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NOVA HEALTH SYSTEMS, INC.

Fax

To: JOHN LAMB **From:** WADE ABRAHAM

Fax: +44 1535 635582 **Pages:** 6 **Including Cover**

Phone: +44 1535 634542 **Date:** 5/25/05

Re: QUALITY AGREEMENT **CC:**

☐ **Urgent** ☒ **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

JOHN, I HAVE MADE THE ADJUSTMENTS WE DISCUSSED BY EMAIL AS WELL AS TWO ADDITIONS. EACH CHANGE/ ADDITION IS NOTED BELOW AND WAS INITIALED BY ME ON THE ATTACHED COPY.

ITEM: 1 - TWO DELETIONS

5 - ONE DELETION

8 - ONE DELETION

10 - ONE DELETION

12 - ONE DELETION

12 vi - ADDED

12 vii - ADDED.

PLEASE LET ME KNOW IF THERE IS ANYTHING ELSE I CAN DO. THANK YOU

Wade

VIAMED

QUALITY AGREEMENT

AN AGREEMENT is made the 20th day of MAY 2005

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

AND NOVA HEALTH SYSTEMS INC. (NOVA HEALTH SYSTEMS INC.) situated at 1001 Broad Street, 3rd Floor P.O.Box 4335, Utica, NY 13504-4335. USA

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 NOVA HEALTH SYSTEMS INC. as specified in the order from Viamed NOVA HEALTH SYSTEMS INC. shall be responsible to Viamed for all sub-contractors on the same terms as pertain to NOVA HEALTH SYSTEMS INC. under this Agreement notwithstanding that Viamed may have approved a sub-contractor and may have demanded that NOVA HEALTH SYSTEMS INC. make purchases from a specified sub-contractor**

IT IS HEREBY AGREED AS FOLLOWS:

1. QUALITY CONTROL SYSTEM

NOVA HEALTH SYSTEMS INC. 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

NOVA HEALTH SYSTEMS INC. 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 NOVA HEALTH SYSTEMS INC.

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

NOVA HEALTH SYSTEMS INC. shall assess and prepare all documentation required for manufacture testing approval packaging and release

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NOVA HEALTH SYSTEMS INC. 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 third parties toViamed prior to Supply to NOVA HEALTH SYSTEMS INC.

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 NOVA HEALTH SYSTEMS INC. 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 NOVA HEALTH SYSTEMS INC. 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 NOVA HEALTH SYSTEMS INC. 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 **NOVA HEALTH SYSTEMS INC.** remains liable for the supply of articles which comply with written specifications

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

7. TESTS

NOVA HEALTH SYSTEMS INC. shall perform tests in accordance with paragraph 3 hereof and protocols shall be kept showing that processes and tests were performed by NOVA HEALTH SYSTEMS INC. in accordance with the documentation referred to in paragraph 3 hereof NOVA HEALTH SYSTEMS INC. 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

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8. DELIVERIES RELEASE AND CERTIFICATES

Prior to delivery NOVA HEALTH SYSTEMS INC. 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 4.2.4 Control of records and 8.2.4 " Monitoring and measurement of processes and product",~~

NOVA HEALTH SYSTEMS INC. 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

NOVA HEALTH SYSTEMS INC. 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

NOVA HEALTH SYSTEMS INC. shall file all documents as detailed in this Agreement under paragraphs,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 NOVA HEALTH SYSTEMS INC. 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 NOVA HEALTH SYSTEMS INC. or a sub-contractor of NOVA HEALTH SYSTEMS INC.

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 NOVA HEALTH SYSTEMS INC. and Viamed such information being the basis for the introduction of requisite improvements to ensure that safety risks operational and production disruptions never occur

NOVA HEALTH SYSTEMS INC. must immediately advise Viamed in writing in respect of any technical problems and suspected defects in articles which NOVA HEALTH SYSTEMS INC. has already delivered to Viamed

NOVA HEALTH SYSTEMS INC. must in such cases ensure that sub-contractors provide supporting information

Viamed must immediately advise NOVA HEALTH SYSTEMS INC. 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 NOVA HEALTH SYSTEMS INC.~~ 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"

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NOVA HEALTH SYSTEMS INC. 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

vi. In no event will supplier be liable to the purchaser for any special, incidental, punitive or consequential damages (including loss of use, data, business or profits) or for the cost of procuring substitute products or solution, arising out of or in connection with this agreement, whether such liability arises from any claim based upon contract, warranty, tort (including negligence), strict liability or otherwise, and whether or not the applicable party has been advised of the possibility of such loss or damage. In no event shall the supplier's total aggregate liability under this agreement exceed the purchase price paid by purchaser hereunder.

vii. This agreement shall be governed and construed in accordance with the laws of the United States of America and the State of New York without giving effect to its rules regarding conflicts of laws. Any lawsuit initiated by either party based upon this Agreement shall be initiated only in a court in New York State of the United States of America.

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 NOVA HEALTH SYSTEMS INC. : **Wade Abraham**
Tel: 315-798-9018
Fax: 315-798-9337

SIGNED ON BEHALF OF VIAMED LIMITED:

Name :

Position : President

SIGNED ON BEHALF OF NOVA HEALTH SYSTEMS INC.

Name :

Position : Managing Director