Sub-contractor Quality Agreement Standard Terms - Medical CE & FDA Technical Compliance Register

# SUB-CONTRACTOR QUALITY AGREEMENT STANDARD TERMS

## EXECUTIVE SUMMARY

This document delineates the mandatory quality and regulatory compliance framework governing all sub-contractor engagements for the manufacture, assembly, and testing of medical aesthetic devices. As an OEM manufacturer operating under the stringent purview of FDA 21 CFR Part 820 and the European Medical Device Regulation (MDR) 2017/745, this Quality Agreement establishes the non-negotiable baseline for product safety, traceability, and performance. All sub-contractors must adhere to these terms to ensure that finished devices meet the specified clinical performance standards, thereby safeguarding patient outcomes and maintaining our market authorization.

## CLINICAL ARCHITECTURE & DESIGN COMPLIANCE

The design transfer process mandates that all sub-contractor manufacturing activities strictly mirror the Design History File (DHF) and Device Master Record (DMR). Sub-contractors are required to implement a process validation protocol, including Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ), for all critical production and test equipment. The agreement explicitly prohibits any deviation from approved component sourcing, assembly procedures, or software build versions without prior written authorization from the OEM's Quality Assurance (QA) department. This ensures that the clinical architecture—encompassing the optical source, delivery system, and user interface—remains perfectly congruent with the pre-market clinical evaluation data.

## KEY INDICATIONS & CAPABILITIES (AS PER AGREEMENT)

The Quality Agreement stipulates that the manufacturing process must consistently produce devices capable of delivering therapeutic energy parameters as specified in the cleared Indications for Use (IFU). Sub-contractors shall have in place robust capability studies (e.g., Cpk > 1.33) for key performance metrics such as wavelength accuracy, pulse duration, and energy fluence. This framework guarantees that every unit produced meets the clinical capability required for effective treatments across all cleared indications, including hair removal, vascular lesions, and skin rejuvenation, without relying on end-user calibration.

## COMPLIANCE & STANDARDS

Adherence to ISO 13485:2016 is the bedrock of this agreement. Sub-contractors must maintain an effective Quality Management System (QMS) subject to unannounced audits by the OEM and its Notified Bodies. Furthermore, the agreement mandates compliance with IEC 60601-1 (Medical Electrical Equipment Safety) and IEC 60825-1 (Laser Product Safety). The sub-contractor is contractually obligated to report any safety incidents, non-conformances, or corrective actions (CAPAs) to the OEM within 24 hours of detection. Full traceability of components (from raw materials to serial number

assignment) is a contractual prerequisite.

TECHNICAL SPECIFICATIONS (PRODUCTION TOLERANCES)

The following production tolerances and environmental conditions are set forth to ensure output consistency. The sub-contractor is responsible for ensuring that all test equipment utilized for final verification is certified and traceable to national or international standards.

| **Parameter** | **Specification (Sub-contractor Compliance Mandate)** |
|---|---|
| Laser Type / Wavelength Tolerance | ± 3 nm (e.g., 808nm ± 3nm) |
| Energy Fluence Consistency | ± 5% across treatment area (e.g., 10 J/cm² ± 0.5 J/cm²) |
| Cooling System Performance (Cryo) | Sapphire tip surface temperature maintained at -5 °C to 0 °C within 2 seconds |
| Spot Size Uniformity | Energy density variation < 5% across the entire spot dimension (e.g., 15x15mm) |
| Pulse Duration Accuracy | ± 2% of set value (e.g., 100ms ± 2ms) |

CLINICAL PROTOCOLS (POST-MARKET SURVEILLANCE)

In alignment with the OEM's post-market surveillance (PMS) obligations under MDR and FDA regulations, the sub-contractor agrees to a 5-year record retention policy for all production and test records. These records must be made available to the OEM and regulatory authorities upon request. The agreement includes provisions for a closed-loop feedback system, where clinical complaints received from the field are systematically reviewed to implement manufacturing process improvements. This proactive approach ensures that the manufacturing workflow continuously evolves to enhance device safety and treatment efficacy, solidifying the sub-contractor's role as a critical partner in patient care.