Medical CE & FDA Technical Compliance Register: Code of Conduct for Manufacturing Partners

COMPLIANCE REGISTER OVERVIEW

This document constitutes the formal Code of Conduct for Manufacturing Partners engaged in the production of aesthetic medical devices for the OEM platform. It establishes binding requirements across quality management, regulatory conformity, ethical labor practices, environmental stewardship, and supply chain integrity. Partner organizations are assessed against this register prior to onboarding and throughout the commercial relationship. Compliance is a precondition for continued authorization, not a discretionary objective.



QUALITY MANAGEMENT SYSTEM REQUIREMENTS

Partners must maintain a certified Quality Management System aligned with ISO 13485:2016 and, where applicable, ISO 9001:2015. Certification bodies must be accredited under IAF multilateral recognition arrangements. The QMS scope must explicitly cover the design, manufacture, packaging, and distribution of the specific device categories supplied. Partners shall permit scheduled and unannounced audits, maintain complete device history records, and demonstrate closed-loop corrective and preventive action (CAPA) systems. Non-conformances affecting safety or performance must be reported within 48 hours.

REGULATORY CONFORMITY AND MARKET AUTHORIZATION

All devices must carry valid CE marking under the applicable Medical Device Regulation (EU) 2017/745, supported by a notified body certificate and a current technical file. For United States distribution, partners must demonstrate compliance with FDA 21 CFR Part 820 and provide evidence of 510(k) clearance or exemption status as applicable. Technical documentation must be retained for a minimum of ten years post last manufacture. Partners shall notify the OEM immediately of any regulatory action, field safety corrective action, recall, or notified body suspension.

Compliance Domain	Requirement	Verification Method

Quality Management	ISO 13485:2016 certification	Accredited certificate and audit report
EU Regulatory	CE marking under MDR 2017/745	Notified body certificate and technical file
US Regulatory	FDA 21 CFR Part 820 compliance	510(k) clearance or exemption documentation
Labor Standards	ILO core conventions adherence	Social audit and workforce records
Material Traceability	Full critical component traceability	Lot tracking and supplier declarations
Conflict Minerals	OECD due diligence reporting	Annual disclosure statement

ETHICAL MANUFACTURING AND LABOR STANDARDS

Partners shall uphold fundamental labor rights in accordance with ILO core conventions. Employment must be freely chosen, child labor strictly prohibited, working hours lawful and documented, and wages paid fairly and on time. Freedom of association and collective bargaining shall be respected. No form of discrimination, harassment, or forced labor is tolerated. Partners must maintain

transparent records of workforce composition and shall extend these standards to all sub-tier suppliers. Grievance mechanisms must be accessible and non-retaliatory.

SUPPLY CHAIN AND MATERIAL INTEGRITY

Partners are responsible for full material traceability of critical components, including optical sources, cooling assemblies, and electronic control modules. Conflict minerals sourcing must be disclosed and reported per OECD due diligence guidance. Counterfeit components are strictly prohibited; all purchased parts must be sourced through authorized channels with verifiable provenance. Sub-tier supplier changes affecting form, fit, or function require prior written approval. Inventory segregation and shelf-life control for consumables must be maintained.


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