

# SUMMARY OF LEGAL & REGULATORY REQUIREMENTS

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Requirement	Reference
Medical Device Regulations (UKCA Compliance)	UK Medical Devices Regulations 2002 (SI 2002/618)
Small steam sterilizers performance	BS EN 13060:2014+A1:2018
Sterilization validation & monitoring	ISO 17665-1:2006, BS EN ISO 14937:2009
Construction & safety features	BS 3970-4:2021
Health Technical Memorandum (HTM) compliance	HTM 01-01 Part C (Steam Sterilization)
Waste disposal & infection control	HTM 07-01

## FINAL NOTES

If you operate a CQC-registered healthcare setting, your sterilization process should align with CQC's fundamental standards (including Regulation 15: Premises and Equipment).

In dental practices, autoclaves should also comply with FGDP and HTM 01-05 standards.

### TABLETOP AUTOCLAVE COMPLIANCE CHECKLIST

(For healthcare, dental, and aesthetics settings in the UK)

#### 1. Regulatory Compliance

- UKCA or CE Marking (for devices used in Northern Ireland)
  - Verify that the autoclave has UKCA marking (formerly CE marking) as per the UK Medical Devices Regulations 2002 (SI 2002/618).
- Compliance with BS EN 13060 (Small Steam Sterilizers)
  - Ensure the autoclave meets BS EN 13060:2014+A1:2018 standards for Type B, S, or N sterilizers.
- CQC Compliance (if applicable)
  - If operating in a CQC-registered setting, ensure compliance with Regulation 15 (Premises and Equipment) and infection prevention guidance.
- HTM 01-01 Part C Compliance (NHS & regulated environments)
  - Follow the sterilization guidelines in Health Technical Memorandum (HTM) 01-01: Part C for decontamination and sterilization.
- Infection Control Compliance
  - Ensure compliance with Health and Social Care Act 2008 (Code of Practice on Infection Prevention & Control).
- Waste Management Compliance (HTM 07-01)
  - Follow HTM 07-01: Safe Management of Healthcare Waste for disposal of sterilized waste materials.

#### 2. Installation & Validation

- Initial Validation & Performance Qualification (PQ)
  - Ensure the autoclave undergoes installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) as per ISO 17665-1:2006.
- Sterilization Cycle Validation
  - Confirm that sterilization cycles effectively kill biological indicators (BI) tests at 121°C or 134°C).

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### 3. Routine Maintenance & Testing

Daily Checks

Check water levels and ensure filters are clean.

Weekly Testing

Conduct a biological indicator (spore test) to validate sterilization efficacy.

Run an automatic control test cycle quartly

Monthly & Periodic Checks

Check and replace door seals if necessary.

Annual Service & Calibration

Schedule a professional service and calibration to verify pressure, temperature, and sterilization efficacy.

### 4. Record-Keeping & Documentation

Sterilization Logbook

Maintain a record of each sterilization cycle.

Validation & Maintenance Records

Keep annual inspection and maintenance certificates for regulatory inspections.

Incident & Non-Conformance Reporting

Log any sterilization failures or deviations and take corrective actions.

Operator Training Records

Document staff training and competency assessments for autoclave operation and infection control.

### 5. Safe Use & Staff Training

Operator Training

Ensure all staff using the autoclave are trained on:

Proper loading and unloading procedures.

Recognizing and responding to cycle failures.

PPE requirements (gloves, heat protection if needed).

Emergency Procedures

Have procedures in place for power failures, pressure malfunctions, and failed sterilization cycles.

Risk Assessments

Conduct risk assessments for autoclave use, considering steam burns, pressure hazards, and biohazard waste handling.

### FINAL COMPLIANCE CHECK

If ALL boxes are ticked, your tabletop autoclave is compliant with UK regulatory and safety standards.