Procedure: Production Identification and Traceability

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| Author signs to confirm technical content | | | |
| Prepared by: | Job title: | Signature: | Date: |
| Subject matter expert reviewer signs to confirm technical content | | | |
| Reviewed by: | Job title: | Signature: | Date: |
| Quality representative signs to confirm document complies with quality management system | | | |
| Authorised by: | Job title: | Signature: | Date: |

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Most product identification and part numbering systems are acceptable. Modify this document to describe how it is done in the company.

# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for product identification and traceability.

# Scope

The scope of this procedure includes materials, parts, subassemblies and other components and finished products at [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Engineering Manager |  |
| Production Manager |  |
| Quality Manager |  |
|  |  |

Amend roles and responsibilities according to your company processes and structure.

# Procedure

## Identification of purchased products

Edit this procedure to describe the product identification system use at the company. Ensure that any changes are matched in the quality manual.

Purchased materials, parts and components are identified with unique part numbers, codes or descriptive names. This same identification is used throughout the device’s life cycle.

If purchased products are marked with another name or number that is not used in [Company], the products are relabelled either by the supplier or by the company’s storeman (refer to Procedure QP707: Verification of Purchased Product).

Purchased products are identified by marking, labelling or tagging the packaging or containers and, where appropriate and practical, by labelling the products itself. Products may also be identified by labelling a dedicated location for holding the product (i.e. a dedicated bin or rack in the warehouse).

Component identification is retained, either on the part or the container, while the product is in storage and when released for production. Identification is maintained until the component is incorporated into the device.

Production documentation must identify all the components used in the manufacture of a device (including part and any batch or lot numbers).

## Identification during production

Describe how the company’s products are identified during production.

This procedure utilises work orders to trace part and lot numbers. If work orders are not used, products must be securely identified by an alternative method.

Manufactured parts and subassemblies are identified by work orders through-out production. The work order accompanies products as they move through work stations (refer to Procedure QP708: Production Work Order and History Record) and are kept with the materials or retained by the supervisor of the areas where the associated product is being processed.

Alternative or additional safeguards are for the bin or container holding the components to be identified with the part numbers or for the parts themselves to be marked with the number directly.

## Identification of finished product

Finished products are identified by a label, permanently affixed to the product. The label includes:

* the name and model of the product
* the name, address and phone number of the manufacturer
* a unique serial number

Labels are designed, manufactured, controlled and applied in accordance with Procedure *QP713: Labelling and Packaging*.

Labels for small devices may be on the container in which they are packed. Edit the above as applicable to the company. The identification may contain any information that uniquely identifies the product. Delete references to serial numbers if not relevant.

Identification of finished products is verified at final inspection (refer to Procedure Q*P804: Final Acceptance Inspection*).

## Identification of returned product

Products returned for servicing are brought to the service desk in the service department and tagged with a job number. This process is described in Procedure QP711: Installation *and Servicing*.

Delete this clause if products are not received for servicing.

New products returned for exchange, refund or some other reason are labelled HOLD and placed in a designated holding (quarantine) area.

Where biological contamination is possible or suspected, the products are labelled BIO HAZARD and transferred to a decontamination area (refer to Procedure *QP709: Cleanliness and Control of Product*).

Delete the above clause if biological contamination is not an issue. Adjust procedure QP709 accordingly.

## Traceability

Traceability is only required for implantable and active implantable devices. However, it is common practice for most companies to maintain some degree of traceability of their product and its components.

ISO 13485 specifies, “In defining the records required for traceability, the organization shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements.” It may therefore be important to retain records of the environmental conditions under which the product was manufactured.

Traceability also extends to distribution of the finished product. The standard specifies, “The organization shall require that its agents or distributors maintain records of the distribution of medical devices to allow traceability and that these records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained.”

If traceability is not required, specify this in the quality manual, delete this section from the procedure and remove traceability from the title.

This procedure addresses both regulatory and voluntary systems of traceability - modify as appropriate.

Traceability is maintained for regulatory requirements and/or for internal needs, to facilitate corrective actions. Traceability is based on identifying components and finished product or batches with unique control numbers and on recording environmental conditions under which the device is manufactured.

Edit to reflect whether individual products or batches are tracked or date/time stamps are used, etc.

Where traceability is a regulatory requirement, the Engineering, Production and QA Managers identify the parts, components and environment for which traceability is needed.

The selection process focuses on components and systems which could result in sudden, catastrophic device failure and that could be expected to cause significant injury to the end user.

Traceability requirements must be justified and the justification documented in the Device Master Record (refer to Procedure QP402: Device Master Record).

Expand this section to explain in more detail how the selection of components for traceability is made and justified. It may also be necessary to justify why components are not traced.

Where traceability is not a regulatory requirement, QA may specify some traceability to facilitate corrective and preventive actions or to address other needs. This is based on specific internal needs, e.g. to:

* support a system of configuration management
* facilitate processing of warranty claims
* collect data for performance or reliability studies
* monitor performance of a supplier
* manage legal risks

The extent of traceability includes:

* serial or batch or lot numbers
* identification of purchase orders for critical materials and components
* identification of key process and inspection equipment
* identification of production operators and inspectors
* process parameters for selected manufacturing processes
* environmental monitoring data
* inspection and test procedures and results

The traceability information required for a product is identified and recorded in the work order for that product (refer to Procedure Q*P708: Production Work Order and History Record*).

Add to or delete from the above list, as applicable. Explain how traceability requirements are documented. This procedure assumes that work orders are used.

## Traceability records

Edit this section to reflect the company’s actual procedures and practices.

Purchase orders provide the link between purchased materials, parts and components and the final manufactured product. Records include:

* materials certificates
* certificates of analysis
* inspection and test reports

Work orders are the traceability record linking the product to its production history. Additionally, some data may also be recorded in logs, tables or databases associated with a work station or processes. Work orders and other records are maintained in the Device History Record.

## Acceptance status identification

This section follows the Quality Manual section 7.5.3 and procedures QP707, QP803 and QP804. Ensure that these are coordinated and do not conflict.

The status of both passed and failed materials must be identified at all times, either by labelling or by secure segregation/quarantine. (It is not sufficient to label rejected materials and assume unlabelled materials are satisfactory.) The standard specifically requires that all materials are identified at all times.

In order to prevent misuse of non-conforming materials, the pass/fail status of parts, components, intermediates or product must be clearly identified after each inspection or test.

The status of product is identified by a label marking or location. Where location is the only means of identification, the location is clearly marked and segregated to prevent mixing with products with a different status.

Identification of acceptance status is described in the following documents:

* Procedure QP707: Verification of Purchased Product
* Procedure QP803: In-Process Inspections
* Procedure QP804: Final Acceptance Inspection.

Non-conforming products are labelled REJECTED with sticker or label and/or are quarantined in a secure location. Whenever non-conforming product is identified, the non-conformity is documented using a Non-Conformance Report (NCR) as per Procedure *QP805: Control of Non-conforming Product*.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP402 | Device Master Record |
| QP707 | Verification of Purchased Product |
| QP708 | Production Work Order and History Record |
| QP709 | Cleanliness and Control of Product |
| QP711 | Installation and Servicing |
| QP713 | Labelling and Packaging |
| QP803 | In-Process Inspections |
| QP804 | Final Acceptance Inspection |
| QP805 | Control of Non-conforming Product |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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