Supplier Qualification Records Redacted Excerpt - Official Clinical Overview & Technical Datasheet

EXECUTIVE SUMMARY

The Supplier Qualification Records Redacted Excerpt represents a curated disclosure of verified manufacturing, quality assurance, and regulatory compliance data pertaining to a premier medical aesthetic device platform. This document serves as an authoritative reference for clinical procurement teams, regulatory affairs specialists, and med spa operators evaluating the supply chain integrity of advanced dermatological systems. The redacted nature of these records ensures proprietary supplier identities remain confidential while demonstrating adherence to ISO 13485:2016, FDA Quality System Regulation (21 CFR Part 820), and EU MDR 2017/745 requirements. The underlying device architecture supports multi-wavelength selective photothermolysis, epidermal cooling, and high-fluence energy delivery for indications including hair removal, vascular lesion clearance, and pigmented lesion treatment. All qualification data has been independently audited and verified across a three-tier supplier network.

CLINICAL ARCHITECTURE & DESIGN

The device platform operates on a modular hardware topology comprising a diode laser stack, a thermoelectric cooling engine, and a sapphire-tipped handpiece with integrated water circulation. The supplier qualification records confirm that all critical components—including laser bars, optical fibers, and control PCBs — are sourced from facilities holding current ISO 13485 certification and FDA registration. The chassis is constructed from medical-grade ABS and aluminum alloy, designed for continuous operation in clinical environments. The redacted excerpt validates that each supplier maintains a documented traceability system from raw material to finished assembly, with batch-level records available upon regulatory request.

KEY INDICATIONS & CAPABILITIES

The system is qualified for use in the following clinical applications: permanent hair reduction across all Fitzpatrick skin types (I – VI), treatment of benign vascular lesions including telangiectasia and hemangiomas, and clearance of epidermal and dermal pigmented lesions. The supplier qualification records confirm that all optical components meet the required damage threshold and wavelength stability tolerances. The device supports spot sizes ranging from 6mm to 15mm × 15mm square, with pulse durations from 10ms to 400ms and fluence up to 120 J/cm². The cooling system—comprising TEC, sapphire, water, and forced air — is qualified for continuous operation without thermal drift exceeding ±2°C.

COMPLIANCE & STANDARDS

The redacted excerpt demonstrates that all suppliers have been audited against the following standards: ISO 13485:2016 (Medical Devices Quality Management), ISO 14971:2019 (Risk Management), IEC 60601-1 (Electrical Safety), IEC 60601-1-2 (EMC), and IEC 60825-1 (Laser Safety). The device carries CE marking under EU MDR 2017/745 and is listed with the FDA under 510(k) clearance. Supplier qualification records confirm that all manufacturing sites maintain active registration with the relevant notified bodies and have passed unannounced surveillance audits within the last 12 months.

TECHNICAL SPECIFICATIONS

The following specification matrix is derived directly from the redacted supplier qualification records and represents the verified performance envelope of the platform.

Parameter	**Specification**
Laser Type / Wavelength	808nm Diode / 755/808/1064nm
Spot Size	6mm, 10mm, 15×15mm
Cooling System	TEC + Sapphire + Water + Wind
Fluence Range	10–120 J/cm²
Pulse Width	10–400ms
Repetition Rate	1–10 Hz
Electrical Requirements	110–240V, 50/60Hz, 2000VA
Dimensions (Chassis)	450mm × 400mm × 1200mm
Weight	45 kg
Supplier Certifications	ISO 13485, FDA, CE, IEC 60601-1
Traceability	Batch-level, audited annually
Warranty	24 months, parts and labor

CLINICAL PROTOCOLS

Qualified treatment protocols are embedded in the device firmware and are based on validated clinical studies. The supplier qualification records confirm that all energy delivery parameters are calibrated at the factory using NIST-traceable instrumentation. Recommended protocols include: hair removal (fluence 10–40 J/cm², pulse width 30–100ms, spot size 15 × 15mm), vascular lesions (fluence 40–80 J/cm², pulse width 10–30ms, spot size 6–10mm), and pigmented lesions (fluence 20–60 J/cm², pulse width 10–20ms, spot size 6–10mm). All protocols require the sapphire cooling tip to be in direct contact with the skin at 0–5°C.