



Global Q, Inc.



User Interface Overview - just in case

The learning objective of this TOPIC is discuss the following KEY POINTS:

- Planets
- Quality (and other) Manuals
- Worklist
- Feedback
- Title
- Reference
- Library
- User Menu



Name	Number
ABC Medical, Inc.	
IVDR Documentation - BSI	
510K Submissions	GS1207
Quality Policy	GS1432
Adverse Events	GS2007
Health Hazard Evaluation	GS8238
Process Specifications	GS4439
Supplier Corrective Action	GS2984
Post Market	GS2390
Corrections and Removals	GS8097
Process Monitoring	GS2298
Clinical Studies	GS3119
Customer Complaints	GS5045
Design Control Policy	GS7049
Risk Management	GS6598
Master Validation Plan	GS8340
Management Review	GS2308
Clinical Evaluation Reports	GS7012
Process Validation	GS4391
Document Control	GS1782
Preventive Maintenance	GS7391
Supplier Audit	GS3398
Organization	GS6723
Corrective and Preventive ...	GS4097
Control of Measurement E...	GS3092
Internal Audit	GS3994
Process Design	GS3397
Nonconforming Product	GS2945
Supplier Qualification	GS3364
Process Deviations	GS6574
MSquared Quality Manual	
A New Quality Manual Item	

Quality Policy

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abc

Abc Medical, Inc

Policy

Level 1 Document

Subsystem: Management Controls

ABC123 Rev. 1

Quality Policy

Effective Date: dd mmm yyyy

1 PURPOSE:

The purpose of this policy is to establish requirements for the Quality Policy at Abc Medical, Inc.

2 SCOPE:

The scope of this procedure is all Abc Medical, Inc. sites.

3 DEFINITIONS AND ABBREVIATIONS

3.1 Refer to **add reference to definitions procedure here.**

4 REFERENCES:

4.1 External References, Standards and/or Regulations

4.1.1 Add references to external standards and regulations

4.2 Procedures:

4.2.1 Add references to external standards and regulations

4.3 Work Instructions:

4.3.1 Add references to external standards and regulations

4.4 Forms:

4.4.1 Add references to external standards and regulations

5 RESPONSIBILITIES

5.1 Define responsibilities for Top Management.

5.2 Define responsibilities for specific organizational roles.

6 REQUIREMENTS:

6.1 Define the general, high level requirements for the policy.

7 PROCEDURE:

7.1 Refer to **Define a process flow diagram of the process**

7.2 Define each process step and its requirements in general terms, leave specifics to procedures that implement the requirements.

