## **Comprehensive Medical Device Compliance Checklist**

| Compliance checklist | | Yes | No | Not sure | Action plan |
| --- | --- | --- | --- | --- | --- |
| Regulatory Monitoring | Are all relevant regulatory updates reviewed and understood? |  |  |  |  |
| Is there a system for disseminating regulatory information within the company? |  |  |  |  |
| Documentation and Record Keeping | Are all device records and documentation up-to-date and compliant with current regulations? |  |  |  |  |
| Do you maintain detailed records of design changes and their compliance implications? |  |  |  |  |
| Staff Training and Competence | Are all employees involved in design, production, and quality control trained on current regulations? |  |  |  |  |
| Is there a record of training sessions and employee competencies? |  |  |  |  |
| Internal Audit and Risk Assessment | Have you conducted a comprehensive risk assessment for each device? |  |  |  |  |
| Are internal audits scheduled regularly, and do they cover all aspects of regulatory compliance? |  |  |  |  |
| Supplier and Third-Party Compliance | Do you assess the compliance status of your suppliers and third-party collaborators? |  |  |  |  |
| Are there mechanisms to ensure that supplied materials and components meet regulatory standards? |  |  |  |  |
| Post-Market Surveillance | Is there a system for monitoring device performance and adverse events post-market? |  |  |  |  |
| Are there procedures for addressing compliance issues identified post-market? |  |  |  |  |
| Continuous Improvement | Do you have a process for continuously updating compliance strategies based on audit findings and market feedback? |  |  |  |  |
| Are there channels for employees to suggest improvements in compliance practices? |  |  |  |  |
| *Note: this checklist is given as an example and more compliance questions can be added.* | | | | | |