QC 21 Non Conformance Report

Date	22.10.2020
Issue id unique identifier	**201671**
BSI Ref (if applicable) unique identifier	1970716-202010-N3
Responsibility Person Overall responsible	Derek Lamb
Non-Conformance statement of the problem	The statement of the problem: The verification of purchased products is not fully effective as the sampling size of incoming goods wasn't seen to have been clearly defined. The organization explained that due to the Covid19 pandemic they needed to handle a wide amount of incoming goods and a sampling method was used, however no deviation was seen to have been documented in this regard.
Investigation By: Person responsible	Derek Lamb / Helen Lamb
Investigation Issue id (if applicable) Root Cause Analysis	**201675** Our system has different levels of QA required on our incoming stock, depending on the supplier and type of stock. Due to the Covid 19 global pandemic we realised we had to get 50 times more stock though the company, than we had before. Sales 2019 – Quantity sold 870 Units. Sales 2020 – Quantity sold 49,694 Units, due to the pandemic. The need for the pandemic stock was immediate. Any delays to the delivery from the supplier to the end user would result in less ventilators in immediate use and almost certainly the loss of lives. Since we are not required to QA any of the stock we buy in, to sell, as the stock is fully CE from the Supplier. The decision was made to batch QA some of the stock coming in. **Root Cause Analysis** We did not update the procedures to reflect this. We also did not include a statement about this in the COVID 19 action plan

	or in the document index. The system itself was updated, by management, to indicate the type of QA that was required e.g. no QA, full QA or batch QA. Which then allowed the product to be released for sale. But when we updated the system to allow batch QA of some products when Covid 19 became an issue in March 2020, we did not update the relevant VOP or procedures.
Corrective Action By: Person responsible	Derek Lamb
Corrective Action Issue ID (if applicable): Relevant and Proportionate Corrective Action	#201710 #201713
Time Scale for Corrective Action Time for completion of all identified actions	Immediate Action and Corrective Action to be carried out by 22nd November 2020
Corrective Action:	**Immediate Action** To update the relevant VOP and Covid 19 action plan to reflect the decisions made about batch testing and sample size. **Corrective Action** We will update the Covid 19 action plan to cover the worse case scenarios for when emergency measures need to be taken. Make sure a Covid 19 or other extreme national or international crisis plan, is referred to in all tasks and mini audits. So that we have a record of our decisions and a plan of how to move forward, for each task, in an extreme national or international crisis.
Follow-up future issue id (Effectiveness verification)	

Effectiveness verification	This can be verified from the reviewing the VOP and procedures related to QA and stock control. Also the Covid 19 action plan.
Closed By:	
Closed on	