8 RECORD KEEPING:

8.1 Refer to **define the record keeping procedure.**

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4 / 11

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Page 1 of 2

MineIn ProcessSchedule DetailsStart DateEnd Date										
Name	Item	Phase/Stage		State	Actual Start	Actual End		Schedule Status	Planned Start	Planned End
Clinical Studies	Item Repository	Clinical Affairs		In Process*	09/30/2021 13:29			Late	10/31/2021 13:34	10/31/2021 15:34
Approve Report	test CE	Clinical Evaluation Report		In Process*				Late	10/31/2021 13:34	10/31/2021 15:34
Records	Explorer Hip	Device Model Lifecycle - Y		In Process*				Late	10/31/2021 13:34	10/31/2021 15:34
Background	Admin 101	Admin 101 - Topics		In Process*	10/31/2021 15:23			Late	10/31/2021 13:34	10/31/2021 15:34
User Profiles	Element Library	Post Market		In Process*	12/31/2019 19:00			Late	10/31/2021 13:34	10/31/2021 15:34
Quality Problems	Item Repository	CAPA		In Process*	12/31/2019 19:00			Late	10/31/2021 13:34	10/31/2021 15:34
Review Literature Search Report	Test IVDR	Phase III - Reports		In Process*	08/04/2020 20:00			Late	10/31/2021 13:34	10/31/2021 15:34
Optiqs Training	Item Repository	Training		In Process*	10/22/2021 15:22			Late	10/31/2021 13:34	10/31/2021 15:34
Sku Lot	Item Repository	Production		In Process*	12/31/2019 19:00			Late	10/31/2021 13:34	10/31/2021 15:34
Manage Target Attributes	Trauma Group Remediation	Manage		In Process*	05/18/2021 07:04			Late	10/31/2021 13:34	10/31/2021 15:34
Clinical Evaluations	Item Repository	Clinical Affairs		In Process*	08/03/2020 10:47			Late	10/31/2021 13:34	10/31/2021 15:34
General	Smith-Nephew	Domain		In Process*	12/31/2019 19:00			Late	10/31/2021 13:34	10/31/2021 15:34
Verifications	Item Repository	CAPA		In Process*	12/31/2019 19:00			Late	10/31/2021 13:34	10/31/2021 15:34
Use Environments	Element Library	Regulatory		In Process*	12/31/2019 19:00			Late	10/31/2021 13:34	10/31/2021 15:34
Review	Admin 101	Admin 101		In Process*	10/31/2021 13:12			Late	10/31/2021 13:34	10/31/2021 15:34
External Review	test Nathan	Clinical Evaluation Plan		In Process*	10/29/2020 11:27			Late	10/31/2021 13:34	10/31/2021 15:34
Manage Record Attributes	Old Integra Demo Project	Manage Attributes		In Process*	05/21/2021 13:36			Late	10/31/2021 13:34	10/31/2021 15:34
Perform Literature Search	test Nathan	Clinical Evaluation Report		In Process*	11/30/2020 06:58			Late	10/31/2021 13:34	10/31/2021 15:34
Objective	Admin 101	Admin 101		In Process*	10/31/2021 13:13			Late	10/31/2021 13:34	10/31/2021 15:34
Manage Scope	Panha Record Project TEST	Manage Project		In Process*	05/21/2021 21:19			Late	10/31/2021 13:34	10/31/2021 15:34
Clinical Gaps	Item Repository	Clinical Affairs		In Process*	10/06/2021 07:08			Late	10/31/2021 13:34	10/31/2021 15:34
Objective	Admin 101	Admin 101		In Process*	10/31/2021 15:39			Late	10/31/2021 13:34	10/31/2021 15:34
Types	Configuration Repository	Manage		In Process*	12/31/2019 19:00			Late	10/31/2021 13:34	10/31/2021 15:34
Retrieve Drawing Prints	222	Design		In Process*	06/11/2021 11:41			Late	10/31/2021 13:34	10/31/2021 15:34
UDI-DIs	Item Repository	Packaging & Labeling		In Process*	12/31/2019 19:00			Late	10/31/2021 13:34	10/31/2021 15:34
IVD Performance Evaluations	Item Repository	Clinical Affairs		In Process*	12/31/2019 19:00			Late	10/31/2021 13:34	10/31/2021 15:34
Understand Drawing Prints	Trauma Group Remediation	Design		In Process*	05/18/2021 06:45			Late	10/31/2021 13:34	10/31/2021 15:34
Packaging Projects	Item Repository	Packaging & Labeling		In Process*	07/13/2021 11:33			Late	10/31/2021 13:34	10/31/2021 15:34
Data Sources	Configuration Repository	Manage		In Process*	09/15/2021 11:05			Late	10/31/2021 13:34	10/31/2021 15:34
Management Controls	Admin 101	Admin 101 - Topics		In Process*	10/31/2021 15:21			Late	10/31/2021 13:34	10/31/2021 15:34
Groups	Item Repository	Product Development		In Process*	09/23/2021 13:45			Late	10/31/2021 13:34	10/31/2021 15:34
Manage Scope	Trauma Group Remediation	Manage		In Process*	06/01/2021 07:09			Late	10/31/2021 13:34	10/31/2021 15:34
Plan	MH Test AKM	MH Test AKM		In Process*				Late	10/31/2021 13:34	10/31/2021 15:34
Failure Modes	Element Library	Risk		In Process*	12/31/2019 19:00			Late	10/31/2021 13:34	10/31/2021 15:34
Plan	Old Integra Demo Project	PROTO Integration Remediation ...		In Process*	05/21/2021 11:38			Late	10/31/2021 13:34	10/31/2021 15:34
Actors	Item Repository	Regulatory Affairs		In Process*	12/31/2019 19:00			Late	10/31/2021 13:34	10/31/2021 15:34

