

QC 21 Non Conformance Report

Date	24/09/2019
Issue id unique identifier	155085
BSI Ref (if applicable) unique identifier	1826110-201909-N4
Responsibility Person Overall responsible	Derek Lamb
Non-Conformance statement of the problem	The risk management process is not fully effective as no linkage was provided to the verification activities of the risk control measures and the assessment of risks before and after mitigation were not clearly defined.
Investigation By: Person responsible	Derek Lamb
Investigation Issue id (if applicable) Root Cause Analysis	<p>We did not have a risk assessment in place for the service and production of the Tom Thumb. It should have been present in Intrastats in the document Index.</p> <p>The Tom Thumb is a legacy product manufactured by Viamed. The product itself had an overall risk assessment in the system, but it did not cover service and production procedures.</p>
Corrective Action By: Person responsible	Derek Lamb
Corrective Action Issue ID (if applicable): Relevant and Proportionate Corrective Action	Issue ID 155069 Issue ID 155535 Issue ID 155533 Issue ID 155069 Issue ID 154979 Issue ID 154721 Issue ID 154720
Time Scale for Corrective	Immediate Action to be completed by 19 th

Action Time for completion of all identified actions	October 2019 Corrective action to be completed by 19 th October 2019
Corrective Action:	<p>Immediate Action We will write an up to date Risk Assessment for all stages of the production, service and QA of the Tom Thumb. Which will be added to the product Risk Assessment in the system.</p> <p>We no longer produce this item, but for completeness we will make the Risk Assessment cover all areas to ensure nothing is missed.</p> <p>Corrective Action We will check all production, servicing and QA areas / products for an up to date Risk Assessment, verifying they are fit for purpose and easily accessible to staff.</p> <p>Then add these to the Required Reading to make sure they have been read and that there is a record of it in Intrastats.</p>
Follow-up future issue id (Effectiveness verification)	
Effectiveness verification	
Closed By:	<i>D. Lans</i>
Closed on	<i>7/8/2022</i>