Quality Agreement

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1. Parties

The following quality agreement has been reached between Viamed Ltd. hereinafter referred to as Viamed and XXXXXX , hereinafter referred to as the SUPPLIER

2. Purpose

The purpose of this agreement is to ensure that

0. Development, design, manufacturing, testing, packaging, approval release and delivery are in accordance with the quality assurance measures specified in this agreement;
1. Only fault-free articles, according to written specifications and this agreement are supplied,
2. The intended operating reliability is achieved even after delivery.
3. This agreement assumes mutual trust and responsible behaviour by both parties. A general policy is that neither party shall take advantage of any situations arising during the agreement's period of validity.

3. Application and responsibility

The agreement covers all the articles manufactured and supplied by The SUPPLIER according to Viamed's orders. The SUPPLIER shall be responsible to Viamed for all its sub-contractors on the same terms stipulated in this agreement for The SUPPLIER itself . This will be the case irrespective of whether Viamed has approved a sub-contractor and irrespective of whether Viamed has demanded that purchases be made from a particular supplier.

4. Quality control system

The SUPPLIER must have an introduced efficient quality control system which complies in respect with the stipulation in the current ISO 9001 and EN 46001 and which has been third party-certified and approved by a certifying body, notified in the EU, or have already started a process to introduce ISO 9001/9002 and have achieved compliance within the next 12 months. Compliance with quality system requirements must exist each time an article is manufactured, tested, packaged and released.

5. Development/Design

The SUPPLIER shall be responsible for and pursue development/design work so only fault-free articles are supplied according to written specifications. Design shall be verified against functional specifications. Written documents must be prepared for this purpose and cover both the method and measurement results The documents are to be kept on file according to paragraph 13.

6. Manufacturing documentation

The SUPPLIER shall assess and prepare all documentation required for manufacture, testing, approval, packaging and release so that fault-free articles are supplied according to the written specifications for the respective article. The SUPPLIER shall keep all submitted documentation on file according to paragraph 13.

7 . Manufacturing materials and manufacturing components

The SUPPLIER shall be responsible for the purchase and arrival tests of materials and components. The materials and components must comply with specifications.

8. Manufacturing and process validation

All manufacturing processes are to be validated, and the method and results are to be documented. The documents must be kept according to paragraph 13.

For the assembly of parts of articles The SUPPLIER may only use sub-contractors which have an introduced efficient quality control; system which complies with stipulations in ISO 9001 or 9002 or have already started a process to introduce ISO 9001/9002 and which have planned to comply with the stipulations within the next 12 months. "Assembly" refers to the pre-delivery assembly by the subcontractor of multiple components or manufacturing according to drawings instructions.

Manufacturing of pre-production samples shall be according to paragraph 9.

Series production of new articles and articles after revisions must be started according to paragraph 9 and parts of articles performed by the same sub-contractors which made these parts of the pre-production samples Series production may not employ any other specifications for material, process, measurement equipment, tools or quality control than those approved for manufacturing by Viamed in writing according to paragraph 9.

9. New articles and revisions

Before the manufacturing of new articles starts. Pre-production Samples will then be manufactured performed in validated processes according to these approved documents, The pre-production samples must be checked and approved in writing by Viamed. This written approval by Viamed accordingly documents production quality and series production of a new article may then commence.

If The SUPPLIER plans to make a change, e.g. to use some other material or alter drawings or the production process which leads to a change in the written specification, Viamed must be informed in writing as soon as possible. These changes in written specification of the article must be accepted in writing by Viamed. They may. then be introduced, and previously issued documents must be replaced before the revised production of pre-production samples starts in (a possibly altered) validated processes.

The pre-production samples must be checked and approved in writing by Viamed. This approval by Viamed accordingly documents revised production quality, and series production may start according to the revision.

The SUPPLIER shall perform control measurements of pre-production samples and supply measurement protocols to Viamed showing measurement results confirming The SUPPLIER,s view that submitted pre-production samples are in compliance with the

written specifications.

However, Viamed may inform The SUPPLIER in writing that series production may start at once without the production of preceding pre-production samples.

Pre-production Samples approved by Viamed, or information designating that series production may start without preceding pre-production samples, do not release The SUPPLIER from responsibility for ensuring that supplied articles comply with the specifications.

The aforementioned written information; documentation prepared by The SUPPLIER; protocols and Viamed's written approvals shall be kept on file by The SUPPLIER according to paragraph 13.