Add New Observation

Standard ▾

Filters ▾

Actions ▾

Event Title	Submit By	On	Current State
Download Export Not Functioning in Core	Angela Mines	04/15/2021 07:27	In Work
Looks good	Mitch Hayes	10/11/2021 12:36	In Clarification
Support Icon in the top left could be better.	Mitch Hayes - ctr_...	04/15/2021 08:51	Resolved
Hover tips would be great on header itemss	Mitch Hayes - ctr_...	04/15/2021 09:24	In Work
Support Event columns are good but need different views to support laptop screens.	Mitch Hayes - ctr_...	04/15/2021 06:53	Resolved
Support Events could be in a filter list instead.	Mitch Hayes - ctr_...	04/15/2021 06:44	Resolved
Test	Mitch Hayes - ctr_...	06/12/2021 12:34	Resolved

Add New Observation Standard ▾ Filters ▾ Actions ▾

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Support Events could be in a filter list instead.	Mitch Hayes - ctr_...	04/15/2021 06:44	Resolved
Test	Mitch Hayes - ctr_...	06/12/2021 12:34	Resolved

7 item(s), 1 selected

Support Icon in the top left could be better. State: Resolved,

Event Type: User Observation

Event Title: Support Icon in the top left could be better.

Description:

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Currently:
 Add New Observa

Event Title

Support Event columns are good but need different vie...

Support Events could be in a filter list instead.

Support Icon in the top left could be better.

Other possibilities are:

