KWELL Laboratories	**Document Number:**	SOP-018
	Version:	1
	IDENTIFICATION AND TRACEABILITY	

1 PURPOSE

1.1 The purpose of this procedure is to define the activities related to the identification and traceability of Kwell Laboratories materials and products in accordance with 21 CFR 820.60, 65, 86 and ISO 13485:2016 section 7.5.8, 7.5.9.

2 SCOPE

2.1 This document applies to the identification and traceability of materials, parts, subassemblies and other components; finished products at the design, clinical, and commercial levels; and customer property.

2.2 This document does not apply to exploratory work for part and product investigations and evaluations.

3 REFERENCES

3.1 SOP-001 *Document Control*

3.2 SOP-004 *Risk Management*

3.3 SOP-016 *Incoming Inspection*

3.4 SOP-017 *Handling, Storage and Distribution*

3.5 SOP-020 *Control of Nonconforming Materials*

3.6 21 CFR 820 *Quality System Regulation* (US FDA)

3.7 ISO 13485:2016 *Medical devices – Quality management systems – Requirements for regulatory purposes*

4 RESPONSIBILITIES

4.1 **ENGINEERING AND QUALITY ASSURANCE (QA)** are responsible for ensuring that all parts, processes, and products requiring traceability are assigned unique part and process numbers.

4.2 **MANUFACTURING** is responsible for ensuring that all parts and products requiring traceability are assigned unique lot numbers.

4.3 **QUALITY ASSURANCE** will maintain all records to ensure timely retrieval of traceability documentation.

NOTE: Where responsibility for identification and traceability is outsourced to an authorized supplier, the identification and traceability procedures in use by that supplier may be used on behalf of Kwell Laboratories.

5 DEFINITIONS

5.1 Not Applicable

6 PROCEDURE

6.1 Identification

6.1.1 Identification of Purchased Products

6.1.1.1 Purchased materials, parts, and components are identified by marking, labeling, or tagging the packaging or containers holding them and, when appropriate and practical, by labeling the products themselves.

6.1.1.2 The items shall be identified with the unique part number, part revision, Kwell Laboratories and/or supplier lot number, quantity, acceptance status, and expiration date (if applicable).

6.1.1.3 Product identification shall be maintained while the products are in storage and/or are staged for production.

6.1.2 Identification of Finished Products

6.1.2.1 Finished products are identified by a label that is permanently affixed to the product.

6.1.2.2 The identification label includes the name and model of the product; the name, address, and phone number of the manufacturer; the lot number; the expiration date (if applicable); and other regulatory required labels (as required).

6.1.2.3 The labels are designed, manufactured, controlled, and applied.

6.1.2.4 Identification of finished products is verified at final inspection.

6.2 Traceability

6.2.1 Traceability includes the following:

6.2.1.1 Serial or batch numbers or identification of Purchase Orders (POs) for critical materials and components used

6.2.1.2 Identification of key process and inspection equipment and their operators

6.2.1.3 Process parameters for selected manufacturing processes

6.2.1.4 Inspection and testing results and identification of inspectors

6.2.1.5 Identification of personnel performing final labeling operations

6.2.1.6 Shipment of finished goods

6.2.2 Kwell Laboratories shall establish and maintain a record for each medical device or batch of medical devices that provides traceability to the extent specified in **Section**

6.1.3 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.

6.2.3 The traceability information required for a given product is documented within associated receiving documentation, production work orders, device history records (DHRs), and processed shipping orders for the product maintained in accordance with SOP-001 *Document Control*.

6.3 Traceability Maintenance

6.3.1 All employees involved with traceable materials/ processes must be trained for additional requirements and the need to report all exceptions to management and QA as soon as they occur.

6.3.2 If traceability was to be lost, the following steps are required and coordinated by QA:

6.3.2.1 Immediate notification of management

6.3.2.2 Operations affected must be suspended until traceability is restored

6.3.2.3 Physical inventory of all affected materials/ processes must be taken to establish a base for the investigation and to create a starting point when the operation is resumed

6.3.2.4 A Nonconforming Report (NCR) must be initiated

6.3.2.5 A risk assessment of the event must be completed

6.3.3 Upon completion of the foregoing, distribution operations are resumed.

6.4 To maintain traceability of product once it has been packaged and distributed, Lot Numbers will be assigned to each lot of devices manufactured.

6.5 If there is an issue with the identification or traceability of materials, parts, subassemblies and other components, or finished products at the design, clinical, or commercial levels, a Nonconformance Report shall be initiated.

7 FORMS

7.1 Not Applicable

8 RECORDS

8.1 Purchased materials, components, and parts requiring traceability are documented via Purchase Orders and Incoming Inspection records.

8.2 Distributed products requiring traceability are documented via DHR and will contain part numbers and lot numbers for all materials and components used to distribute the devices.

8.3 All records are kept in accordance with SOP-001 *Document Control*.

9 VERSION HISTORY

Version	C.O. Number	Description of Change
0	CO-14	New Document
1	CO-32	Clerical correction – corrected document number in header