



Old Style View

Issue #375175: BSI Non Conformance 2700663-202509-N2

Add File

*** NON Conformance Header it must contain reasoning to explain why this is or is not a vigilance ISSUE

- 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 / must state in issue if its an observation
- 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

Meeting: Non Conformance Issues Section: BSI Minor Non conformances

Created: 11 Sep 2025 12:55:40 PM By: Derek Lamb

Set to User: Helen Lamb

Additional Information:

Subject: BSI Non Conformance 2700663-202509-N2
 Link To Rolling Issue - Task ID: 1276
 Corrective Action Plan: Yes
 Next Action By: Helen Lamb

Show Related Issues (1)

Add Update Message

Issue #375175

Enter your update message here...

Update Complete

Hide Linked Files (5)

- | | | |
|--|--|-----------------------|
| BSI Audit SMO 30133042 Nonconformity Report 11-09-2025.pdf
Ref #375175.15748 · 11/09/25 1:00 pm · Derek Lamb | [Remove]
[Update/History] | Drop new version here |
| 375175.15749 375175.15746 QC 21 First_11_09_25_2.doc_11_09_25_2.doc
Ref #375175.15755 · 11/09/25 4:15 pm · | [Remove]
[Update/History] | Drop new version here |
| 375175.15755 375175.15749 375175.15746 QC 21 N2 First_11_09_25_2.doc HL V1.doc
Ref #375175.15756 · 11/09/25 4:38 pm · Helen Lamb | [Remove]
[Update/History] | Drop new version here |
| Derek_v2.doc_15_09_25.odt
Ref #375175.15769 · 15/09/25 11:10 am · Derek Lamb | [Remove]
[Update/History] | Drop new version here |
| Acceptance of Corrective Action Plan- SMO 30133042.pdf
Ref #375175.15793 · 19/09/25 10:14 am · Derek Lamb | [Remove]
[Update/History] | Drop new version here |

Show all

12 Sep 2025 - #375175.8 - Derek Lamb

Corrective Action Plan updated to: 1

Issue None Conf.

11 Sep 2025 - #375175.7 - Helen Lamb

I have filled in some fields it will need reviewing and adding to but its a start. HL V1

Issue

None Conf.

11 Sep 2025 - #375175.1 - Derek Lamb

Added by Derek Lamb sent to Helen Lamb
The medical devices files process of the organisation is not fully effective, as the organisation has not established requirements to Nonconformity Report
Page 4 of 9
ensure that product labelling is up to date and viable.
The organisation has not documented labelling requirements as a distributor to verify or maintain product labels implemented and placed by the legal manufacturers are current, compliant and remain legible throughout distribution. Technical files were seen historic, predating the sampled product and existing labels on product was seen not recorded. The product sampled was in relation to Temperature Probe – Skin Contact – Ref 1010132021V – SN 210114478 – Type 0212921 – Viamed Ltd – Produced Oct 2021 – Barcode ID 1856344 – Manufacturer Bluepoint Medical GmbH
Interface Agreement – Bluepoint medical GmbH & Co KG – 21/12/2016

Issue

None Conf.

System (initial record)

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11 Sep 2025 Helen Lamb

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Issue

None Conf.