

3D IMAGING SOFTWARE COMPLIANCE CHECKLIST

Defined Intended Use

- Clearly document clinical purpose, patient population, users, and decision-making impact.

Regulatory Classification Confirmed

- Verify FDA (Class I/II) and EU MDR (Class IIa/IIb) classification based on intended use.

510(k) / CE-Mark Strategy Identified

- Determine predicate devices or conformity assessment pathway early.

Software Lifecycle Compliance

- Follow IEC 62304 with documented development, verification, and maintenance processes.

Risk Management Implemented

- Perform risk analysis and implement controls in line with ISO 14971.

Software Verification & Validation Completed

- Ensure system-level verification and validation testing, documented test protocols, traceability, and defined release criteria.

Segmentation & Model Accuracy Validation

- Validate segmentation, mesh quality, and STL accuracy using reference datasets.

Cybersecurity & Data Protection

- Address cybersecurity risks, access controls, and patient data privacy.

Clinical Performance Evidence

- Generate evidence supporting diagnostic or clinical performance claims, where applicable

Usability Engineering Completed

- Conduct usability testing per IEC 62366-1 to reduce use-related risks.

Post-Market Surveillance Plan

- Establish procedures for complaint handling, trend analysis, software updates, and regulatory reporting.