

Medical CE & FDA Technical Compliance Register: Environmental Compliance

Audit Report Excerpt

REGULATORY COMPLIANCE

This Environmental Compliance Audit Report Excerpt constitutes a formal component of the technical file maintained for the subject medical aesthetic device platform. The document establishes verified conformity with applicable environmental directives, hazardous substance restrictions, and electronic waste management protocols governing the manufacture, distribution, and end-of-life disposition of the equipment. All findings presented herein derive from independent third-party audit procedures conducted in accordance with ISO 14001:2015 and ISO 17025:2017 accreditation standards.



ROHS & WEEE DIRECTIVE CONFORMANCE

The device chassis, handpiece assemblies, and electronic control subsystems have been audited for compliance with Directive 2011/65/EU (RoHS 3) and Directive 2012/19/EU (WEEE). Testing confirmed the absence of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers above maximum concentration thresholds of 0.1% by weight in homogeneous materials, with the exception of cadmium, which remains below 0.01%. The audit additionally verified the presence of approved exemption applications for specific solder alloys utilized in high-reliability laser diode driver circuits.

REACH SVHC DECLARATION

In accordance with Regulation (EC) No 1907/2006, the audit assessed the presence of Substances of Very High Concern (SVHC) within all device components. No SVHC substances exceed the 0.1% w/w threshold within any article of the equipment. Supplier declarations have been collected and verified for all Tier 1 and Tier 2 component vendors, confirming full supply chain transparency regarding restricted substance content.

TECHNICAL SPECIFICATIONS

The following matrix summarizes the environmental compliance parameters verified during the audit cycle:

Parameter	Specification
RoHS Compliance	Directive 2011/65/EU (RoHS 3) - Full Conformance
WEEE Registration	Directive 2012/19/EU - Producer Registration Valid
REACH SVHC Content	No SVHC > 0.1% w/w in any article
Packaging Directive	94/62/EC - Heavy Metals < 100 ppm total
Battery Directive	2006/66/EC - Separate Collection Compliant
ISO 14001 Certification	Manufacturing Facility Certified - Valid Through 2027
Audit Standard	ISO 17025:2017 Accredited Third-Party Assessment
Conflict Minerals	Dodd-Frank Section 1502 - CMRT Completed

DISPOSAL & RECYCLING PROTOCOLS

End-of-life disposition procedures mandate that the device not be discarded with unsorted municipal waste. The equipment shall be returned to authorized collection facilities in accordance with local WEEE transposition legislation. The manufacturer provides a take-back program for all professional-grade aesthetic platforms, ensuring controlled disassembly and material recovery. The lithium-ion battery module within the control unit requires separate collection and recycling through certified battery stewardship programs.

FINAL AUDIT VERIFICATION

Based on the evidence reviewed, the subject device platform demonstrates full conformance with the environmental compliance requirements applicable to medical electrical equipment placed on the European Union and United States markets. The audit report excerpt concludes that no non-conformances were identified during the current assessment cycle, and the device remains cleared for continued distribution under existing regulatory approvals.

