VIAMED

Viamed Limited - 15 Station Road - Cross Hills
Keighley -West Yorkshire BD20 7DT - United Kingdom
Tel: +44 1535 634542 Fax: +44 1535 635582
Email: info@viamed.co.uk Website: www.viamed.co.uk

Supplier Audit Checklist

Company: **Envitec Wismar GmbH**
Address: **Alter Holzhafen 18, Wismar 23966, Germany**
Products: **Oxygen Sensors (Medical & Automotive)**
Quality Engineer: **Sheehan Soans – Envitec Wismar GmbH**
Auditor: **Steve Nixon – Viamed Ltd. & Vandagraph Sensor Technologies Ltd.**
Date: **12th April 2018**

Item	Subsystem / Assessment Detail	Auditor Notes	Auditor Observation	Objective Evidence	Findings
Management Controls (main subsystem)					
1	Ensure that the quality manual defines scope of QMS, procedures (or reference to) within QMS, and description of the interaction of processes within QMS.	Review quality manual; review QMS metrics; review critical processes and procedures.	Quality manual reviewed.	200-19-QMH-9	A
2	Verify that criteria and methods are in place to monitor and control processes for effectiveness.	Review QMS metrics; review management reviews.	Documents reviewed.	1. 200-19-QMH-9 2. Managementreview_FY_2016	A
3	Verify that the company has established and conducts management reviews, at least annually.	Request procedure in advance; review management reviews.	Reviewed for FY 2016.	Managementreview_FY_2016	A
4	Confirm management reviews examine suitability and effectiveness of quality systems, improvements needed because of customer requirements, and resource needs.	Review procedure.	Quality manual reviewed.	200-19-QMH-9	A
5	Ensure management review addresses audit results, customer feedback, process performance, CAPAs, previous management reviews, changes to QMS, recommendations for improvement, and new or revised regulatory requirements.	Review management reviews.	Quality manual reviewed.	200-19-QMH-9	A

VIAMED

Viamed Limited - 5 Station Road - Cross Hills
Keighley -West Yorkshire BD20 7DT - United Kingdom
Tel: +44 1535 634542 Fax: +44 1535 635582
Email: info@viamed.co.uk Website: www.viamed.co.uk

6	Verify that the company has established a Quality Manual and Quality System Procedures and Instructions that are appropriate.	Request quality manual and procedures in advance; review documents.	Quality manual reviewed.	200-19-QMH-9	A
7	Verify that the company has an established quality plan.	Request quality plan in advance.	Goals reviewed.	Quality Goal 2017	A
8	Verify that the company has established quality audit procedures and conducts audits.	Request procedure in advance, review audit schedule and documents; review auditor training.	Audit plan 2018 reviewed.	Auditplan_2018_Rev0_20180202	A
9	Ensure that quality audits examine compliance and effectiveness.	Review procedure; review audit records.	Audit plan 2018 reviewed.	Auditplan_2018_Rev0_20180202	A
10	Confirm quality audits are linked to CAPA.	Review procedures.	Audit procedure.	200-20-Interne_Audits-2	A
11	Review organizational structure of firm; confirm resources are available to support processes.	Request organizational chart(s) in advance.	Organizational chart reviewed.	200-10-Orgchart-21_20170601	A
Design & Development / Design Controls (main subsystem)					
Corrective & Preventive Actions (CAPA) (main subsystem)					
1	Verify CAPA procedures comply with regulatory requirements.	Review procedures.	Procedure reviewed: O.K.	200-20-Korrektur-_und_Vorbeugemasnahmen-9	A
2	Verify non-conforming product and CAPA procedures determine the need for investigation and notification.	Review procedures.	Procedure reviewed: O.K.	200-20-Korrektur-_und_Vorbeugemasnahmen-9	A
3	Verify non-conforming product and CAPA procedures define responsibilities for review and disposition.	Review procedures.	Procedure reviewed: O.K.	200-20-Korrektur-_und_Vorbeugemasnahmen-9	A
4	Determine if trend analysis data indicates quality problems; determine if data used for CAPA decisions.	Review procedures; review records of incoming products, components, testing, SPC data.	Procedure reviewed: O.K.	200-20-Korrektur-_und_Vorbeugemasnahmen-9	A
5	Verify device failure investigations determine root cause.	Review procedures; review investigations.	Procedure reviewed: O.K.	200-20-Korrektur-_und_Vorbeugemasnahmen-9	A
6	Verify failure investigations are commensurate with risks.	Review procedures; review investigations.	Procedure reviewed: O.K.	200-20-Korrektur-_und_Vorbeugemasnahmen-9	A

VIAMED

Viamed Limited - 15 Station Road - Cross Hills
Keighley -West Yorkshire BD20 7DT - United Kingdom
Tel: +44 1535 634542 Fax: +44 1535 635582
Email: info@viamed.co.uk Website: www.viamed.co.uk

