

QC 21 Non Conformance Report

Date	24/09/2019
Issue id unique identifier	155083
BSI Ref (if applicable) unique identifier	1826110-201909-N2
Responsibility Person Overall responsible	Derek Lamb
Non-Conformance statement of the problem	<p>The product preservation is not fully effective as no process was seen in place to ensure that the chemicals (grease and sealant used respectively for the lubrication and to lock the regulator screw of the Tom Thumb infant resuscitator) were used within their lifetime.</p>
Investigation By: Person responsible	Derek Lamb
Investigation Issue id (if applicable) Root Cause Analysis	<p>The grease and sealant used in the workshop for servicing was not reviewed regularly to ensure it had not gone past its manufacturer recommended life span.</p> <p>With the original manufacturer not having a use by date or expiry date on the product. We missed reviewing these products and we did not have a process in place, to check the manufacturers data sheets for a life span of the product.</p>
Corrective Action By: Person responsible	Derek Lamb
Corrective Action Issue ID (if applicable): Relevant and Proportionate	<p>Process ID7940</p> <p>Process ID7944</p>

Corrective Action	Issue ID 154977 Issue ID 154978 Issue ID 154987 Issue ID 154986 Issue ID 154985 Issue ID 154984 Issue ID 154983 Issue ID 154982 Issue ID 154981 Issue ID 154980 Issue ID 154979 Issue ID 154976
Time Scale for Corrective Action Time for completion of all identified actions	Immediate Action to be completed by 19 th October 2019 Corrective action to be completed by 19 th October 2019
Corrective Action:	<p>Immediate Action</p> <p>A questionnaire will be sent to all relevant staff to list any sealant, glues, greases, sprays and tapes that are used in production, servicing and repairs for Viamed and VST. To check their data sheets and make sure none are over their use by date or manufacturers shelf life.</p> <p>A new process will be added in to Intrastats, which will generate the requirements of all the processes eg. Risk Assessments, Measurable Objectives and Training Requirements. This will generate Rolling Task, Rolling Issue and Rolling Audit Task.</p> <p>A Rolling Task will be added to check the Data Sheets on products used, for a life span. This Task will also included a statement to tell staff to dispose of any that have reached what the manufacturer states is the shelf life.</p> <p>The Rolling Audit will Ensure the task is completed in a timely manner each year.</p> <p>This process is a new addition to the system and does not affect any existing processes.</p>

	<p>A question will be added to Audit 11 Repairs, Servicing and Returns to review this Process.</p> <p>Corrective Action</p> <p>All all the relevant procedures will be updated to state that a check needs to be carried out on all products used in production and servicing, to make sure they are within their use by dates or manufacturers shelf life.</p> <p>Moving forwards will have regular reviews and issues sent to make sure that all new and existing products used in production or servicing, are looked at regularly and disposed of when they are past the use by date or shelf life.</p> <p>All current and new relevant procedures will include this process. To make sure we do not miss this again.</p>
Follow-up future issue id (Effectiveness verification)	TASK 1010 /1011
Effectiveness verification	Dhuf
Closed By:	Dhuf
Closed on	7/8/2022