

# Engineering Verification Test (EVT) Sign-off Template - Official Clinical Overview & Technical Datasheet

## ENGINEERING VERIFICATION TEST (EVT) SIGN-OFF TEMPLATE: OFFICIAL CLINICAL OVERVIEW & TECHNICAL DATASHEET

### EXECUTIVE SUMMARY

This document serves as the definitive Clinical and Technical Datasheet for the Engineering Verification Test (EVT) Sign-off Template, a critical quality gate within the New Product Introduction (NPI) lifecycle for premium medical aesthetic devices. The EVT phase represents the inaugural convergence of theoretical design and physical hardware, validating that the core subsystems meet the fundamental clinical and safety requirements established during the Design Input phase.

This Datasheet provides an authoritative overview of the EVT Sign-off Template architecture, its role in mitigating early-stage design risks, and its function as a foundational document for subsequent Design Verification (DVT) and Production Validation (PVT) phases. The EVT Sign-off Template, when rigorously applied, ensures that the device platform is clinically viable, electrically sound, and compliant with essential safety standards before significant investment in tooling and manufacturing is committed.



## CLINICAL ARCHITECTURE & DESIGN

The EVT Sign-off Template is structured around a comprehensive evaluation of the device's core clinical architecture. This is not a superficial checklist but a deep-dive technical audit that verifies the integrity and performance of the system's primary building blocks. The template mandates a systematic review of the optical source, specifically ensuring that the laser diodes or flashlamps deliver the intended wavelengths (e.g., 808nm, 755nm, 1064nm) within the specified tolerance. Furthermore, it rigorously tests the essential safety interlocks, including the skin contact sensor, thermal monitoring systems (internal and external), and emergency stop functionality. The Template verifies that the initial mechanical design meets ingress protection (IP) requirements and is robust enough to withstand the rigors of a clinical environment.

## KEY INDICATIONS & CAPABILITIES

The primary utility of the EVT Sign-off Template is to provide a structured, objective, and data-driven methodology for evaluating the prototype's capability to perform fundamental treatment parameters. It confirms that the device can deliver the required fluence ( $J/cm^2$ ) and pulse duration (ms) ranges necessary for effective Selective Photothermolysis across a variety of skin types. The template specifically checks for the performance of key subsystems that directly impact clinical outcomes: the precision of the energy delivery system, the stability of the pulse waveform, and the efficiency of the water and TEC-based cooling mechanisms. Successful EVT sign-off is the first tangible proof that the device design is theoretically sound and practically executable.

## COMPLIANCE & STANDARDS

The EVT Sign-off Template is fundamentally a compliance document. It acts as the preliminary check against a host of international medical device standards, including IEC 60601-1 (General Safety), IEC 60825-1 (Laser Safety), and relevant ISO 13485 quality management system requirements. The template requires engineering teams to provide evidence and test results demonstrating that the device prototype meets the essential performance and safety requirements

defined by these standards. This early verification is crucial, as identifying and rectifying non-compliance issues during the EVT phase is significantly less costly and time-consuming than addressing them at later stages.

#### TECHNICAL SPECIFICATIONS (EVT PHASE FOCUS)

During the EVT phase, the following key performance parameters are stringently measured and verified against design requirements. The data collected forms the core of the EVT Sign-off report. All values are subject to final validation during the DVT phase.

Parameter	Specification
Laser Type / Wavelength	e.g., 808nm Diode / 755/808/1064nm
Peak Optical Power	e.g., 200W - 300W per laser bank
Cooling System	e.g., TEC + Sapphire + Water + Forced Air
Sapphire Tip Temperature	e.g., 5°C to 10°C (Dynamic Cooling)
User Interface	High-Resolution Capacitive Color Touchscreen
Electrical Input	e.g., 100-240V AC, 50/60Hz, 10A Max

## CLINICAL PROTOCOLS

The successful completion and sign-off of the EVT Template authorizes the engineering team to proceed to the next phase of development. The template itself defines the protocols for these initial engineering tests. These protocols include but are not limited to: optical power output and stability over time (e.g., a 30-minute run test), cooling system efficiency measurements at maximum operating power, and the verification of all user and safety interface software functions. The EVT Sign-off Template establishes the baseline for all future performance and safety benchmarks, forming the critical evidence package required for formal regulatory submissions.

