QC 21 Non Conformance Report

Date	23 August 2022
Viamed / VST* Issue id unique identifier ***delete as appropriate**	**269904**
BSI Ref (if applicable) unique identifier	2235543-202208-N1
Responsibility Person Overall responsible	Derek Lamb
Non-Conformance statement of the problem	The process of monitoring and measurement of product is not fully effective because the test equipment (multimeter) used to perform the final testing was not recorded. QA ref1959881.1648041778, Oxygen sensor, Linda Shearing, 23 Mar 2022, #782133 Calibration index, two multimeters - not sure which one was used as was not recorded: CE203 (CE Number), SN: CE203, Next Calibration due: Sep 2022 CE206 (CE Number), SN: 3027310, Next Calibration due: Sep 2022
Investigation By: Person responsible	Derek Lamb
Investigation Root Cause Analysis Issue id (if applicable)	The details of the test equipment that was used to QA oxygen sensors, was not being logged in the computer records, against the barcode of the item being tested. So we did not have a list of the QA test equipment used on an individual oxygen sensor. We have missed this part of the process and this logging of test equipment on oxygen sensors QA forms has never been done. We have only two items of test equipment for these oxygen sensors, and all the test equipment is regularly checked and records kept of the calibration records, in the calibration index. As all the test equipment is checked and verified regularly, the sensors have always been checked with a valid test unit. The sensor themselves have a limited life span and will always eventually fail when in use by the end user and have to be checked every time, before use. There is no clinical risk if a

	faulty sensor got past our QA, it is just an inconvenience for the customer.
Corrective Action By: Person responsible	Derek Lamb
Corrective Action Issue ID (if applicable): Relevant Immediate Corrective action (if applicable)	Review part numbers and plan what needs updating.
Time Scale for Immediate Corrective Action Time for completion of all identified actions	1 Week, by the 7th September 2022
Corrective Action: Relevant and Proportionate Corrective Action	We will add a field to all the digital QA forms, where the Barcode ID of the calibrated test equipment being used, to test the oxygen sensors, will need to be inputted. In the future Intrastats will force the logging of the QA test equipment ID, when any QA is carried out. There will be a box where the ID from the barcode for the test equipment, will need to be entered in to the system, in order for the QA to be carried out. All stock references will be checked and we will confirm the system and forms work as intended.
Time Scale for Corrective Action Time for completion of all identified actions	30 Days by the 22nd September 2022.
Risk Review Confirm action does not have negative affects and/or risks to any other part of the ISO system	
Follow-up future issue id (Effectiveness verification)	
Effectiveness verification	

Closed By:	
Closed on	