SUPPLY CHAIN QUALIFICATION CHECKLIST ULTRAVIOLET LIGHT

(UV) DEVICE PROCUREMENT

Description of Item(s) to be Purchased:

Requested Supplier:

Person requesting the Purchase: Date:

This document can be used to qualify and verify all regulatory, product safety, environmental efficacy and quality requirements have been considered prior to purchasing.

Provide the names, titles and dates of employees who participated in the product qualification.

NAME	DEPARTMENT	DATE OF QUALIFICATION

GENERAL REQUIREMENTS:

The product needs to comply with specific requirements, standards or regulatory bodies. Please indicate verification of compliance by answering yes and include the name, department and date of verification.

1. Vendor & Supplier Qualification Checklist

- ☐ Quality Management System (QMS): ISO 13485:2016 certification documentation reviewed
- ☐ Regulatory Compliance: FDA authorization (De Novo) or clearance (510(k)) for Whole Room Microbial Reduction devices and device listing verified
- ☐ Supplier Risk Assessment: UV Supplier categorized (Tier 1 – High / Tier 2 – Medium / Tier 3 – Low)
- ☐ Well Established: UV Supplier and its products are well established in healthcare and documented history of stable, long-term operations
- ☐ Technical Verification: Vendor capacity to scale production and meet quantity requirements verified

2. Product & Equipment Qualification Checklist

- [ ] Technical Specifications: UV Product data sheets meet the product safety standards required by FDA
- [ ] Compatibility: UV Product compatibility with existing systems and infrastructure confirmed
- [ ] Clinical Effectiveness: Microbial reduction claims have been validated and meet FDA requirements
- [ ] Product Safety Features: UV Product safety features include sensor motion detection and the ability to manually stop device operation from outside the room.
- [ ] Usability: Ease of use, maintenance, and ergonomic considerations assessed
- [ ] Supports Value Based Purchasing (VBP): UV supplier documentation on impact to VBP

3. Supply Chain & Operational Logistics Checklist

- [ ] Warranty and Support: Warranty terms, SLAs, and post-market support documented
- [ ] Packaging & Transport: Packaging validated to prevent damage
- [ ] Training Availability: Virtual and on demand resources available to hospital staff for training on operation and maintenance

4. Documentation & Compliance Requirements

- [ ] Medical Device File (MDF)
- [ ] QMSR Alignment: Supplier compliance with FDA QMSR (21 CFR 820) and ISO 13485 confirmed
- [ ] Quality Agreement: Executed quality agreement defining roles, responsibilities, and audit rights

5. Post-Purchase Monitoring

- [ ] Supplier Review: Ongoing assessment of delivery, quality, and responsiveness conducted
- [ ] Performance Monitoring: Reporting capabilities and/or periodic review of UV device utilization
- [ ] Post Sale Support: Provides or makes available tools for ongoing training, and UV product support