Assessment Report.

Teledyne Analytical Instruments a business unit of Teledyne Instruments, Inc.

Report Author **Jeffrey Tuthill**

Visit Start Date 01/13/2015

Introduction.

This report has been compiled by Jeffrey Tuthill and relates to the assessment activity detailed below:

Visit Ref/Type/Date/Duration	Certificate/Standard	Site address
8085903 Re-certification Audit (RA Opt 2) 01/13/2015 3 Day(s) No. Employees: 65	FM 75659 ISO 13485:2003 CE 02000 Healthcare 93/42/EEC Annex II, Sec 3.2 (2007/47) CE MARKING Stuart Corner	Teledyne Analytical Instruments a business unit of Teledyne Instruments, Inc. 16830 Chestnut Street City of Industry California 91748-1020 USA

Client management system version(s):

Quality System Manual CP-100, Rev 18 / 2014-06-24

To conduct a recertification assessment to determine the continued effective implementation of the company's management system, in accordance with the management standard & BSI Conditions of Contract, to determine whether a recommendation for continuing certification can be made.

To verify Teledyne Analytical Instruments, a business unit of Teledyne Instruments, Inc. (Company ID No. 110223) continues to implement all requirements of ISO 13485:2003 and the most current version of Part 1 of the Canadian Medical Device Regulations. GD210 will be used.

To verify that the management system continues to meet the requirements of 93/42/EEC Annex II 3.2 (M5).

Management Summary.

Overall Conclusion

The objectives of this assessment have been achieved.

I would like to thank all the audit participants for their assistance and co-operation which enabled the audit to run smoothly and to schedule.

Based on the objective evidence detailed within this report, the areas assessed during the course of the visit were found to be effective.

This report is eligible for submission to FDA under FDA ISO 13485 Voluntary Audit Report Submission Program. The organization is intending to submit this report to the FDA under FDA ISO 13485 Voluntary Audit Report Submission Program.

There were no obstacles encountered during the course of the audit. No factors were encountered during the audit that would affect the reliability of this assessment. All areas were covered per the assessment plan.

Audit report authors are per the assessment team listed. The report was finalized and issued on 18-Jan-2015.

There were no outstanding nonconformities to review from previous assessments.

No new nonconformities were identified during the assessment. Enhanced detail relating to the overall assessment findings is contained within subsequent sections of the report.

Mandatory Requirements – Re-Certification.

Review of assessment finding regarding conformity, effectiveness and relevance of the management system:

The organization's management system has been operated and maintained exceptionally well with no nonconformities raised over the entire certification cycle. An excellent job!

Management system strategy and objectives:

To maintain a robust management system with few or no nonconformities to drive a profitable analytical instrumentation manufacturing business.

Review of progress in relation to the organisation's objectives:

Review of the management system occurs annually addressing quality objectives and the quality policy.

Review of assessment progress and the re-certification plan:

The audit duration is reduced by 15% as the Client demonstrates preparedness for certification (eg. Client holds certification with other 3rd party). This has changed what was previously established as the audit duration with 65 employees the surveillance audit = 1.5 days and the recertification audit = 3 days.

BSI Client Management Impartiality and Surveillance Strategy:

Brian Nguyen has performed the previous two continuous surveillance audits and Jeff Tuthill performed this recertification audit. Both auditors have the required P codes and T codes.

Do you want the current Total assessment days / Cycle to continue ?

No

The audit duration is reduced by 15% as the Client demonstrates preparedness for certification (eg. Client holds certification with other 3rd party). This has changed what was previously established as the audit duration with 65 employees the surveillance audit = 1.5 days and the recertification audit = 3 days.

Justified Exclusions

There are no justified exclusions of the standard for certificate : FM 75659

There are no justified exclusions of the standard for certificate : CE 02000

Areas Assessed & Findings.

Opening meeting / QMS, organization changes / Quality manual : 4

The opening meeting was conducted with the presence of the VP/GM, staff members and the Management Representative.

The registration certificates and scope of the registration were confirmed.

The assessment plan, objectives and scope of the assessment were confirmed.

The assessment was performed in English.

Audit Scope:
This visit will cover the location activities for the management system processes at:
16830 Chestnut Street, City of Industry, California, 91748-1020, USA

Scope of Certification:
The registration certificates and scope of the registration were confirmed as follows:
The design and manufacture of oxygen monitors and sensors.

