.5.3 "Preventive action"
XX must always and forthwith advise Viamed in writing of:

i. the cause of any defect
ii. ii the steps taken to prevent repetition of any defect in the future
iii. iii an analysis of the risk of patient injury and functional disruption where appropriate
iv. iv any other information requested by Viamed in any complaint matter
v. Both parties hereto agree to inform the other in respect of anything which may impact upon quality and quality control including major changes in staff and organisation Where quality information is addressed to anyone other than the respective Contact Person (as detailed in paragraph 13 below) a copy of such information must always be sent in addition to the Contact Person

13. VALIDITY AND CONTACT PERSONS

This Agreement shall remain in force until terminated by either party hereto serving upon the other written notice of not less than 6 months

The parties hereto have nominated the following as Contact Persons who shall address technical matters or other matters arising out of this Agreement in the first instance

For Viamed: **John S Lamb** **Tel: +44 1535 634542**
Fax: +44 1535 635582

For XX :

SIGNED ON BEHALF OF VIAMED LIMITED:

Name :

Position :

SIGNED ON BEHALF OF XX

Name :

Position :

Appendix A1

Certificate contents

Deliveries must be accompanied by a certificate specifying that the supplied articles comply with all the written specifications.

Certificates shall be based on documented, approved results from:

The checks the supplier deems necessary to ensure that all delivered articles, including their marking and packaging, comply with specifications, e.g. on arrival inspections of materials and components, inspections during and after the manufacturing process and inspections of marking and packaging.

Certificates must contain the following information, where applicable:
The supplier's company name, registration number and address
Text certifying that all delivered articles comply with all the written specifications of the article.
Viamed's order number.
Viamed's article designation and article number.
The number of approved units
The date the certificate was issued.
A signature, name, tel. no., fax no., and department of the person responsible for ensuring that certificate information is correct.
A signature, name, tel. no., fax no-, and department of the person responsible for releasing the articles.

Deliveries without an accompanying certificate will be deemed defective as will deliveries containing defective parts which were approved by any unauthorized employee of Viamed
Any "approval" of deliveries by Viamed must be in writing, and a copy of same must in such instances accompany the certificate with the defect specified.

The policy of Viamed is to return deliveries deemed to be defective.