

Medical CE & FDA Technical Compliance Register: Essential Health and Safety Requirements (EHSR) Checklist

STRATEGIC COMPLIANCE POSITIONING

The Essential Health and Safety Requirements (EHSR) Checklist represents the foundational regulatory instrument governing the conformity assessment of medical aesthetic devices within the European Economic Area and aligned global jurisdictions. This authoritative register delineates the mandatory safety objectives established under Annex I of Council Directive 93/42/EEC (MDD) and its successor Regulation (EU) 2017/745 (MDR), providing OEM manufacturers, notified bodies, and clinical end-users with a unified framework for verifying device safety, performance integrity, and patient protection throughout the total product lifecycle. The EHSR Checklist functions not merely as a compliance artifact but as a strategic engineering blueprint that embeds risk mitigation directly into device architecture, ensuring that every subsystem from optical delivery to thermal management satisfies the highest tier of regulatory scrutiny before market authorization is granted.



REGULATORY ARCHITECTURE & HARMONIZED STANDARDS INTEGRATION

The EHSR Checklist operates at the intersection of statutory law and applied engineering standards. Each checklist item maps directly to harmonized standards promulgated by CEN and CENELEC, including EN ISO 13485:2016 for quality management systems, EN ISO 14971:2019 for risk management, EN 60601-1:2006+A1:2013 for general electrical safety, and EN 60601-1-2:2015 for electromagnetic compatibility. The structural logic of the checklist mandates that manufacturers demonstrate conformity not through declarative assertion but through verifiable objective evidence, including type-test reports, design verification protocols, biocompatibility assessments per ISO 10993, and clinical evaluation reports per MEDDEV 2.7/1 Rev. 4. The register is organized into eleven principal domains: general requirements, chemical and biological properties, infection and microbial contamination, construction and

environmental properties, devices with a measuring function, protection against radiation, protection against excessive temperatures, protection against electrical hazards, protection against mechanical and thermal risks, protection against energy supply risks, and information supplied by the manufacturer. Compliance within each domain is binary and non-negotiable; failure in any single requirement constitutes grounds for withholding CE certification and subsequent market access.

KEY EHSR DOMAINS & APPLIED SAFETY CONTROLS

The following domains constitute the mandatory evaluation sequence for aesthetic laser and intense pulsed light platforms. General requirements demand that devices achieve the performance intended by the manufacturer under normal conditions of use, with risks reduced to the lowest practicable level consistent with the state of the art. Chemical and biological properties require assessment of patient-contacting materials, particularly handpiece optics and cooling interfaces, for cytotoxicity, sensitization, and irritation potential. Infection and microbial contamination protocols necessitate validated reprocessing instructions for reusable components, including handpiece sterilization cycles and disposable tip management. Construction and environmental properties mandate robust chassis design capable of withstanding clinical wear, transport shock, and electromagnetic interference

without degradation of safety margins. Protection against radiation encompasses optical radiation hazards per EN 60825-1, requiring precise labeling, key control interlocks, emission indicators, and protective eyewear specifications. Protection against excessive temperatures demands thermal cutoffs, continuous temperature monitoring at the sapphire interface, and automatic shutdown thresholds validated under single-fault conditions. Electrical safety verification per EN 60601-1 includes leakage current limits, dielectric strength testing, protective earthing continuity, and patient isolation diagrams. Mechanical risk controls address handpiece strain relief, cable flex endurance, and drop-test integrity.

TECHNICAL SPECIFICATIONS

The EHSR Checklist is maintained as a controlled document under the manufacturer's quality management system, with revision tracking, approval signatures, and integration into the technical file. Each checklist entry is cross-referenced to specific design verification test reports, risk management file entries, and supplier declarations of conformity. The document is subject to notified body review during initial conformity assessment and periodic surveillance audits. Non-conformities are logged in a corrective and preventive action (CAPA) system with defined remediation timelines and effectiveness verification.

EHSR Domain	Regulatory Reference	Verification Method
General Requirements	MDR Annex I, 1-9	Risk Management File per EN ISO 14971
Chemical & Biological	MDR Annex I, 10.1-10.6	Biocompatibility Testing per ISO 10993
Infection & Microbial	MDR Annex I, 11.1-11.5	Validated Reprocessing Instructions
Construction & Environmental	MDR Annex I, 12.1-12.6	Environmental Simulation Testing
Measuring Function	MDR Annex I, 13	Calibration Traceability Records
Radiation Protection	MDR Annex I, 14.1-14.7	EN 60825-1 Laser Safety Testing
Excessive Temperature	MDR Annex I, 15	Thermal Cutoff & Fault Testing
Electrical Hazards	MDR Annex I, 16	EN 60601-1 Type Testing
Mechanical & Thermal Risks	MDR Annex I, 17	Strain Relief & Drop Testing
Energy Supply Risks	MDR Annex I, 18	Single Fault Condition Validation
Manufacturer	MDR Annex I, 19-23	Labeling & IFU Review

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GLOBAL MARKET ACCESS & POST-MARKET SURVEILLANCE INTEGRATION

The EHSR Checklist does not terminate at the point of CE marking. It constitutes a living compliance instrument requiring continuous maintenance and revalidation in response to design changes, adverse event reporting, and evolving harmonized standards. Manufacturers must establish a post-market surveillance system per MDR Article 83, integrating vigilance reporting, trend analysis, and periodic safety update reports (PSURs) for Class IIb and III devices. The checklist is re-audited annually under EN ISO 13485 internal audit protocols and updated whenever a relevant standard is revised or a new clinical hazard is identified. For devices seeking FDA clearance via the 510(k) pathway, the EHSR Checklist serves as a complementary evidentiary framework supporting substantial equivalence arguments, particularly regarding safety and effectiveness endpoints. Integration with unique device identification (UDI) systems ensures traceability from component-level procurement through clinical utilization, enabling rapid field safety corrective actions when required. Ultimately, the EHSR Checklist functions as the bedrock assurance that every aesthetic device bearing the manufacturer's mark delivers measurable clinical benefit without compromising the fundamental safety contract between

medical technology and patient welfare.

