



DN 3141: SciLog Certificate of Compliance Released: 8/2/10

Title: Sensor Material, Production, Calibration, Storage & Shipment

This document applies to SciLog P/N: 080-594PS(X), 080-595PS(X), 080-596PS(X), 080-597PS(X), 080-599PS(X), 080-694PS(X), 080-695PS(X), 080-696PS(X), 080-697PS(X), 080-699PS(X), 080-794PS(X), 080-795PS(X), 080-796PS(X), 080-797PS(X), 080-799PS(X)

SciLog Inc. manufactures disposable, pre-calibrated sensors (pressure, conductivity & temperature) for use in biopharmaceutical laboratories, pilot plants and production facilities. The pre-calibrated sensors are intended for single-use purification applications. Each sensor has a unique Sensor ID number. Sensor-specific calibration data and ID number are stored in gamma-stable sensor memory. The stored data is stable for at least two years or longer.

Sensor Material: Fluid contacting surfaces are made of medical-grade polysulfone meeting USP Class VI. Sensing elements meet USP Class VI and USP Class V specifications. Sensors and sensor material has been performance-tested (see www.scilog.com) after exposure to:

1. **Gamma Irradiation** (34kGy), SciLog DN:3129, DN:3140, DN:3142, DN:3151
2. **Autoclaving** (123°C, 20psi, 30min), SciLog DN:3131, DN:3130, DN:3127
3. **pH 14** (100hr Exposure Test), SciLog DN:3124, DN:3123, DN:3135
4. **pH 2** (100 hr Exposure Test), SciLog DN:3137, DN:3138
5. **70% Isopropyl Alcohol** (100 hr Exposure Test), SciLog DN: 3125; DN:3126
6. **Sanitization**, SciLog DN:3016, DN:3021, DN:3022, DN:3023
7. **Material Compliance:** DN:3142 (Latex), DN:3147 (BSE), DN:3148 (USP), DN:3149 (USP Tox)

Sensor Production: SciLog maintains material, production and lot compliance documentation by Sensor ID. Sensors are lot traceable by Sensor ID. Compliance testing of sensor inventory is carried out at regular intervals. Sensors are manufactured in Class 100 000 environment.

Sensor Factory Calibration: All sensors are pre-calibrated and ready for use. Sensor-stored calibrations are stable for at least two years. All sensor factory calibrations are carried out with NIST-traceable equipment and NIST-traceable standard solutions at 25.0°C. SciLog maintains data base of sensor calibrations by Sensor ID. SciLog provides a Calibration Certificate for each sensor by Sensor ID. "Out-of-Box" sensor performance documentation is available, SciLog DN:3134, DN:3132, DN:3133.

Sensor Storage & Shipment: All SciLog sensors are stored & shipped in sealed, plastic Tyvek pouches. Gamma irradiated sensors are stored and shipped in double pouches.

Monitor Re-Certification: All SciLog Monitors are factory calibrated and should be re-calibrated annually. A re-calibration service is available. (SciLog DN:3112).

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