Quality Manual version: Quality Manual CP100, Revision 18, 2014-06-24
Exclusions and Non-Applications of Requirements in the QMS:
7.5.1.2.1 Cleanliness of product and contamination control since the product is not sterile
7.5.1.2.2 Installation activities
7.5.1.3 Particular requirements for sterile medical devices
7.5.2.2 Particular requirements for sterile medical devices
7.5.3.2.2 and 8.2.4.2 Particular requirements for active implantable medical devices and implantable medical devices.

Significant Changes:
1) There have not been any major or significant changes to the QMS, structure, or device.
2) There have been no significant changes and regulatory notifications for over the certification cycle.

Adverse Incidents, Field Safety Corrective Actions and Recalls:
There have been no adverse incidents, recalls, or requirement for field safety corrective actions or mandatory problem reports.

Corporate Identity of the Manufacturer:
(information obtained from http://www.teledyneinstruments.com/profile.asp as of 2-20-2014)
Teledyne Instruments is a group of business units with expertise in monitoring, process control and precision measurement instrumentation.

Corporate Headquarters (information obtained from http://www.tet.com/inquiries.asp)
1049 Camino Dos Rios, Thousand Oaks, CA 91360, USA
805-373-4545

Description of the manufacturer:
(information obtained from http://www.teledyne-ai.com/profile.asp as of 2-20-2014)
Teledyne Analytical Instruments is a world leader in the design and manufacturing of high quality gas and liquid analyzers. With over 50 years of experience, Teledyne's product line includes electrochemical sensors, analyzers, and custom systems which combine expertise in electronics, chemistry and engineering. TAI provides scientific solutions for chemical analysis problems.

Critical Subcontractors:
Authorized European Representative:
Viamed, Ltd.
15 Station Road, Cross Hills
Kieghley, West Yorkshire BD20 7DT
United Kingdom, Tel: +44 (0) 1535 634542
Senior Management of the Assessment Location(s).
Mr. Thomas Compas, VP/General Manager

Dates of the Audit:
January 13-15, 2015

Other certificates / registrations:
1) ISO 9001:2008 certificate number 96-653i issued by Intertek with an expiry date of September 8, 2014
2) FDA registration number 2026424
3) FDB certificate number 60335

Management responsibility (interview with Sr. Manager on site) / Quality policy / Quality objectives : 5

Contact(s): Tom Compas - VP/GM; Vasu Narasihmhan - Director, Operations / Management Representative; Roger Starlin - QA Manager.
Document(s): Quality System Manual CP-100, Rev 18.

Interviewed the VP/GM regarding management commitment and management responsibility. The following issues were addressed;
a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, (Specified communication through management reviews, monthly staff meetings, all hands meetings every quarter.)
b) establishing the quality policy, (The quality policy is in the quality system manual, posted in the facility, all employees are trained on the quality policy and it is discussed at management review meetings.)

c) ensuring that quality objectives are established, (Discussed at management review meetings. Five quality objectives are established with measurable goals as KPIs.)
d) conducting management reviews, and (Management reviews are held once a year on-site.)
e) ensuring the availability of resources. (Resource needs are discussed at management review meetings and at staff meetings. Discussing resource is a continual process at the organization.). Based on the VP/GM's responses to the above questions, it was determined that he is committed to the success of the QMS.

Responsibility, authority, and communication is defined in section 5.5 of the quality manual. Analysis of data is defined in section 8.4 of the quality manual. The organizational chart was reviewed. The Ops Director has been designated as the Management Representative as documented in section 5.5.2 of the quality manual. The management review is now conducted once a year. The management review records dated 5/8/2014 were reviewed and the evidences of quality system planning, customer focus, feedback, provision of resource, and the following data analysis / process measurement were noted:
- Management System: 1) Management Commitment, 2) Effectiveness of company policy and objectives, 3) Internal communications; - Operational Performance: 4) Customer delivery performance, 5) Inventory turns, 6) Linear shipment, 7) Supplier performance (non-medical), 8) Materials Management; - Customer Service: 9) Product Field Return Activity, 10) Trends and actions; - Resource Management: 11) Competency of personnel, 12) Plan to fill identified competency gaps, 13) Employee engagement; - Quality Management System: 14) Audit program, 15) CA status, 16) Certified Product Status / Issues;
- Product Performances: 17) poNC (percentage of Nonconformance for scrap, rework, warranty), 18) Sensor Yield, 19) Instrument Yield & Moving Average. There has been no change to the quality policy since the last BSI visit. The quality objectives are measurable and consistent with the quality policy.
Conclusions:
Top Management has demonstrated its commitment to quality management throughout its planning and review activities. These activities are judged to be in compliance with clause 5 of ISO 13485:2003. The management review process appeared to be effective and in compliance with clause 5.6 of ISO 13485:2003.

