QC 21 Non Conformance Report

Date	**Created: 31/10/17** **Updated: 07/01/18**
Issue id unique identifier	106959
BSI Ref (if applicable) unique identifier	1548900-201710-M1
Responsibility Person Overall responsible	John Lamb
Non-Conformance Statement of the problem	Design and development and risk management is not effective because evidence of a controlled process could not be demonstrated. Evidence 1. The risk management process VM3COP27.11 includes a scale of 1-4 for severity and occurrence, but does not identify how to determine the boundary/limits between scales. 2. Evidence of consideration of Risk for the Tom Thumb design change in 2005 could not be provided at this assessment. 3. Evidence of updating the Tom Thumb design inputs for a design change in 2005 could not be provided at this assessment. (ref Tom Thumb specification document #2247 dated 6 June 1997) 4. Evidence of Tom Thumb design inputs containing the outputs of risk management could not be provided at this assessment (ref Tom Thumb specification document #2247 dated 6 June 1997 and Tom Thumb risk management file dated 29/9/2017) 5. Evidence of performing a design review on the Tom Thumb design change in 2005 could not be provided at this assessment. 6. Evidence of performing validation of the design change to Tom Thumb in 2005 could not be provided at this assessment. 7. Evidence of appropriate controls related to responsibility authority for design and development between VST and the subcontractor could not be provided at this assessment (ref contract #13859)

Investigation By: Person responsible	Derek Lamb
Investigation Issue id (if applicable) Root Cause Analysis	106959 EACH SECTION HAS BEEN DONE ON A SEPARATE SHEET TO MAKE IT EASIER TO FOLLOW. BELOW IS A SUMMARY ROOT CAUSE OVERVIEW General overview Root Cause The Digital Index was started in 2006, so all technical files were scanned in, at things time, retrospectively. Problems arouse due to needing files prior to this date. During to the past 12 years Viamed has moved away from new design and development. We are maintaining the design files for the few remaining products developed in the 1908's and 1990's. As no products have required change since 2005 there are no recent design changes to audit / demonstrate. Any products that have required redesign have been dropped from the EC certificate and our range for example our 800 Series SpO2 fingers probes. (previously on the certificate) As such VOP 17 the Design Research and Development, control document, has not had the in depth review required to stay up to date. Note the post market surveillance control document VM3COP27.11 has continued to be updated and reviewed. Information regarding the 2005 change was located in the obsolete Goldmine database archives, which are not directly accessible like the modern Digital files so were unavailable during the actual audit.

	SEE INDIVIDUAL FILES ATTACHED
Corrective Action By: Person responsible	Derek Lamb / John Lamb
Corrective Action Issue ID (if applicable): Relevant and Proportionate Corrective Action	
Time Scale for Corrective Action Time for completion of all identified actions	Immediate Action: 28/11/2017 Corrective Action: 31/01/2018
Corrective Action:	Overall Immediate Action Information from the 2005 design change added to the technical files documentation. Overall Corrective Action VOP 17 to be fully reviewed and brought upto date. Document ID7393 - identifying how to determine the boundary/limits between scales of risk management to be updated to reflect the updated risk management process. SEE INDIVIDUAL FILES ATTACHED
Follow-up future issue id (Effectiveness verification)	
Effectiveness verification	

Closed By:	
Closed on	