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CHECKLIST:

KEY COMPLIANCE STEPS

For manufacturers of AI-based medical devices.

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Checklist:
Key Compliance Steps for Manufacturers of AI-based Medical Devices

Under both the EU Medical Device Regulation (MDR) or In Vitro Diagnostic Regulation (IVDR) and the EU Artificial Intelligence Act (AI Act)

1. **Classification and Scoping**

- Determine if your product is a medical device under MDR/IVDR.
- Assess if the AI component qualifies as a high-risk AI system under the AI Act (most AI in medical devices will be high-risk).

2. **Conformity Assessment Pathway**

- Choose the appropriate conformity assessment procedure under MDR/IVDR.
- For AI Act, prepare for additional conformity assessment (unless exempted due to overlap with MDR/IVDR).

3. **Risk Management**

- Implement a risk management system that addresses both:
  - Clinical risks (MDR/IVDR)
  - AI-specific risks (bias, robustness, cybersecurity, etc.) under the AI Act.

4. **Technical Documentation**

- Update your technical file to include:
  - AI model architecture and training data description
  - Performance metrics (accuracy, robustness, etc.)
  - Human oversight mechanisms
  - Data governance and traceability

5. **Quality Management System (QMS)**

- Ensure your QMS (e.g., ISO 13485) integrates:
  - AI lifecycle management
  - Continuous monitoring and post-market updates
  - Logging and auditability of AI decisions

6. **Human Oversight**

- Define and document human-in-the-loop or human-on-the-loop mechanisms.
- Ensure users can override or interpret AI outputs safely.

7. **Transparency and Instructions**

- Provide clear instructions for use that explain:
  - AI functionality
  - Limitations and intended use
  - How users should interpret AI outputs

8. **Post-Market Surveillance**

- Implement a post-market monitoring system for:
  - AI performance drift
  - Adverse events or malfunctions
  - Real-world data feedback loops

9. Cybersecurity and Data Protection

- Ensure compliance with:
  - GDPR for personal data
  - Cybersecurity requirements under MDR and AI Act

10. Coordination with Notified Bodies

- Engage early with your Notified Body to:
  - Clarify expectations for AI documentation
  - Align on conformity assessment timelines