

✓ *MEDICAL SOFTWARE CHECKLIST KIT*

*A kit of eight checklists for meeting US and EU
medical device software standards*

Checklists for:

- ✓ ISO 13485:2016 (SEPT Product 89)
- ✓ IEC 62304:2015 (SEPT Product 85)
- ✓ UL 1998-2004 (SEPT Product 32)
- ✓ ISO/IEC 90003:2014 (SEPT Product 81)
- ✓ ISO 9001:2015 (SEPT Product 86)
- ✓ FDA S/W Validation Guidelines (SEPT Product 18)
- ✓ FDA Guidance for use of OTS S/W (SEPT Product 34)
- ✓ FDA Pre-market Submission Guidelines (SEPT Product 57)



SEPT Product 90

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