## **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.* |