Internal audit : 8.2.2

Contact(s): Roger Starlin - QA Manager.
Document(s): Internal Quality Audits - QA 417, Rev 22
Record(s): Year 2014 Internal / External Audit Schedule.

The organization utilizes internal resources to conduct internal audits. There were five trained internal auditors to support the internal audit 2014 schedule. All planned audits for 2014 were completed. All five auditors have received external training for internal auditor per the QA Manager. Verified the QA Manager's training for ISO 9001 Internal Auditing, completed March 2-3, 2000. Course provided by Alliance for International Management Systems. Sampled the internal audit report of the areas of QMS, clauses 7.1 - 7.3 (12/8/14 by RS), with no Findings noted. Sampled the internal audit report of the areas of QMS, clauses 8.2.1, 8.5.1, 8.3, 8.5.2, 8.5.3 (12/19/14 by VN), with no Findings noted.

Conclusions:
The internal audit process was noted to be effective and in compliance with the ISO 13485:2003 clause stated above.

Feedback / Customer complaints / MPR / Vigilance / Advisory notices (Recalls) / CARs / PARs : 8.2.1, 8.5.1, 8.5.2, 8.5.3

Contact(s): Roger Starlin - QA Manager.
Document(s):Customer Communication - CS 400, Rev 12; Medical Product Complaint Handling And Medical Device Reporting - CP 207, Rev 21; Product Recall - CP223, Rev 5; Medical Product Failure Analysis - CP245, Rev 0; Customer Repair Processing TD 403, Rev 16; Corrective / Preventive Action QA 421, Rev 10.

CS 400 addresses feedback criteria and Customer Service represents customer feedback status at the management review meetings. Since the BSI visit in February of 2013, there has been no MDR, no vigilance report, no MPR, no product recall, and no advisory notice. Complaints on the medical device for 2014 totaled twelve with none of them requiring a CAR, or PAR to be issued. The last complaint issued was examined; CCR #2738-14, received 10/14/4, closed 12/19/14 with no CAR justification and authorized.
The complaint handling and feedback processes were noted to be effective and in compliance respectively with the ISO 13485:2003 clauses stated above.

The CAR & PAR numbers 302 and 303 were selected and reviewed. CAR 302 was initiated 7/28/14, implemented 7/29/14 and the EC target 9/9/15. PAR 303 was initiated 7/21/14 and was implemented and verified 10/2/14.
Based on the objective evidence the CAR/PAR process is deemed to be effective.

Control of monitoring and measuring devices / Infrastructure (preventive maintenance, data system backup) / Work environment (PPE) : 7.6, 6.3, 6.4

Contact(s): Roger Starlin - QA Manager; Pamfilo Rongavilla - Machine Shop Supervisor; Daniel Lopez - Production Supervisor.
Document(s):Calibration Program - QA 412, Rev 11; Machine Shop Maintenance - MS 401, Rev 6; Sensor Department Monthly Maintenance - SD 401, Rev 2; Production Floor Equipment Maintenance - PD 401, Rev 4; BACKUP AND RECOVERY MANAGEMENT, Rev 8/08/05; Handling of Electrostatic Sensitive Devices - CP 233, Rev 6.

Calibration is a service provided by two outside metrology labs; Cal Lab Inc. dba CLI Metrology for meters, calipers, etc. and Pennoyer-Dodge for gages. All calibration / test fixture validation data is maintained electronically on ACCESS database, which shows currently 308 measuring instruments in the calibration system. The following calibration certificates were randomly sampled from the records.
(1) DMM #CC05887 - cal due: 4/15/15, calibrated by CLI Metrology with NIST traceability specified on the certificate.
(2) O-Scope #CC05842 - cal due: 5/30/15, calibrated by CLI Metrology with NIST traceability specified on the certificate.
(3) Signal Gen. #636716 - cal due: 5/19/15, calibrated by CLI Metrology with NIST traceability specified on the certificate.
(4) Ring Gage #2611-137 - cal due: 5/22/15, calibrated by Pennoyer-Dodge with NIST traceability specified on the certificate.
(5) Plug Gage #CC09010 - cal due: 12/17/15, calibrated by Pennoyer-Dodge with NIST traceability specified on the certificate.

Preventive maintenance in the Machine Shop was verified for the 31 milling and cutting machines. The weekly maintenance report (1/5/15 to 1/9/15) was examined and it was noted that maintenance was recorded on all 31 machines in the shop. The preventive maintenance frequency and cycles are specified in procedure MS 401.
Preventive maintenance was verified in the Sensor Department. Per SD 401 monthly maintenance is performed on various process machines in the Sensor area. Sampled Monthly Maintenance Logs, dated 11-10-14 and 12-4-14, and noted that preventive maintenance was recorded for all required process equipment in both logs. Example: Sealing Machine SEN #246, verified in both the 11-10-14 and the 12-4-14 logs.
Interviewed the IT personnel and determined that data system backup is routinely performed on the computer servers in accordance with BACKUP AND RECOVERY MANAGEMENT, Rev 8/08/05.

