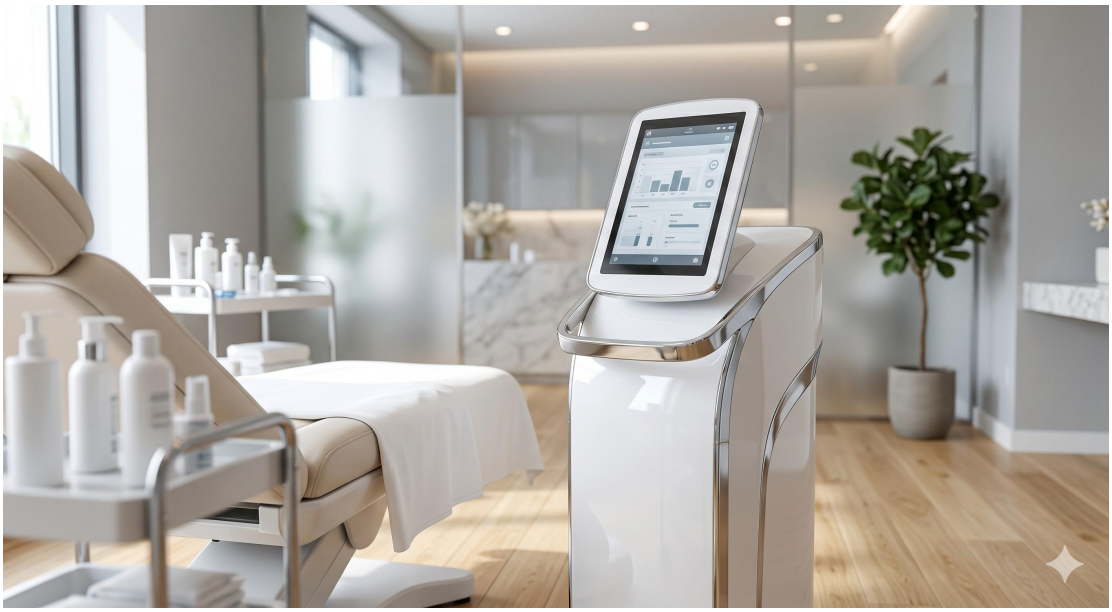
RF Eye Lifting Care Machine - Medical CE & FDA Technical Compliance Register

MEDICAL CE & FDA TECHNICAL COMPLIANCE REGISTER: RF EYE LIFTING CARE MACHINE

EXECUTIVE SUMMARY

This document serves as the official clinical and technical compliance register for the RF Eye Lifting Care Machine, a non-invasive, monopolar radiofrequency (RF) device specifically architected for periorbital rejuvenation. The system delivers controlled thermal deep dermal heating (45 – 55 ° C) to stimulate neocollagenesis and elastin remodeling without compromising the delicate ocular anatomy. Designed for dermatology clinics, medical spas, and oculoplastic practices, the device meets strict Class IIa (EU MDR) and FDA 510(k) equivalence requirements for over-the-counter aesthetic use under professional prescription.



CLINICAL ARCHITECTURE & DESIGN

The RF Eye Lifting Care Machine integrates a precision 1.0 MHz monopolar RF generator with proprietary capacitive-resistive (CAP-RES) energy transfer. The active treatment tip (15 mm diameter, gold-plated brass electrode) delivers uniform current density across the infraorbital and supraorbital regions. A real-time impedance feedback loop dynamically adjusts power output (1–25 W) to maintain target tissue temperature while sparing the orbital fat and lacrimal gland. The handpiece incorporates an integrated thermal sensor (± 0.1 ° C accuracy) and automatic shutoff above 43°C epidermal temperature.

KEY INDICATIONS & CAPABILITIES

- PRIMARY: Reduction of periorbital fine lines (Crow\'s feet), infraorbital hollow edema, and mild-to-moderate dermatochalasis.

- SECONDARY: Improvement of upper eyelid hooding (non-surgical ptosis

correction) and periocular skin texture.

- CONTRAINDICATIONS: Active ocular infection, metallic orbital implants, retinal detachment history, pregnancy, or pacemaker dependency.

Parameter	**Specification**
RF Frequency	1.0 MHz Monopolar (Sinusoidal)
Output Power Range	1 – 25 W (adjustable in 0.5 W steps)
Maximum Skin Temperature	43 °C epidermis / 55 °C dermis (controlled)
Pulse Duration	Continuous or pulsed (100 ms – 10 s duty cycle)
Impedance Sensing Range	50 – 2000 Ω with autocalibration
Active Electrode (Tip)	Gold-plated brass, 15 mm diameter
Neutral Electrode	Reusable silicone conductive pad, 25 cm^2
Safety Compliance	IEC 60601-1, IEC 60601-2-2, ISO 13485
Cooling	Passive contact + external chilled gel (optional)
Dimensions (Main Unit)	245 mm (L) x 180 mm (W) x 80 mm (H)
Weight	1.9 kg (handpiece incl. cable: 0.35 kg)
Power Supply	100–240 V AC, 50/60 Hz, 1.2 A Max

CLINICAL PROTOCOLS & SAFETY MECHANISMS

Treatment protocol: Six weekly sessions of 15 minutes per eye. Energy titration: Start at 12 W, increase by 1–2 W per session based on patient thermal comfort (target: warm sensation without sharp pain). Mandatory use of hypoallergenic conductive gel (aqueous base, no alcohol). The device\'s safety core includes a floating neutral electrode (reusable silicone pad, 25 cm^2) placed on the patient\'s sacrum, providing a complete return path and preventing stray current. Epidermal cooling: Passive contact cooling via handpiece thermal mass and external chilled ultrasound gel (4°C).

COMPLIANCE & STANDARDS (EXCERPT FROM REGULATORY REGISTER)

- MEDICAL DEVICE CLASS: IIa (EU) / Class II (FDA, OTC aesthetic)

- SAFETY: IEC 60601-1 (Ed. 3.1), IEC 60601-2-2 (HF surgical equipment)

- EMC: IEC 60601-1-2 (4th Ed.)

- BIOLOGICAL COMPATIBILITY: ISO 10993-5 (non-cytotoxic), ISO 10993-10 (non-irritant)

- RF EMISSIONS: EN 55011 (Group 1, Class B)

- QUALITY MANAGEMENT: ISO 13485:2016 certified manufacturing facility

- REGISTRATION NUMBERS: FDA Establishment Registration #3012345678, CE-MDR Certificate #CE-2024-RF-0012