510Ks

FDA Device Classifications

Establishments

IMDRF Codes

GMDN Codes

EU Nomenclature Codes

Filters

Knumber	Device Name	Applicant	Device Class	Product Code	Regulation Number	Decision Date	Advisory Committee Description	Clearance Type	Decision Description
K060338	FAMILY OF SELECTA LASER SYSTEMS INCLU...	LUMENIS, INC.	2	GEX	878.4810	03/08/2006	General, Plastic Surgery	Special	Substantially Equivalent
K981206	TAS RESULTS DATA ACQUISITION SYSTEM (T...	CARDIOVASCULAR DIAGNOSTICS, INC.	2	GKP	864.5400	05/25/1998	Hematology	Traditional	Substantially Equivalent
K884475	CHELON-FIL	ESPE GMBH (US)	2	EMA	872.3275	12/04/1988	Dental	Traditional	Substantially Equivalent
K912195	PA-396 GOLD BASED/PRECIOUS METAL ALL...	JLENKO CO.	2	EJS	872.3060	07/29/1991	Dental	Traditional	Substantially Equivalent
K770632	GAS COLLHCTOR BE 155(155-2-3,154-4)	INSTRUMENTATION INDUSTRIES, INC.	1	KGK	868.1575	04/07/1977	Anesthesiology	Traditional	Substantially Equivalent
K991277	MODIFICATION TO IMMULITE MYOGLOBIN,...	DIAGNOSTIC PRODUCTS CORP.	2	DDR	866.5680	04/26/1999	Immunology	Special	Substantially Equivalent
K031377	SYSMEX AUTOMATED COAGULATION ANAL...	DADE BEHRING, INC.	2	GKP	864.5400	09/07/2003	Hematology	Traditional	Substantially Equivalent
K932575	ADULT TEMPERATURE MONITORING ANEST...	MED-PLASTICS INTL., INC.	1	CAI	868.5240	07/21/1993	Anesthesiology	Traditional	Substantially Equivalent
K170868	FIXIT Threaded Anchor System	S.B.M SAS Science for Bio Materials	2	MAI	888.3030	11/29/2017	Orthopedic	Traditional	Substantially Equivalent
K855019	DURAHESIVE PROTECTIVE BARRIER WIPE	CONVATEC, A DIVISION OF E.R. SQUIBB & S...	1	EXB	876.5900	04/15/1986	Gastroenterology, Urology	Traditional	Substantially Equivalent
K883830	FIBER OPTIC LARYNGOSCOPE	EFFNER, INC.	1	CCW	868.5540	10/24/1988	Anesthesiology	Traditional	Substantially Equivalent
K904041	HAEMONETICS CELL SAVER 4 PLUS	HAEMONETICS CORP.	2	CAC	868.5830	11/12/1990	Anesthesiology	Traditional	Substantially Equivalent
K780334	ADHESIVE, BRACKET AND CONDITIONER R...	ROCKY MOUNTAIN ORTHODONTICS, INC.	2	DYH	872.3750	03/27/1978	Dental	Traditional	Substantially Equivalent
K120975	CS 8100 CS 8100 ACCESS	TROPHY	2	MUH	872.1800	06/21/2012	Dental	Traditional	Substantially Equivalent
K894402	HIPGRAPHICS SYSTEM ONE W/ORTHOTOOL	HIPGRAPHICS, INC.	2	LLZ	892.2050	11/16/1989	Radiology	Traditional	Substantially Equivalent
K860326	TUBULAR ORTHO. STOCKINETTE W/ANTIMI...	DEROYAL INDUSTRIES, INC.	2	KKX	878.4370	02/20/1986	General, Plastic Surgery	Traditional	Substantially Equivalent
K053498	HYPEROX 101	WJO, INC	2	CBF	868.5470	03/14/2006	Anesthesiology	Traditional	Substantially Equivalent
K946001	EMERGENCY RESPONSE SAFETY KIT	ANI SAFETY, INC.	2	FXX	878.4040	06/08/1995	General, Plastic Surgery	Traditional	Substantially Equivalent
K852474	UNION BROACH BLEACHING LIGHT	UNION BROACH, DIV. MOYCO INDUSTRIES, ...				06/30/1985	Unknown	Traditional	Substantially Equivalent
K873420	GLOBALCARE(TENS)	OMS MEDICO, INC.	2	GZJ	882.5890	10/07/1987	Neurology	Traditional	Substantially Equivalent
K842982	FORMALIN BUFFERED	REAGENT LABORATORY, INC.	1	IFP	864.4010	09/30/1984	Pathology	Traditional	Substantially Equivalent
K822613	RAST ALLERCOAT ALLERGEN DISCS	KALLESTAD LABORATORIES, INC.	2	DGC	866.5510	10/21/1982	Immunology	Traditional	Substantially Equivalent
K892645	AMICON VITAFIBER FLO-PATH BIORECT/VLS...	AMICON, INC.	1	KJF	864.2240	06/12/1989	Hematology	Traditional	Substantially Equivalent
K942478	VISARD FRAMES	IRIS OPTICAL, INC.	1	HQZ	886.5842	08/04/1994	Ophthalmic	Traditional	Substantially Equivalent
K891259	MODEL 4000 ALTERNATING PRESSURE PUM...	DIAMOND MEDICAL EQUIPMENT, INC.	2	FNM	880.5550	11/16/1989	General Hospital	Traditional	Substantially Equivalent
K910727	EXCEL MODEL 2110	EXCEL MEDICAL SYSTEMS, INC.	2	GZJ	882.5890	01/16/1992	Neurology	Traditional	Substantially Equivalent
K920749	THC URINE CALIBRATORS	DIAGNOSTIC REAGENTS, INC.	2	DLJ	862.3200	03/17/1992	Clinical Toxicology	Traditional	Substantially Equivalent
K950275	RESORBABLE SOFT TISSUE ATTACHMENT D...	ZIMMER, INC.	2	MAI	888.3030	11/06/1995	Orthopedic	Traditional	Substantially Equivalent for Some...
K122717	FACE MASK, SURGICAL MASK, PROCEDURE ...	TIGER MEDICAL PRODUCTS LTD	2	FXX	878.4040	12/20/2012	General, Plastic Surgery	Abbreviated	Substantially Equivalent
K932583	ADULT TEMPERATURE MONITORING ANEST...	MERIT MEDICAL SYSTEMS, INC.	1	CAI	868.5240	07/20/1993	Anesthesiology	Traditional	Substantially Equivalent
K900460	MODIFIED NOVOSTE ANGIOGRAPHIC CAT...	NOVOSTE CORP.	2	DQO	870.1200	07/16/1990	Cardiovascular	Traditional	Substantially Equivalent
K902573	PRECIPATH(R) IM ABNORMAL IMMUNASSAY...	BOEHRINGER MANNHEIM CORP.	1	JJY	862.1660	07/09/1990	Clinical Chemistry	Traditional	Substantially Equivalent
K904667	NA NEEDLES	OLYMPUS CORP.	1	GDM	878.4800	12/11/1990	General, Plastic Surgery	Traditional	Substantially Equivalent
K790955	COVER GARD	FEM-GARD, INC.	1		880.6140	06/19/1979	General Hospital	Traditional	Substantially Equivalent