Work environment is controlled in Production areas where PPE is required. PCB assembly area requires ESD protection per CP 233. The ESD Smocks, Grounded Wrist Straps and/or Heal straps are required to be worn in the area. ESD Testing Wrist & Heal Strap Log was completed daily and maintained at the ESD testing station. Safety glasses are required to be worn in the Machine Shop and Sensor Department. Safety glasses and signage requiring their use is posted at the entrances of both areas.

Based on the objective evidence these processes are deemed to be effective.

Production provisions: activities and related processes - sensors, instruments and PCB's - medical devices / Identification and traceability / Label control / Inspection / Testing / DHR review : 6.3, 6.4, 7.5.1.1, 7.5.3, 8.2.4

Contact(s): Roger Starlin - QA Manager; Pamfilo Rongavilla - Machine Shop Supervisor; Daniel Lopez - Production Supervisor (Sensors); Raymond Garcia - Assembler; Estela Rivas - Assembler; Nary Keo - Assembly; Donna Werremeyer - QA; Steve Aguilar - Supervisor (PCB); Eric Calderon - Buyer/Planner; Cheryl Noennick - Buyer/Planner; Lupe Montenegro - Production Lead
Document(s): Machine Shop Operating Procedure - MS 400, Rev 6; Operational Routings - MS 402, Rev 5; Machine Shop Quality Control - QA 402, Rev 5; Sensor Department Operating Procedure - SD 400, Rev 10; Production Floor Operating Procedure - PD 400, Rev 10; Product Identification and Traceability - CP 229, Rev 6; Instrument Production Line In-Process Inspection Product Assurance - QA 404, Rev 7; QA Final Inspection - QA 405, Rev 10.

Machine Shop: Toured the Machine Shop with the Supervisor. The Machine Shop performs custom jobs with small quantities and is equipped with 31 milling, lathes and stamping machines that are maintained on preventive maintenance schedules. Machine jobs are completed against Job Cards, which are issued by planning. An active job was examined in the Machine Shop during the audit. Job Card - WO #0103903, PN D90904, Start Qty. = 1 pc., 19" Panel Detail. Job ops are as follows: (1) Punch on Machine FC 1000II, (2) De-burr on Belt Sander 1-13-15, (3) Final inspection 1-14-15 - visual and dimensional using calibrated calipers 584809-4, cal due: 3/10/15 and caliper 584827-3, cal due: 7/16/15.

Sensor Department: Toured the Sensor Department with the Production Supervisor. Sensor assembly consists of approximately 6 tasks across dry and wet operations. The dry operation consists of press fitting cylinders and 5 Assemblers were working in dry assembly at the time of the audit. Sampled Router WO 0102657, PN C41131M, Qty: 800. Approximately 300-400 are completed per day in Dry Operations. Wet Operations consist of Sintering, Expansion, Filling, Closing and Sealing. A 100% leak test is performed on the sealed Sensors per TP-48785, Rev 16, entitled "Leak Testing Sensors That Contain Potassium Hydroxide (KOH) Electrolyte. The treated Sensors are set in a bath of phenolphthalein solution overnight and any leaking Sensors are scrapped. Sampled Job PN A5, WO 0110158, Qty 70 in leak testing. Verified Maintenance Logs 11-10-14 and 12-4-14 for Sintering Machine and one of the Sealing Machines SEN #246. Examined the labeling process and control for Sensors utilizing Zebra Printers and Legitronic Labeling Software, Version 3.73.2031. All labels are printed from drawings and completed label jobs are logged into Sensor Department - Label Information Checklist and all entries are verified by QA stamp-off. Last entry in Checklist; Date Code: A5, Cell Class: B3C, Qty: 7, Dwg: A-10084H, SN Sequence: 503840 - 503846, Bag Label Dwg. A-46130A. A Router in Final Inspection was sampled W/O 0095243, PN C57283GEN, Qty: 150.

