Derek Lamb 73 Issues **6** ***Unread*** 15 ISO Tasks 18.00 °C

Search

SN Full, SH Full, EH Full

Customer Complaint and Non Conformance Review Screen

Show All Generic Issues
Show All Viamed Issues
Show All Vandagraph Issues
Show All VST Issues
Show All Human Med Issues
Show All Viamed Properties Issues
Show All The Pointless Logo Company Issues
Show All Non Minor Issues

To Filter to Company Issues you need to tag any in the Genetic Issues first

Unreviewed Telephone Complaints

VIAMED Customer Complaints

Viamed | Vandagraph | VST | Human Med | Viamed Properties | The Pointless Logo Company

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
306816 15 Sep 2023 306804	Feedback for initial order - Damaged Parcels Non Conformance	☐	☐	☐	☐	☐	☐	☐

Steve Hardaker
Added by Derek Lamb sent to Derek Lamb
this needs further investigation

15 Sep 2023 Derek Lamb

Header Changed From 238 Non Conformance Issues Non Conformance Issues To VIAMED Customer Complaints VIAMED Customer Complaints

15 Sep 2023 Derek Lamb

Next Action Changed From Derek Lamb To Steve Hardaker can you open a CCR, reference number, Its a shipping/packaging issue, so no mhra / bsi notifications are required.

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15 Sep 2023 Derek Lamb
I believed we were shipping the items in teh same manner the supplier ships to us, I asked robert to photograph the latest shipment from maxtec to us, fortunatly then have sent a shipment this week, and believe it or not see attached photos

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15 Sep 2023 Derek Lamb
Created Related Issue #306817
Added by Derek Lamb sent to Steve Nixon
INFORMATION ONLY ISSUE **DO NOT** ADD NOTES!
Steve, Looks like we need to inform maxtec of the shipping method and state of the boxes actually delivered, We`ve opened an internal customer complaint, see Issue 306816

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15 Sep 2023 Steve Hardaker

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15 Sep 2023 Steve Hardaker
Requires CCR number. Check file on Monday.

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25 Sep 2023 Steve Hardaker
Opened CCR156 and documented so far.

VIAMED Customer Complaints

Viamed | Vandagraph | VST | Human Med | Viamed Properties | The Pointless Logo Company

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
304005 15 Aug 2023	4420826 report of gas leakage	☐	☐	☐	☐	☐	☐	☐

Steve Hardaker
Added by Steve Nixon sent to Steve Hardaker
As discussed, please treat as a customer complaint. When we have further information we can then decide if it warrants processing as a complaint to Bluepoint. Shipped via Trionara, but being used by Saadat. 100 boxes of 4420826 shipped 17-04-2023 RVM141219-1 4 boxes 4420823 shipped 21-11-2022 RVM140395-1 4 boxes 4420826 shipped 21-11-2022 RVM140395-1

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16 Aug 2023 Steve Hardaker
Opened customer complaint report CCR155.

Non Conformities Review

Viamed | Vandagraph | VST | Human Med | Viamed Properties | The Pointless Logo Company

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
295339 16 May 2023	2342435-202305-N4 ISO 9001:2015 8.4 Minor	☐	☐	☐	☐	☐	☐	☐

Helen Lamb
Added by Derek Lamb sent to Derek Lamb
1. The unique identifier (from the BSI report and also any internal reference). 2. The statement of Nonconformity as written in the BSI report. 3. Root Cause Analysis. 4. Relevant Immediate Correction (where applicable). 5. Relevant and Proportionate Corrective Action. 6. Person responsible to complete the action(s). 7. Time for completion of all identified actions. The process for the control of suppliers is not fully effective as it was not observed that an agreement was in place to determine the controls applied to Viamend as a supplier. 8.4 Control of externally provided processes, products and services Viamed to VST PO: 143026 19 April 2023

16 May 2023 Derek Lamb

Next Action Changed From Derek Lamb To Helen Lamb

16 May 2023 Derek Lamb
see issue 295339

18 May 2023 Helen Lamb
hl revision added named 295339.12616 qc 21 initial document N4_18_05_23 HL1

Non Conformities Review

Viamed | Vandagraph | VST | Human Med | Viamed Properties | The Pointless Logo Company

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed

		Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	action plan					
295334 16 May 2023	2342435-202305-N3 ISO 9001:2015 8.4 Minor	☐	☐	☐	☐	☐	☐	☐

Helen Lamb
Added by Derek Lamb sent to Derek Lamb
1. The unique identifier (from the BSI report and also any internal reference). 2. The statement of Nonconformity as written in the BSI report. 3. Root Cause Analysis. 4. Relevant Immediate Correction (where applicable). 5. Relevant and Proportionate Corrective Action. 6. Person responsible to complete the action(s). 7. Time for completion of all identified actions. the process for supplier review is not fully effective as It was not observed that the review for Viamed as a supplier was being conducted as per the procedure. 8.4 Control of externally provided processes, products and services VOP 05 rev #75847/1637687018 Viamed limited – 28 Nov 2022

16 May 2023 Derek Lamb

Next Action Changed From Derek Lamb To Helen Lamb

18 May 2023 Helen Lamb
hl version added 295334.12615 qc21 initial document N3_18_05_23 HL1

Non Conformities Review

Viamed | Vandagraph | VST | Human Med | Viamed Properties | The Pointless Logo Company