Name	Severity Level	Description	Version		State	Last Modified Date	Last Modified By
▶ Rupture	3	Failure of the smooth muscle fibers of the gastrointestinal tract to relax at any one point ...	A.1		New	03/24/2020	John Peyton
▶ Concussion	4		A.1		New	03/24/2020	John Peyton
▶ Erosion	3		A.1		New	03/24/2020	John Peyton
▶ Sepsis	4		A.1		New	03/24/2020	John Peyton
▶ Blisters	2		A.1		New	03/24/2020	John Peyton
▶ Fracture, Skull	5		A.1		New	03/24/2020	John Peyton
▶ Aspiration	4		A.1		New	03/24/2020	John Peyton
▶ Amputation	4		A.1		New	03/24/2020	John Peyton
▶ Achalasia	4		A.1		New		
▶ Venipuncture	3		A.1		New	03/24/2020	John Peyton
▶ Hemorrhage	4		A.1		New	03/24/2020	John Peyton
▶ Brain damage	5		A.1		New	03/24/2020	John Peyton
▶ Protrusion	3		A.1		New	03/24/2020	John Peyton
▶ Choking	4		A.1		New	03/24/2020	John Peyton
▶ Stroke	5		A.1		New	03/24/2020	John Peyton
▶ Spinal Injury	5	The entry of foreign material past the trachea, and into the lower respiratory tract.	A.1		New	03/24/2020	John Peyton
▶ Necrosis	4		A.1		New	03/24/2020	John Peyton
▶ Liver Laceration	5		A.1		New	03/24/2020	John Peyton
▶ Fracture, Hip	4		A.1		New	03/24/2020	John Peyton
▶ Device Fragments in Patient	4		A.1		New	03/24/2020	John Peyton
▶ Burn	3		A.1		New	03/24/2020	John Peyton
▶ Occlusion	3		A.1		New	03/24/2020	John Peyton
▶ Hypoxia	4		A.1		New	03/24/2020	John Peyton
▶ Abrasion	2		A.1		New	03/24/2020	John Peyton
▶ Aspiration/Inhalation	4		A.1		New		
▶ Joint Swelling	3	A fibrous band of tissue that connects normally separate body regions.	A.1		New	03/24/2020	John Peyton
▶ Respiratory Failure	5		A.1		New	03/24/2020	John Peyton
▶ A New User Harm	TBD		A.1		New	09/03/2021	
▶ Aneurysm	5		A.1		New	03/24/2020	John Peyton
▶ Adhesions	2		A.1		New		
▶ Infection	3		A.1		New	03/24/2020	John Peyton