PCB Assembly: Toured the PCB Assembly area with the Production Supervisor. There was no production of pcb assemblies for the AX/MX 300 (Medical Device) at the time of the audit. Interviewed the Buyer/Planners and the Production Lead. Jobs are planned and kitted by the Buyer/Planner and the kits are assembled and inspected, and sent to stock for further assembly in finished product. Per the Supervisor PCB kits are 80% SMT and 20% Thru Hole. There are six assemblers for thru-hole production and the AX/MX 300 PCB assembly is thru-hole. ESD controls (smocks, grounded wrist-straps, or heel-straps

Analyzer Assembly: Toured the AX/MX assembly area with the QA Manager. There was no AX/MX builds at the time of the audit. Jobs are kitted and delivered to the area in production. The kits are assembled, and in-process inspected per controlled procedures. The assembled units are routed to the Test Department for test and final inspection, and sent to stock awaiting order. When an order is received the assembled unit(s) are routed back to production for kitting with accessories and prepared for shipment.
Sampled the following DHRs; (1) AX300 Control Unit, W/O 0100722, PN C75327A, Rev 4, Qty: 6, S/N: 312630 - 312635, QA Final Insp.: 12/19/14. (2) AX300 Control Unit, W/O 0093615, PN 375327A, Rev 4, Qty: 6, S/N: 312375 - 312380, QA Final Insp.: 11/14/14. (3) MX300-I Control Unit w/Alarm, W/O 0103348, PN C75705A, Rev 5, Qty: 50, S/N: 312908 - 312957, QA Final Insp.: 12/19/14. Seven process steps were stamped off in each DHR.

Based on the objective evidence the processes assessed are deemed to be effective.

Planning of product realization / Design and development / Risk management / Process Validation : 7.3, 7.1, 7.5.2

Contact(s): Roger Starlin - QA Manager
Document(s): Design Control and Verification - ED 400, Rev 18; Sensor Design - SR 401 Rev 8; Risk Management For Medical Devices - CP 252, Rev 0; Internal Test Fixture Validation Program - QA 411, Rev 3.

The design control process documented in the above procedures consists of approximately 8 steps. (1) Feasibility Study, (2) Design & Development Planning, (3) Pre-Development Activities, (4) Design Input, (5) Design Output, (6) Design Review & Verification, (7) Design Validation and (8) Critical Design Review. There has been no new design activity for medical devices at the organization for several years.

Risk management for medical devices is documented in CP 252, which is in accordance with EN ISO 14971:2012. Examined risk analysis elements of the DHF for the Micro Fuel Cell, UFO 130 Fast Oxygen Sensing Unit and the Oxygen Analyzer, Model MX 300 / AX 300, all completed 10-9-2003. Per the QA Manager Risk Plans will be updated to EN ISO 14871:2012 when major design changes are made. Examined the ECO #03-0038, which released the MX 300 / AX 300, dated 06/18/2003.

Examined the last validation on the MX 300 / AX 300 Test Fixture TED/AI39, which was dated 12/11/14, next due is 6/11/15. Five channels were tested for six data points each using a multi-meter and a current source.

Based on the objective evidence the processes are deemed to be effective.

Customer related processes / Order fulfillment : 7.2

Contact(s): Roger Starlin - QA Manager; Sharon Wade - Sales Administration
Document(s): Contract Review & Order Processing - SA 400, Rev 11

The Sales Administrator was interviewed and the sales order activities was demonstrated via the Oxygen Analyzers. Customers can order products via email, phone, or fax. The completed sales order numbers 00044039-1 shipped to EU AR, Viamed in the UK, 00045183-1 shipped to EU AR, Viamed in the UK, 00036541 shipped to Distributor, Benson Medical in Canada were selected and reviewed.

The customer related processes including the sales order fulfillment appeared to be effective and in compliance with the ISO 13485:2003 clauses stated above.

Purchasing / Supplier management (control of outsourced processes) : 7.4.2, 7.4.1

Contact(s): Roger Starlin - QA Manager
Document(s): Procurement Branch - PU 400, Rev 18; Vendor Selection - PU 402, Rev 14.

PU 400 was examined relative to purchasing and the following Purchase Orders were sampled. PCB FAB Vendor, Evergreen: (1) PO 0015757 - 5/2/14, (2) PO 0023423 - 9/2/14, (3) 0022091 - 8/7/14, (4) PO 0026914 - 11/17/14. Case (Enclosure) Vendor, Oasis Enterprises: (5) PO 0024877 - 11/20/14 and P102296 - 10/5/12. LCD Display Vendor, ELECSYS INTERNATIONAL: (1) PO P103545 - 12/18/12 and PO 0016852 - 4/30/14.

PU 402 was examined and it was noted that the procedure covers vendor selection and control of outsourced processes. Supplier files (Procurement Vendor File Maintenance Form) for the three Vendors (1. Evergreen, 2. Oasis and 3. ELECSYS) listed above was examined, including the receiving inspection records from the initial purchase to the most recent for Vendors 1. and 2. The records show that the initial and continuing qualification of the key suppliers is documented and maintained.

