Medical CE & FDA Technical Compliance Register: 532nm 1064nm Dual Wavelength Tattoo Laser

## DEVICE IDENTIFICATION AND CLINICAL SCOPE

The 532nm 1064nm Dual Wavelength Tattoo Laser is a Class IV medical aesthetic platform engineered for the selective photothermolysis of exogenous pigmentation. This device integrates two clinically validated wavelengths within a single Q-switched or Pico-second emission architecture (model-dependent configuration), enabling operators to address both epidermal and dermal chromophores with precision. The system is indicated for professional use in dermatology clinics, medical spas, and hospital aesthetic centers.

## INTERNAL HARDWARE TOPOLOGY AND OPTICAL ARCHITECTURE

The laser cavity utilizes a solid-state Nd:YAG rod pumped by high-frequency flashlamps or diode stacks, generating a fundamental 1064nm output. Frequency doubling via a KTP (Potassium Titanyl Phosphate) crystal yields the 532nm wavelength. Optical path switching is managed by a motorized harmonic separator, ensuring <10ms transition time between wavelengths. The resonator incorporates a variable attenuator and beam expander to maintain Gaussian profile stability across the entire fluence range. Pulse generation is controlled by a real-time FPGA system, providing adjustable pulse widths from 5ns to 10ns (Q-switched configuration) or 300ps to 800ps (Pico-second configuration).

## EPIDERMAL PROTECTION MECHANISMS

A cascaded thermal management system protects the stratum corneum during high-fluence procedures: (1) Contact sapphire window at 0°C to +4°C, (2) Recirculating water chiller maintaining laser head at 20°C ± 1°C, (3) Forced air convection over thermoelectric coolers (TEC). Dynamic cooling device (DCD) with cryogen spray (optional) provides pre- and post-pulse epidermal anesthesia. Skin temperature is monitored via an integrated infrared thermistor with automatic fluence attenuation if 42°C is exceeded.

## TREATMENT ADVANTAGES AND CHROMOPHORE SPECIFICITY

- 532nm wavelength: Optimal absorption by melanin and red/yellow tattoo inks. Penetration depth ~0.5 – 1mm. Indicated for epidermal pigmented lesions (lentigos, ephelides, café-au-lait macules) and brightly colored tattoos (red, orange, yellow).

- 1064nm wavelength: Deeper penetration ~2 – 4mm, minimal melanin absorption. Indicated for professional dark ink tattoos (black, blue, green), dermal nevi, and darker skin phototypes (Fitzpatrick IV–VI).

- Dual-wavelength sequential mode: Allows single-pass clearance of polychromatic tattoos without handpiece changes.

| **Parameter** | **Specification** |
|---|---|
| Laser Type / Wavelength | 532nm (KTP) and 1064nm (Nd:YAG) dual solid-state |
| Pulse Duration (Q-switch) | 5–10 ns (software adjustable) |
| Pulse Duration (Pico option) | 300–800 ps |
| Maximum Fluence (532nm) | 1.5 J/cm² (10ns) / 0.8 J/cm² (pico) |
| Maximum Fluence (1064nm) | 12 J/cm² (10ns) / 2.5 J/cm² (pico) |
| Spot Sizes (Round) | 1mm, 2mm, 3mm, 4mm, 6mm, 8mm diameters |
| Repetition Rate | 1 – 10 Hz (single shot to continuous train) |

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|---|---|
| Cooling System | Sapphire contact cooling (0 – 4 °C) + recirculating water chiller + TEC + forced air |
| Skin Temperature Monitoring | IR thermistor with automatic safety shutoff >42°C |
| Handpiece Connection | Articulated articulating arm with internal beam homogenizer |
| User Interface | 10.4-inch capacitive touchscreen, graphical patient log, preset library (14 skin types) |
| Power Supply | 100–240 VAC, 50/60 Hz, 1500 VA max |
| Dimensions (W x D x H) | 45 cm x 55 cm x 110 cm (control console) |
| Weight | 55 kg (console + articulated arm) |
| Certifications | CE 2797 (Class IIb), FDA 510(k), ISO 13485, IEC 60825-1, RoHS 3, REACH |

REGULATORY COMPLIANCE AND QUALITY ASSURANCE

The device bears the following certifications: CE 2797 (Medical Device Regulation EU 2017/745 Class IIb), FDA 510(k) clearance KXXXXXX (pending

model-specific listing), ISO 13485:2016 manufacturing facility, IEC 60825-1:2014 laser safety classification, RoHS 3 compliance, and REACH SVHC disclosure. Optical output is validated to EN ISO 13694:2018. Electromagnetic compatibility meets IEC 60601-1-2:2014 (4th Edition). Each unit is supplied with a technical file and Declaration of Conformity.