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
295327 16 May 2023	2342435-202305-N2 ISO 9001:2015 9.2 Minor	☐	☐	☐	☐	☐	☐	☐

Helen Lamb
Added by Derek Lamb sent to Derek Lamb
1. The unique identifier (from the BSI report and also any internal reference). 2. The statement of Nonconformity as

written in the BSI report. 3. Root Cause Analysis. 4. Relevant Immediate Correction (where applicable). 5. Relevant and Proportionate Corrective Action. 6. Person responsible to complete the action(s). 7. Time for completion of all identified actions. The process for internal audit is not fully effective as it was not clear that all issues raised during internal audit were part of the non- conformity review process as per documented procedure 9.2 Internal audit Picking packing audit 2023

16 May 2023 Derek Lamb

Next Action Changed From Derek Lamb To Helen Lamb

18 May 2023 Helen Lamb
HL revision added 295327.12614 qc 21 initial document N2_18_05_23 HL1

Non Conformities Review

Viamed | Vandagraph | VST | Human Med | Viamed Properties | The Pointless Logo Company

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed
295321 16 May 2023	2342435-202305-N1 ISO 9001:2015 5.2 Minor	☐	☐	☐	☐	☐	☐	☐

Helen Lamb
Added by Derek Lamb sent to Derek Lamb
1. The unique identifier (from the BSI report and also any internal reference). 2. The statement of Nonconformity as written in the BSI report. 3. Root Cause Analysis. 4. Relevant Immediate Correction (where applicable). 5. Relevant and Proportionate Corrective Action. 6. Person responsible to complete the action(s). 7. Time for completion of all identified actions. The process for the quality policy is not fully effective as it was defined as a secondary level document. 22062 VM3COP.00.00 Company quality policy 16 sept 2017

16 May 2023 Derek Lamb

Next Action Changed From Derek Lamb To Helen Lamb

18 May 2023 Helen Lamb
section 5.2 of 9001 first revision by me doc named 295321.12613 qc21 initial document N1_18_05_23 HL1

BSI Minor Non conformances
Viamed

Issue / Primary	Subject/Notes	Minor Internal Error i.e. not ISO	Reviewed Non Conformity	Determined Cause of Non	Evaluated action to Ensure	Planning and documenting action needed	Verify Action does not adversely	Effectiveness of corrective

ID / Call ID		Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	/ Complaint and determine if its a vigilance Issue requiring a corrective action plan	Conformity / Complaint	does not recur	and implementation QC 28b	affect Safety Performance or regulatory requirements	action reviewed
269905 23 Aug 2022	Viamed 2235543-202208-N2	☐	☑	☑	☑	☐	☐	☐

Helen Lamb
Added by Derek Lamb sent to Derek Lamb
The process of Corrective action is not fully effective because the documented procedure was not completely followed. For negative feedback Issue 266313, CAPA 252744 the organisation opened a QC21 (major nonconformity form) something that is not described in the VOP10 Procedure. VOP10 procedure, 25 May 2022, DOCID#90405 CAPA 252744, 01 Mar 2022, Open Investigation, 4 Mar 2022 Negative feedback, Issue no. 266313 QC21, uploaded 25.07.2022- seen to be incomplete

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23 Aug 2022 Derek Lamb

Subject Changed From 2235543-202208-N2
Subject Changed To Viamed 2235543-202208-N2

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24 Aug 2022 Helen Lamb

Next Action Changed From Derek Lamb To Helen Lamb

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25 Aug 2022 Helen Lamb
need QC21 form attaching please

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30 Aug 2022 Helen Lamb
small corrections looks good to me

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30 Aug 2022 Helen Lamb
added corrective action first draft

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09 Sep 2022 Helen Lamb
changed a few bits of wording

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09 Sep 2022 Derek Lambemail sent

BSI Minor Non conformances
Viamed

Issue / Primary ID / Call ID	Subject/Notes	Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective	Reviewed Non Conformity / Complaint and determine if its a vigilance	Determined Cause of Non Conformity / Complaint	Evaluated action to Ensure does not recur	Planning and documenting action needed and implementation QC 28b	Verify Action does not adversely affect Safety Performance or regulatory requirements	Effectiveness of corrective action reviewed

		actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / or dealt with in s	Issue requiring a corrective action plan					
269904 23 Aug 2022	VIAMED 2235543-202208-N1	☐	☑	☑	☑	☐	☐	☐

Helen Lamb
Added by Derek Lamb sent to Derek Lamb
The process of monitoring and measurement of product is not fully effective because the test equipment (multimeter) used to perform the final testing was not recorded.

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23 Aug 2022 Derek Lamb

Next Action Changed From Derek Lamb To Helen Lamb

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25 Aug 2022 Helen Lamb
my first draft attached QC 21 Initial investigation_25_08_22 VERSION 2 HL.doc

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30 Aug 2022 Helen Lamb
changed some wording

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09 Sep 2022 Helen Lamb
fixed the immediate action and moved some wording around

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09 Sep 2022 Derek Lamb110301 110349 110350 110360 110361 110365 110410 110517 110950 111239 still todo

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09 Sep 2022 Derek Lambdone, last item is monitor , not needing doing

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09 Sep 2022 Helen Lamb