Based on the objective evidence the process is deemed to be effective.

Receiving / RMAs (customer property) / Receiving inspection (control of outsourced processes) / Control of nonconforming product : 7.5, 7.5.4, 7.4.3, 8.3

Contact(s): Roger Starlin - QA Manager; John Martinez - Shipping/Receiving; Lupe Hurtado - Shipping Clerk; Jesse Cardenas - QA Inspection.
Document(s): Receiving - WH 400, Rev 13; Quality Assurance Receiving Inspection - QA 401, Rev 12; Control of Nonconforming Product - QA 414, Rev 12; Material Review Board (MRB) - QA 415, Rev 3

Interviewed Shipping/Receiving Personnel, the Shipping Clerk and examined WH 400. Material is received, logged into MRP database, Microsoft AX and routed to Receiving Inspection for purchasing verification. RMAs and LCD Displays are routed to the Test Department. RMAs (customer property) are investigated, and repaired upon approval by Customer Service.LCD Displays are tested for acceptance and routed back to PCB production for assembly. Examined the receiving records for the most recent recent of material for MX/AX 300 builds. Last receipt of the Sensor Fab, PN D65453, 36000 pcs. was 10/1/14. Last receipt of MX Case, PN C75898B was 12/16/14.

Interviewed QA Inspection and examined QA 401. For received material to be inspected, QA Inspection pulls the History Card on the material, performs inspection per reference instructions. Inspection results, and instrument with calibration due date is recorded on the History Card and electronically on Access database. Inspected material is placed on shelf outside QA Inspection area to be located into stock warehouse. Examined record of receiving inspection performed on D65453, 36,000 pcs. on 10/1/14. AQL sample size was 200 pieces based on table in QA 401. Dimensional used a caliper #505626 with cal due: 2/11/15. Part of the inspection was verification of the CofC from the vendor, Evergreen, dated 9/25/14, which specified RoHS compliance.

Nonconforming material is maintained in a DMR (Discrepant Material Report) Cabinet, which is kept locked with restricted access in the warehouse. Each item in quarantine is identified by a DMR form. There was no medical device material in the DMR Cabinet at the time of the audit.

Based on the objective evidence the processes are deemed to be effective.

Customer service (RMA, repairs) : 7.5.1.2.3, 7.5.4

Contact(s): Roger Starlin - QA Manager; Long Bui - Technician
Document(s): Customer Repair Order Processing - TD 403, Rev 16

Interviewed the Technician in the Test Department and examined procedure TD 403. Repairs are done on customer owned analyzers by the Test Department through the RMA process using TD 403. Sampled a RMA #5111, received 12/30/14, MX300, S/N 260706. Unit is out of warranty. Investigation completed, broken plug mount on the case, requires case replacement. The repair is awaiting customer approval. The Technician logs the RMA status electronically on Access database.

Based on the objective evidence the process is deemed to be effective.

Preservation of product (warehouse) / Shipping : 7.5.5, 7.5.1.1

Contact(s): Roger Starlin - QA Manager; Glen Coon - Warehouse Supervisor; John Martinez - Shipping/Receiving
Document(s): Stock Room - WH 401, Rev 7; Packaging - WH 402, Rev 6; Shipping - WH 405, Rev 6; Material Shelf Life - WH 406, Rev 9; Handling, Storage, Packaging, Delivery & Preservation - WH 411, Rev 6.

Interviewed personnel in the warehouse and examined the procedures listed as Document(s) above. Accepted received goods are stored in the stockroom by date received, Receiver initials, location, quantity, revision and part number. Received goods are traceable by date and there is none that requires special storage conditions. Finished goods storage was also assessed and product with shelf life was sampled. Verified storage of P/N C43C90-R17MED, S/N 497413 - 497441, Qty: 30, Mfg. Date: 1/7/15, Exp. Date: 1/7/17. All material is utilized and shipped from the stockroom and warehouse using FIFO.

Packaging for shipment is per WH 402 and WH 609 for preparing finished goods for shipment. Verified packaging of Sensors C44611-R22MED, DOT Approval CA2001010017. Each shipping box contains 100 units. Shipment is to VIAMED in Yorkshire, UK via UPS Worldwide under SO 00044026.

Based on the objective evidence the processes are deemed to be effective.