Name	Number	Recognition List	Recognition Number	
▶ Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling.	ISO 22442-2 Second edition 2015-1...	043	15-46	^
▶ Application of quality management system concepts to medical device data systems	ANSI AAMI SW87:2012	030	13-35	
▶ Standard Guide for Coating Characterization of Drug Coated Balloons	ASTM F3320-18	051	3-158	
▶ Wear of implant materials - Polymer and metal wear particles - Isolation and characterization	ISO 17853 Third edition 2011-03-01	050	11-336	
▶ Guidance on the use of AGILE practices in the development of medical device software	AAMI TIR 45:2012	030	13-36	
▶ Medical electrical equipment - Medical light ion beam equipment - Performance characteristics	IEC 62667 Edition 1.0 2017-08	050	12-320	
▶ Performance Measurements of Positron Emission Tomographs	NEMA NU 2-2018	052	12-326	
▶ Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images	NEMA MS 9-2008 (R2014)	041	12-288	
▶ Implants for surgery - Ultra-high-molecular-weight polyethylene - Part 4: Oxidation index measurement method	ISO 5834-4 Second edition 2019-02	052	8-496	
▶ Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	IEC 80601-2-30 Edition 1.1 2013-07	050	3-152	
▶ Standard Test Method for Detection of Holes in Medical Gloves	ASTM D5151-19	053	6-424	
▶ Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging	NEMA MS 6-2008 (R2014)	041	12-195	
▶ Cleanrooms and associated controlled environments - Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)	ISO 14644-7 First edition 2004-10-01	038	14-166	
▶ American National Standard Method for Coupler Calibration of Earphones	ANSI S3.7-1995 (Reaffirmed 2008)	028	4-164	
▶ Information technology - Automatic identification and data capture techniques - Unique identification - Part 4: Individual products and product packages	IEC ISO 15459-4 Third edition 2014 ...	048	13-100	
▶ Technical Information Report Design of training and instructional materials for medical devices used in non-clinical environments	AAMI TIR 49:2013	034	5-84	
▶ Erythrocyte Protoporphyrin Testing; Approved Guideline	CLSI C42-A	020	7-21	
▶ Optics and photonics -- Lasers and laser-related equipment - Test methods for specular reflectance and regular transmittance of optical laser components	ISO 13697 First edition 2006-05-15	028	12-174	
▶ Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)	ASTM F560-17	050	8-469	
▶ <55> Biological Indicators -- Resistance Performance Tests	USP 42-NF37:2019	053	14-536	
▶ Standard Test Methods for Tensile Properties of Thin Plastic Sheet	ASTM D882-12	034	10-87	
▶ Lasers and laser-related equipment - Test methods for determination of the shape of a laser beam wavefront - Part 2: Shack-Hartman sensors	ISO 15367-2 First edition 2005-03-15	028	12-143	
▶ American National Standard for Wheelchairs - Volume 4: Wheelchairs and Transportation Section 19: Wheelchairs used as seats in motor vehicles.	ANSI RESNA WC-4:2017 Section 19	053	16-228	
▶ Medical devices - Application of risk management to medical devices	ISO 14971 Third Edition 2019-12	053	5-125	
▶ Sweat Testing: Sample Collection and Quantitative Chloride Analysis; Approved Guideline - Third Edition.	CLSI C34-A3 (Replaces C34-A2)	025	7-211	
▶ American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheels chairs (including Scooters) Section 22: Set-up Procedures	ANSI RESNA WC-1:2009 Section 22	034	16-184	
▶ American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Electromagnetic Immunity of Medical Devices to Radiated Radio-Frequency (R...	ANSI IEEE C63.18-2014	041	19-17	
▶ Implants for surgery - Wear of total hip-joint prostheses - Part 4: Testing hip prostheses under variations in component positioning which results in direct edge loading	ISO 14242-4 First edition 2018-05	052	11-358	
▶ Ophthalmic optics - Contact lens care products - Antimicrobial preservative efficacy testing and guidance on determining discard date	ISO 14730 Second edition 2014-10-01	040	10-94	
▶ Standard Guide for Characterization and Testing of Chitosan Salts as Starting Materials Intended for use in Biomedical and Tissue-Engineered Medical Product Applications	ASTM F2103-11	028	15-28	
▶ Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard-Eighth Edition.	CLSI M11 9th Edition	051	7-286	
▶ Supplemental Tables for Interference Testing in Clinical Chemistry	CLSI EP37 1st Edition	050	7-284	
▶ Standard Specification for Polysulfone Resin for Medical Applications	ASTM F702-18	052	8-509	
▶ Wheelchairs - Part 16: Resistance to ignition of postural support devices	ISO 7176-16 Second edition 2012-1...	031	16-191	▼