10. Tests

The SUPPLIER shall perform tests according to paragraph 6. Protocols shall be kept showing that processes and tests were performed by The SUPPLIER. according to the documentation described in paragraph 6. The protocols are to be kept on file according to paragraph 13.

The SUPPLIER must also perform quality control to identify any discrepancies and defects. Each discrepancy and defect must immediately cause steps to be taken, especially when discrepancies/defects are discovered in final inspection. Discrepant/defective or suspicious parts of any batch must be separated from the rest of the batch in an effective manner.

11. Deliveries, release and certificates

Prior to delivery, The SUPPLIER must approve and release articles. Release shall be based on the results of documented, approved tests of materials/components and on tests performed during the manufacturing process up to final inspection, including pre-packaging with markings and contents and according to ISO 9001, Paragraph 4.10.4 "Final inspection and testing"'.

The SUPPLIER shall be responsible for ensuring that supplied articles comply with the specifications and stipulate that this is the case in certificates accompanying deliveries (certificate contents are specified in the Appendix)

12. Traceability

ThE SUPPLIER shall ensure traceability between received materials/components, and quality documents on file for articles delivered to Viamed.

13. Filing quality control documents

THE SUPPLIER shall file all documents covered by this agreement's points 5, 6, 8, 9, 10, 11

and 15, as well as according to ISO 9001, paragraph 4.10.5 "inspection and Test Records" paragraph 4.16 'Control of Quality Records".

if and when Viamed requests any final test document on file, citing serial/batch numbers of articles delivered to Viamed, copies of such documents must be retrievable and supplied to Viamed.

Documents must be kept on file for 5 years (11yrs for UK) after issuance.

14. Audits

After reasonable notice, Viamed shall (under normal working hours) have the right to visit The SUPPLIER and if possible also any of the suppliers's assembly sub-contractors according to paragraph 8 which have not been third party-certified and approved by a certifying body notified in the EU, to carry. out a quality audit and check processes and documents on file.

This right of access shall also be ensured when Viamed is the subject of some public agency's inspection and the agency demands to inspect The SUPPLIER or a sub-contractor of The SUPPLIER

15. Quality Information

The continuous exchange of quality information between The SUPPLIER and Viamed is important. This information is the basis for the introduction of requisite improvements in so timely a fashion that safety risks, operational disruptions or production disruptions never occur.

The SUPPLIER must as soon as possible advise Viamed in writing about any technical problems and suspected discrepancies and defects in articles which The SUPPLIER has already delivered to Viamed. The SUPPLIER must ensure that its sub-contractors provide it with the corresponding information.

Viamed must immediately advise The SUPPLIER in writing of any corresponding discoveries.
Discrepant articles for which Viamed submits claims or returns will be processed as complaints. Both Viamed and The SUPPLIER shall process complaints according to ISO9001, paragraph 4.14.2. The SUPPLIER must always, and without delay, advise Viamed in writing of

0. the cause of the discrepancy
1. the steps taken to prevent repetition of the discrepancy in future
2. an analysis of the risk of patient injury and functional disruption
3. other information requested by Viamed in any complaint matter.
4. The parties agree to inform each other about anything else with an impact on quality', quality control or understandings according to this agreement, including major changes in staff and organisation.
5. If quality information is addressed to any person other than the respective contract person (see paragraph 16), a copy of this information must always be sent to that contact person.

16. Validity and contact persons

If either party wishes to make a change in the agreement, these changes will be made by mutual consent and a new agreement issued;

The parties have appointed the following people as contact persons for dealing with technical matters or specific articles according to this agreement:

For Viamed: **Tel: 49(0)3841-703232**

Fax: 49(0)3841-703234

For THE SUPPLIER **Tels**

Fax:

This agreement has been issued in duplicate, one copy supplied to each party-

Viamed-
Date.....

THE SUPPLIER
Date.....

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.

0. Certificates must contain the following information, where applicable:
1. The supplier's company name
2. Text certifying that all delivered articles comply with all the written specifications of the article.
3. Viamed's order number.
4. Viamed's article designation and article number.
5. The number of approved units
6. The date the certificate was issued.
7. A signature, name, tel. no., fax no., and department of the person responsible for ensuring that certificate information is correct.
8. A signature, name, tel. no., fax no-, and department of the person responsible for releasing the articles.
9. Deliveries without an accompanying certificate will be deemed discrepant/defective. This will also be the case for deliveries containing discrepant/defective articles which were verbally "approved" by some Viamed employee. Any "approval" by Viamed must be in writing, and a copy of same must in such instances accompany the certificate with the discrepancy/defect specified.

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