Control of documents / Control of records : 4.2.3, 4.2.4

Contact(s): Roger Starlin - QA Manager
Document(s): Engineering Change Order (ECO) - CP 202, Rev 10; Engineering Change Request (ECR) - CP 218, Rev 8; Change Control Board (CCB) - DC 403, Rev 7; Master List - DC 415, Rev 4; Document Control - DC 417, Rev 5; Customer Supplied / External Documents - DC 423, revision 3; Inactive / Obsolete DC 424, Rev 4; Procedure Distribution - DC 616, Rev 1; Control of Quality Records - CP 204, Rev 20.

Reviewed and verified the procedures listed as Document(s) above.

It was noted the organization has documented procedures that define the controls needed
a) to review and approve documents for adequacy prior to issue, -covered by CP 202,
b) to review and update as necessary and re-approve documents, -covered by CP 202,
c) to ensure that changes and the current revision status of documents are identified, - covered by DC 415,
d) to ensure that relevant versions of applicable documents are available at points of use, - covered by DC 415,
e) to ensure that documents remain legible and readily identifiable,- covered by DC 417 and CP 204,

f) to ensure that documents of external origin are identified and their distribution controlled, - covered by DC 423,
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose. - Covered by DC 424,

Changes to documents are covered by an ECO and ECR process and authorized by the CCB - reference DC 403.
Examples of document changes noted are ECO 14-0123 12/14/14 and ECO 14-0053 2/16/11.

Obsolete document retention is specified in CP 204 and is stated as 10 years from date of obsolescence.

Review of records retention procedure (CP 204) shows the maximum retention time is indefinite and does not mention the lifetime of the medical device. The lifetime of the AX/MX 300 Analyzer is specified as 30 years in the Technical File.
Processes are deemed to be effective.

Competence, awareness & training : 6.2.2

Contact(s): Roger Starlin - QA Manager
Document(s): Training / Re-Training - CP 200, Rev 15.

Resource needs are addressed at Management Review and when deemed necessary to maintain the QMS and/or to meet customer needs. Sampled 4 training records; 2 Temps in the Sensor Department, an Assembler 2 from Sensor Department and a Facilities/Safety Management 2 with Internal Auditor qualification. Each individual record showed the employee had the appropriate training for their function and job roles. The first 3 were trained on the Sensor procedure SD 400, Rev 10. The fourth was trained on CP233, Rev 6 for ESD and his QMS Auditor Workshop for auditor training was completed Sept 18-19, 2001.
Process appears to be effective.

Regulatory checklist / Technical file / HC device licenses : 4.2.1

Contact(s): Roger Starlin - QA Manager; Vasu Narasihmhan - Director, Operations

The regulatory checklist was completed with no issues noted.
There has been no new medical device license issued by HC in recent years. There has been no change / amendment to the device license number 8339 "Oxygen Sensor", class 2 since 2003-07-23, device license number 66350 "Oxygen Monitor", class 3 since 2007-05-23, and to the device license number 66351 "Oxygen Analyzers", class 2 since 2007-05-23.
The Product Technical File for AX300-I & MX300-I was sampled and reviewed.

During the course of the visit logos were found to be used correctly.

Assessment Participants.

On behalf of the organization:

Name	Position
Vasu Narasihmhan	Director QA/RA/Procurement
Roger Starlin	QA Manager
Tom Compas	VP/GM
Donna Werremeyer	QA
Steve Aguilar	Production Supervisor (PCB)
Eric Calderon	Buyer/Planner
Cheryl Noennick	Buyer/Planner
Lupe Montenegro	Production Lead
Pamfilo Rongavilla	Machine Shop Supervisor
Daniel Lopez	Production Supervisor (Sensors)
Raymond Garcia	Assembler
Estela Rivas	Assembler
Nary Keo	Assembly
Sharon Wade	Sales Administration

The assessment was conducted on behalf of BSI by:

Name	Position
Jeffrey Tuthill	Team Leader

Continuing Assessment.

The program of continuing assessment is detailed below.

Site Address	Certificate Reference/Visit Cycle	
Teledyne Analytical Instruments a business unit of Teledyne Instruments, Inc. 16830 Chestnut Street City of Industry California 91748-1020 USA	Contract 200489850	
	Visit interval:	12 months
	Visit duration:	1.5 Days
	Next re-certification:	01/01/2018

Re-certification will be conducted on completion of the cycle, or sooner as required. An entire system re-assessment visit will be required.

Re-certification Plan.

