### QUALITY SYSTEMS
- ISO 13485: Medical devices – Quality Management Systems
- FDA Title 21 - Part 820: Quality System Regulation (QSR)
- ISO 10005: Quality Management Systems – Quality Plans

### BIOCOMPATIBILITY
- ISO 10993: Biological evaluation of medical devices

### STERILIZATION
- FDA Guidance 1615: Sterility Info in 510(k) Subs Guidance
- ISO 11135: Sterilization of health care products – EtO
- ISO 11137: Sterilization of health care products - Radiation
- ISO 14161: Sterilization of health care products-biological indicators

### PACKAGING AND LABELING
- ISO 11607: Packaging for terminally sterilized medical devices
- ISTA 1, 2, 3: ISTA Pre-shipment Test Procedures
- ASTM F1886: Determining Integrity of Seals by Visual Inspection
- ASTM F88: Test Method for Seal Strength of Flexible Materials
- ASTM F2096: Pouch Bubble Test
- ASTM F1929: Pouch Dye Penetration Test
- ASTM F2503: MRI label marking
- ISO 15223: Symbols to be used with medical device labels

### ACCELERATED AGING
- ASTM F1980: Standard guide for accelerated aging

### CLEANROOMS / CONTROLLED ENVIRONMENTS
- ISO 14644: Cleanroom and associated controlled environments
- ISO 14698: Cleanroom - Biocontamination Control

### ELECTRICAL, SOFTWARE
- IEC 60601: Medical electrical equipment
- IEC 62304: Medical devices software

### RISK MANAGEMENT
- ISO 14971: Application of risk management to medical devices

### STATISTICAL TECHNIQUES
- ISO 16269: Statistical interpretation of data

### HUMAN FACTORS
- ANSI/AAMI HE75: Human factors engineering

### CONNECTORS
- ISO 80369: Small-bore connectors for liquids and gases

### VASCULAR DEVICES
- ISO 25539: Cardiovascular implants – Endovascular devices
- ISO 10555: Intravascular catheters – Sterile and single-use
- FDA Guidance 1545: Intravascular Stents and Delivery System
- FDA Guidance 1608: PTCA Catheters
- AAMI TIR42: Particulates - vascular devices
- ASTM F2081: Dimensional Attributes of Vascular Stents
- ASTM F2942: Axial, Bending, Torsional Durability - Vascular Stents
- ISO 5840: Cardiovascular implants – Cardiac valve prostheses
- ISO 7198: Vascular prostheses – Tubular vascular grafts and patches
- ISO 12417: Vascular device-drug combination products
- ASTM F2477: In vitro pulsatile durability testing of vascular stents

### ORTHOPEDIC DEVICES
- ISO 7206: Partial and total hip joint prosthesis
- ISO 7207: Partial and total knee prosthesis
- ISO 14242: Wear of total hip-joint prostheses
- ISO 14243: Wear of total knee-joint prostheses
- ASTM F1800: Cyclic fatigue –metal tibial tray, total knee joint repl.
- ASTM F543-13E1: Metallic medical bone screws
- ISO 17853: Wear of implant materials-Polymer and metal wear part.

### ACTIVE IMPLANTS
- ISO5841: Cardiac pacemakers
- ISO 10310: Marking and packaging of implantable neurosimulators
- ISO /TS 10974: MRI safety of patients with active device
- ISO 11318: Connector assembly DF-1, implantable defibrillators
- ISO 27185: Symbols for cardiac rhythm mngt. device labels

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This list is intended as a quick reference for the most general and commonly used standards and guidance documents. It is by no means a comprehensive list. It is the responsibility of the user to verify the validity and applicability of each standard.