

Medical Device Assembly Audit Checklist

Audit Date		Auditor	
Location		Department	
Device/Product Name			

Checklist

Audit Item	Yes	No	N/A	Comments
Work instructions available and current				
Personnel properly trained and certified				
Assembly area cleanliness and organization				
Material identification and traceability				
Tools calibrated and in good condition				
Handling and storage of components/devices				
Documentation completed and signed off				
Device assembly meets specifications				
Nonconformance procedures followed (if found)				
Final inspection and testing performed				

Findings & Notes

Auditor Signature

Date