TELEDY-0009801967-000|Contract 200489850

		Visit1	Visit2	Visit3	Visit4	Visit5	Visit6
Business area/Location	**Date (mm/yy):**	02/16	02/17	01/18			
	Duration (days):	1.5	1.5	3.0	0.0	0.0	0.0
Complaints processes		X	X	X			
Control of nonconforming material		X		X			
Control of records incl regulatory records			X	X			
Corrective & preventive action processes		X	X	X			
Customer related process / sales / order			X	X			
Customer related shipping / wareh'se / pick'g / disp / traceab'y			X	X			
Document control incl Tech Documentation			X	X			
Follow-up from previous assessment		X	X	X			
Goods-in / receipt insp / mat'l stores / traceab'y		X		X			
Identification & traceability		X	X	X			
Incidents / recalls / advisory notice / notific'n / reports / vigilance		X	X	X			
Internal Audit process		X	X	X			

Manufacturing processes including:	X	X	X			
Mgt responsibility, policy, organization	X	X	X			
Mgt review-objectives / target's / data analysis / feedback	X	X	X			
Planning of product realization / Design & development processes / Risk management		X	X			
Pre-certification review		X				
Preventive maintenance & maint'ce process	X		X			
Process/product measures / Process validation	X		X			
Product mfg processes: instruments / PCB		X	X			
Product mfg processes: sensor	X		X			
Product verification/batch records	X	X	X			
Production planning		X	X			
Purchasing, outsourcing & supplier mgt	X		X			
QMS, QMS certificate, scope / product changes	X	X	X			
Re-calibration process	X		X			
Re-certification (full)			X			
Regulatory checklist / Technical file / HC device license status - as applicable	X	X	X			
Resources incl training & competence	X		X			
Service / Customer property		X				
Top Mgt / cust foc / policy / obj / tgt / communication			X			
Work env't / infrast're processes wrt this visit	X	X	X			

Next Visit Plan.

Visit objectives:

To conduct a surveillance assessment to determine the continued effective implementation of the company's management system, in accordance with the company objectives, the management standard & BSI Conditions of Contract and to determine whether a recommendation for continuing certification can be made.

To verify Teledyne Analytical Instruments, a business unit of Teledyne Instruments, Inc. (Company ID No. 110223) continues to implement all requirements of ISO 13485:2003 and the most current version of Part 1 of the Canadian Medical Device Regulations.

To verify that the management system continues to meet the requirements of 93/42/EEC Annex II 3.2 (M5).

Date	Assessor	Time	Area/Process	Clause
01/01/2016	Assessor 1	7:30	Arrive - setup / Opening meeting	
01/01/2016		8:00	QMS, QMS certificate, scope / product changes / Follow-up from previous assessment	4
01/01/2016		8:30	Mgmt responsibility, policy, organization / Mgmt review / Data analysis	5.1-5.6, 8.4
01/01/2016		9:30	Internal Audit process	8.2.2
01/01/2016		10:30	Feedback / Complaints processes (incidents, recalls, advisory notices, med. device problem reports, vigilance / Corrective action / Preventive action	8.2.1, 8.5
01/01/2016		12:00	Lunch	
01/01/2016		1:00	Manufacturing processes including: Sensor Department / Product verification / Batch records	6.3, 6.4, 7.5.1.1, 7.6, 8.2.4, 8.3
01/01/2016		2:30	Preventive maintenance & maint'ce process / Work environment & infrastructure / Re-calibration process	6.3, 6.4, 7.6
01/01/2016		3:30	Purchasing, outsourcing & supplier mgt	7.4.2, 7.4.1
01/01/2016		4:30	Daily debrief	
01/02/2016		7:30	Arrive - setup / Goods-in / Rec. inspection / Mat'l stores / Identification & traceability / Control of nonconforming material	7.4.3, 7.5.5, 7.5.3, 8.3
01/02/2016		8:30	Process/product measures / Process validation / Reg. checklist (for surveillance audit) / HC device license status	8.2.4, 7.5.2, 4.2.4
01/02/2016		9:30	Resources incl training & competence	6.2.2
01/02/2016		10:30	Interim report preparation	
01/02/2016		11:30	Closing Meeting	

Please note that BSI reserves the right to apply a charge equivalent to the full daily rate for cancellation of the visit by the organization within 30 days of an agreed visit date. It is a condition of Registration that a deputy management representative be nominated. It is expected that the deputy would stand in should the management representative find themselves unavailable to attend an agreed visit within 30 days of its conduct.

Notes.

The assessment was based on sampling and therefore nonconformities may exist which have not been identified.

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Should you wish to speak with BSI in relation to your registration, please contact our Operations Support Team:

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Appendices.

The audit duration is reduced by 15% as the Client demonstrates preparedness for certification (eg. Client holds certification with other 3rd party). This has changed what was previously established as the audit duration with 65 employees the surveillance audit = 1.5 days and the recertification audit = 3 days.