7	Verify controls exist to prevent non-conforming product from being released.	Review investigations; review non-conformance records.	Procedure reviewed: O.K.	200-20-Korrektur-_und_Vorbeugemassnahmen-11	A
8	Verify appropriate actions were taken for quality problems.	Review procedure; review CAPA records.	Procedure reviewed: O.K.	200-20-Korrektur-_und_Vorbeugemassnahmen-11	A
9	Determine CAPA actions were effective, verified, validated, documented, and implemented appropriately.	Review procedure; review CAPA records.	Procedure reviewed: O.K.	200-20-Korrektur-_und_Vorbeugemassnahmen-11	A
10	Verify quality issues and CAPAs were disseminated for management review.	Review procedure; review CAPA records.	Reviewed for FY 2016	Managementreview_FY_2016	A
11	Verify that the company has procedures for handling complaints and investigation of advisory notices / recalls; ensure provisions exist to feed into CAPA system.	Review procedures.	Procedure reviewed: O.K.	200-20-Service-4	A
Medical Device Reporting (MDR)					
Reports of Corrections & Removals (C&R)					
Medical Device Tracking					
Production & Process Controls (main subsystem) (P&PC)					
1	Ensure that the company maintains procedures and records for traceability of each unit, lot, or batch of finished devices and components. NOTE: may not be required for all devices.	Review procedures; review DHRs.	Incoming inspection of complete production process of oxygen sensors was carried out.	Delivery note and final inspection data is sent to Viamed via Email	A
2	Select a process to review.	Selection criteria: -CAPA indicators of process issues -process for higher risk device -degree of risk for process to cause device failures -lack of familiarity and experience with process -process used for multiple devices -variety in process technologies -processes not covered during previous inspections.	Oxygens sensor production.	Incoming Inspection data sheet for Article 1002478 and 01-004327 was reviewed and found to be in compliance. **Inspection of complete production process of oxygen sensors was carried out.**	A

VIAMED

Viamed Limited - 15 Station Road - Cross Hills
Keighley -West Yorkshire BD20 7DT - United Kingdom
Tel: +44 1535 634542 Fax: +44 1535 635582
Email: info@viamed.co.uk Website: www.viamed.co.uk

3	Confirm receiving, in-process, and final acceptance activity records exist.	Review records.	Incoming Inspection data sheet for Article 1002478 and 01-004327 was reviewed and found to be in compliance.	Delivery note and final inspection data is sent to Viamed via Email.	A
Sterilization Process Controls					
1	Review sterilization process procedures; verify sterilization process is validated.	Review procedures; review validation records to ensure processes are effective in: -obtaining SAL -product performance not adversely affected -packaging not adversely affected.	N/A	Non-sterile Products	A
2	Review sterilization control and monitoring activities; ensure processes, equipment, and calibration are current.	Review validation records.	N/A	Non-sterile Products	A
3	Review DHR for sterilization failures; ensure integration with CAPA system.	Review validation records.	N/A	Non-sterile Products	A
4	Ensure sterilization failures were handled properly.	Review sterilization records; review equipment adjustment, calibration, and maintenance.	N/A	Non-sterile Products	A
5	Review personnel records to document personnel are qualified and trained with implemented sterilization activities.	Review validation records.	N/A	Non-sterile Products	A
6	Ensure automated or software driven sterilization processes are controlled and validated.	Review validation records.	N/A	Non-sterile Products	A
Purchasing Controls (main subsystem for virtual manufacturers)					
1	Review supplier evaluation procedures.	Review procedures.	Procedure Reviewed: O.K.	200-20-Einkauf-7	A
2	Ensure suppliers are evaluated for ability to meet specified requirements.	Review procedures	Procedure Reviewed: O.K.	200-20-Einkauf-8	A

VIAMED

Viamed Limited - 15 Station Road - Cross Hills
Keighley -West Yorkshire BD20 7DT - United Kingdom
Tel: +44 1535 634542 Fax: +44 1535 635582
Email: info@viamed.co.uk Website: www.viamed.co.uk

3	Ensure adequacy of specifications of materials and/or services provided by supplier is confirmed	Review procedures	Procedure Reviewed: O.K.	200-20-Einkauf-9	**A**
4	Confirm purchasing information identifies requirements for approval of product, procedures, processes, and equipment, requirements for personnel qualification, and QMS requirements.	Review procedures	Procedure Reviewed: O.K.	200-20-Einkauf-10	**A**
Documentation & Records					
Customer Requirements					
1	Confirm incoming contracts and orders are reviewed to resolve conflicting information and that customer requirements can be met.	Review procedures; review incoming inspection records.	Data sheet for article 1002478 and 01-004327	Incoming inspection data sheet for article 1002478 and 01-004327 was reviewed and found to be in compliance.	**A**
2	Verify that procedures and systems exist for customer communications and feedback; ensure integration with CAPA system.	Review procedures.	Procedure Reviewed: O.K.	200-20-Korrektur-_und_Vorbeugemassnahmen-11	**A**

NC = Non-Conformance
OFI = Opportunity for Improvement
PP = Positive Practice
A = **Acceptable**

Signed:

Name: **Sheehan Soans**
Position: **Quality Engineer – Envitec Wismar GmbH**
Date: **17th April 2018**

Signed:

Name: **Steve Nixon**
Position: **Director – Viamed Ltd. & Vandagraph Sensor Technologies Ltd.**
Date: **16th April 2018**

VIAMED Company registered in England Company Registration Number 01291765
Vandagraph Sensor Technologies Company registered in England Company Registration Number 03116422