Cosmetic Surgery
OF
THE ROYAL
LIVER BUILDING

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 quartley

✅ 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.