



SOP 3 - Traceability and Audit Trail

SOP Number	SOP-03
Title	Traceability and Audit Trail for Comfort Kits
Location	Secure Production Room - Clubclass / Dr Sunshine Records
Responsible	Quality Director

Purpose

To ensure that every Comfort Kit produced by Dr Sunshine can be traced from production through purchase and final distribution. This traceability system provides transparency and accountability, confirming that all pre-purchased Comfort Kits are assembled and delivered as intended.

Scope

This SOP applies to all Comfort Kits produced, sold and distributed by Dr Sunshine. It covers the recording of information relating to:

- Batch production
- Individual kit identification
- Customer details
- Recipient details
- Traceability records

Procedure

1. Batch Production Identification

Comfort Kits are produced in batches. Each batch is assigned a unique batch number.

Example:

Batch 01 - 50 kits

Batch 02 - 50 kits

Batch numbers are recorded on the production board and in the traceability record.

2. Individual Kit Identification

Each Comfort Kit receives a unique identifier consisting of:

- Batch number
- Kit number within the batch

Example - Batch 03 Kit 017

This identifier is written on the label attached to the kit.

3. Recording Customer Details

When a Comfort Kit is purchased, the following information is recorded in the traceability record:

- Kit identifier (Batch + Kit number)
- Name or redacted reference of the customer
- Contact number of the customer

Customer details may be partially redacted to protect privacy while still maintaining accountability.

4. Recording Recipient Details

When a Comfort Kit is delivered, the following information is recorded:

- Kit identifier (Batch + Kit number)
- Contact number of the recipient (where available)
- Date of distribution

This allows the team to confirm that the kit has been delivered to a recipient.

5. Traceability Record

All information is recorded in a central traceability log maintained by the Quality Director.

The traceability record includes:

- Batch number
- Kit number
- Customer reference
- Customer contact number
- Recipient contact number (if available)
- Distribution date

This record allows the team to confirm the complete journey of every Comfort Kit.

Quality Control Check

QC 5 - Traceability Verification

Each kit must be traceable.

Outcome - The full audit trail of the kit is confirmed.

Continuous Improvement

The traceability system supports:

- Transparency with customers
- Verification that all purchased kits are produced and distributed
- Accurate reporting of programme impact

Record Keeping

- Traceability records are stored in a secure digital document.
- Access is restricted to the Quality Director and authorised team members.
- Records are retained for reporting and audit purposes.

Approved by Giuseppe Ciliberti - Quality Director

Date 5th January 2026