

Medical Device Assembly Batch Record

Batch & Product Information

Product Name		Product Code	
Batch / Lot No.		Date	
Quantity to Assemble		Device Serial No(s)	
Manufacturing Order No.		Assembled By	

Components Used

Component Name	Part No.	Lot/Batch No.	Qty Used	Inspected By

Assembly Process Steps

Step/Operation	Performed By	Date	Comments / Notes

In-Process Checks & Results

Check / Inspection Item	Criteria / Limit	Result	Checked By	Date

Comments / Deviations

Final Review & Release

Reviewed By		Date	
Released By		Date	