Medical Uniform Compliance Document Checklist

Healthcare & Medical Uniform Solutions — LantaoWork.com

Purpose

An audit-ready compliance document checklist covering antimicrobial, fluid barrier, chemical safety, and regulatory pathway requirements for medical uniforms. Use this checklist before every accreditation survey, procurement cycle, or supplier review.

Section 1: Antimicrobial & Performance Testing

- [ ] **AATCC TM100 — Quantitative Antibacterial Finish Assessment** — Per-batch third-party lab report from ISO 17025-accredited lab. Must show: test organism, contact time, inoculum concentration, % reduction vs. control, pass/fail against ≥99% criterion. Report date within 12 months.
- [ ] **ISO 20743 — Determination of Antibacterial Activity** — Supplementary international standard. Required for global procurement programs referencing ISO rather than AATCC methods.
- [ ] **AATCC 147 — Antibacterial Activity Assessment (Qualitative)** — Zone of inhibition test. Supplementary to quantitative TM100 data. Useful for visual demonstration of antimicrobial activity.
- [ ] **ISO 15797 — Industrial Laundering Simulation** — After-laundering test reports for dimensional stability, colorfastness, seam integrity at 100+ cycles at 60-75°C. AUDIT CRITICAL
- [ ] **Chlorine Bleach Fastness (ISO 105-C06 / AATCC 61)** — ≥Grade 4 after specified wash cycles. Required for facilities using chlorine-based disinfection laundry protocols.

Section 2: Fluid Barrier (AAMI PB70)

- [ ] **ANSI/AAMI PB70 Level Classification** — Specify Level 1, 2, 3, or 4 based on intended use. Level 2 typical for general medical uniforms with fluid contact risk.
- [ ] **AATCC 42 — Water Impact Penetration Test** — Per-batch test report. Level 2 limit: ≤ 4.5g penetration.
- [ ] **AATCC 127 — Hydrostatic Pressure Test** — Per-batch test report. Level 2 limit: ≥ 20 cm H_2O.

Section 3: Chemical Safety & Restricted Substances

- [ ] **OEKO-TEX Standard 100 — Class I or II Certification** — Current certificate. Class I: products for babies/sensitive skin (direct skin contact, extended wear). Class II: products with direct skin contact (scrubs, underscrubs). Verify certificate number at oeko-tex.com.
- [ ] **REACH Regulation (EC) No. 1907/2006 Compliance** — Documentation for all chemical substances in fabric, dyes, and finishes. SVHC (Substances of Very High Concern) declaration if applicable.

- [ ] **California Proposition 65** — Compliance documentation if products ship to California. Required for any detectable level of listed chemicals.
- [ ] **CPSIA (Consumer Product Safety Improvement Act)** — For children's medical garments (pediatric scrubs). Lead content and phthalate testing.

Section 4: Regulatory Pathway Documentation

- [ ] **FDA Registration Pathway** — Medical textiles with antimicrobial claims may require FDA establishment registration and device listing. Confirm classification (Class I exempt, Class II 510(k)) with regulatory counsel. Obtain FDA Establishment Registration number if applicable.
- [ ] **CE Marking / EU MDR 2017/745** — For EU-bound medical textiles. Confirm classification (Class I, Class IIa). Obtain CE certificate and Declaration of Conformity from Notified Body if applicable.
- [ ] **UKCA Marking (UK market)** — For UK-bound medical textiles post-Brexit. Confirm applicable UK Approved Body requirements.
- [ ] **TGA (Australia)** — For Australia-bound medical textiles. Confirm ARTG listing requirements if applicable.

Section 5: Sustainability & Social Compliance

- [ ] **GRS (Global Recycled Standard)** — Current certificate if using recycled polyester. Verify certificate at textileexchange.org.
- [ ] **BSCI / Sedex / WRAP Social Compliance** — Current audit report with score and validity date. SMETA 4-pillar audit preferred for healthcare procurement.
- [ ] **ISO 14001 Environmental Management** — Current certificate. Scope must include textile/apparel manufacturing.

Section 6: Supplier Quality Management

- [ ] **ISO 9001:2015** — Current certificate. Scope must include medical apparel manufacturing. Verify through issuing body's online directory.
- [ ] **Supplier Audit Report** — Most recent on-site quality audit. Third-party or internal with documented auditor qualifications.
- [ ] **Corrective Action Log** — Documented CAPA (Corrective and Preventive Action) system. Evidence of closed-loop quality issue resolution.

Section 7: Per-Shipment Documentation Package

> **This is what should arrive with every shipment:**

- [ ] Batch-level AATCC TM100 + ISO 20743 antimicrobial test reports
- [ ] Batch-level AATCC 42 + AATCC 127 fluid barrier test reports (if applicable)

- [ ] ISO 15797 industrial wash durability verification
- [ ] Spectrophotometer ΔE color reading vs. approved seal sample
- [ ] QC inspection photos from all 3 gates (incoming, in-line, pre-shipment)
- [ ] OEKO-TEX Standard 100 certificate (current, within validity period)
- [ ] Packing list with batch traceability numbers cross-referenced to test reports

> **Pro Tip:** Create a digital compliance binder organized by shipment/batch. When the surveyor arrives, you hand them one file — not a folder of scattered PDFs from different suppliers with different formats. This alone can reduce survey prep time from 3 days to 30 minutes.