Inflammation Imaging Device Regulatory & AI Checklist

REGULATORY CLASSIFICATION & STRATEGY

- Define intended use, indications for use, and user population clearly
- Confirm device classification with regulatory authority.
- Determine if AI/ML functions affect intended use and regulatory pathway.

RISK MANAGEMENT & SAFETY ENGINEERING

- Document risk management process in accordance with ISO 14971
- Identify hazards related to device functionality and AI/ML components, & Evaluate AI-specific risks.

AI/ML DEVELOPMENT & DOCUMENTATION

- Maintain version control of AI models and training data.
- Document dataset sources, preprocessing methods, and bias mitigation strategies.
- Define performance metrics and validation results clearly.
- Establish cybersecurity and data protection controls for AI systems

VERIFICATION, VALIDATION & CLINICAL EVALUATION

- Conduct verification and validation in accordance with lifecycle requirements
- Use representative clinical data for testing.
- Compare AI outputs with established clinical standards.
- Include sensitivity, specificity, and reproducibility data.

QUALITY MANAGEMENT SYSTEM (QMS)

- Align development with QMS standards (e.g., ISO 13485).
- Integrate software lifecycle and cybersecurity controls.

REGULATORY SUBMISSION PREPARATION

- Provide comprehensive technical and clinical evidence.
- Include AI transparency documentation (explainability where applicable).
- Prepare risk management files covering AI-related hazards.

LABELING, USABILITY & HUMAN FACTORS

- Ensure labeling accurately describes AI functionality and intended use
- Describe AI limitations, known failure scenarios, and contraindications
- Define user responsibilities and required human oversight

POST-MARKET SURVEILLANCE & ALGORITHM LIFECYCLE MANAGEMENT

- Monitor real-world performance and safety data.
- Track algorithm drift and define update/change control procedures.
- Maintain periodic safety and performance review processes
- Update risk management and clinical evaluation based on PMS data
- Report adverse events per regulatory requirements.