

93/42/EEC amended by 2007/47/EC  
Medical Device Directive

requires

requires

requires

Process Standards

EN 62304  
Software Life-Cycle

IEC/TR 80002-1  
Software Risk Management

Management Standards

EN ISO 13485  
Quality Management

EN ISO 14971  
Risk Management

EN 62366  
Usability Engineering

requires

requires

affects

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Development and Maintenance  
of Safe and Reliable Medical Software