

QC 21 Non Conformance Report

Date	07/12/17
Issue id unique identifier	109958
BSI Ref (if applicable) unique identifier	1565762-201712-N1
Responsibility Person Overall responsible	Derek Lamb
Non-Conformance statement of the problem	Management review is not fully effective because not all inputs and outputs required by ISO 13485:2016 or ISO 9001:2015 were demonstrated to be considered and covered in the samples provided for Viamed and Vandagraph Sensor Technologies.
Investigation By: Person responsible	Derek Lamb
Investigation Issue id (if applicable) Root Cause Analysis	<p>Root Cause: As part of the Immediate action, from a previous Non Conformance, extra Board Meetings were held in a short time frame. This meant the template used for the Headings and Subjects to be covered was not updated in line with ISO9001:2015 and ISO13485:2016.</p> <p>We missed a heading when updating.</p>
Corrective Action By: Person responsible	Derek 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: 08/12/2017 Corrective Action: 01/02/2018
Corrective Action:	Immediate Action

	<p>Management Review Blank Minutes 20xx, DOCID 8927, is to be updated to reflect changes in 9001:2015 and 13485:2016, ensuring all headers are correct and present.</p> <p>VOP 13 to be updated to include reference to the required new inputs, in line with ISO9001:2015 and ISO13485:2016.</p> <p>Corrective action</p> <p>“Management review record for Viamed dated 11 October 2017, Management review record for Vandagraph Sensor Technologies dated 18 October 2017”</p> <p>These were extra reviews due to a previous non conformance. The regular Management Review linked to Process ID 7846 task 746, is scheduled to become live 8 Jan 2018. Where missing inputs will be covered.</p>
Follow-up future issue id (Effectiveness verification)	
Effectiveness verification	
Closed By:	
Closed on	7/8/2022