# Engineering Change Order

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| --- | --- | --- | --- |
| Requester | | | |
| Name |  | Position |  |
| Change description | | | |
|  | | | |
| Rationale for change | | | |
|  | | | |

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| --- | --- | --- | --- |
| Quality Manager | | | |
| Status of approval | | | |
| Approved | | Refused | |
| Reason for refusal | | | |
|  | | | |
| Assigned number | | ECO YY-XXX | |
| Impact on other documents | | | |
|  | | | |
| Assigned reviewers according to SOP-701 | | | |
|  | Name | | Role in organizational chart |
| Author |  | |  |
| Reviewer |  | |  |
| Approver |  | |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Quality Manager | | | | | |
| Identify actions resulting from change: | | | | | |
| Product implications | | **Required actions** | | | **Status** |
| Impact on risk management file: | | N/A: no additional risks identified | | |  |
| Impact on validity of validation/verification: | | N/A: no impact on V&V | | |  |
| Impact on regulatory submissions: | | N/A: change requires no notification of regulatory authorities | | |  |
| Impact on stock of existing product: | | N/A: no product in stock | | |  |
| Customers to be informed: | | N/A: no requirements/ agreements to inform customers were identified N/A: product not on the market | | |  |
| Training needs, list of staff to be informed: | | N/A: relevant staff involved in review process | | |  |
| Closure checklist | | | | | |
| Documentation of review | |  | Consent of author, reviewer and approver documented in commit message or in record (e.g. ZIP file, name as REC-702 - ECO) | | |
| Server | |  | Changes committed to git | | |
| Actions resulting from product implications: | |  | All actions completed or recorded (scheduled) | | |
| Closure | | | | | |
| Name | Function | Date | | Signature | |
|  | QM |  | |  | |