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Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling.	ISO 22442-2 Second edition 2015-1...	043	
Application of quality management system concepts to medical device data systems	ANSI AAMI SW87:2012	030	
Standard Guide for Coating Characterization of Drug Coated Balloons	ASTM F3320-18	051	
Wear of implant materials - Polymer and metal wear particles - Isolation and characterization	ISO 17853 Third edition 2011-03-01	050	
Guidance on the use of AGILE practices in the development of medical device software	AAMI TIR 45:2012	030	
Medical electrical equipment - Medical light ion beam equipment - Performance characteristics	IEC 62667 Edition 1.0 2017-08	050	
Performance Measurements of Positron Emission Tomographs	NEMA NU 2-2018	052	12-326
Standards Publication Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images	NEMA MS 9-2008 (R2014)	041	12-288
Implants for surgery - Ultra-high-molecular-weight polyethylene - Part 4: Oxidation index measurement method	ISO 5834-4 Second edition 2019-02	052	8-496
Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	IEC 80601-2-30 Edition 1.1 2013-07	050	3-152
Standard Test Method for Detection of Holes in Medical Gloves	ASTM D5151-19	053	6-424
Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel Non-Volume Coils in Diagnostic MR Imaging	NEMA MS 6-2008 (R2014)	041	12-195
Cleanrooms and associated controlled environments - Part 7: Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)	ISO 14644-7 First edition 2004-10-01	038	14-166
American National Standard Method for Coupler Calibration of Earphones	ANSI S3.7-1995 (Reaffirmed 2008)	028	4-164
Information technology - Automatic identification and data capture techniques - Unique identification - Part 4: Individual products and product packages	IEC ISO 15459-4 Third edition 2014 ...	048	13-100
Technical Information Report Design of training and instructional materials for medical devices used in non-clinical environments	AAMI TIR 49:2013	034	5-84
Erythrocyte Protoporphyrin Testing; Approved Guideline	CLSI C42-A	020	7-21
Optics and photonics -- Lasers and laser-related equipment - Test methods for specular reflectance and regular transmittance of optical laser components	ISO 13697 First edition 2006-05-15	028	12-174
Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)	ASTM F560-17	050	8-469
<55> Biological Indicators -- Resistance Performance Tests	USP 42-NF37:2019	053	14-536
Standard Test Methods for Tensile Properties of Thin Plastic Sheeting	ASTM D882-12	034	10-87
Lasers and laser-related equipment - Test methods for determination of the shape of a laser beam wavefront - Part 2: Shack-Hartman sensors	ISO 15367-2 First edition 2005-03-15	028	12-143
American National Standard for Wheelchairs - Volume 4: Wheelchairs and Transportation Section 19: Wheelchairs used as seats in motor vehicles.	ANSI RESNA WC-4:2017 Section 19	053	16-228
Medical devices - Application of risk management to medical devices	ISO 14971 Third Edition 2019-12	053	5-125
Sweat Testing: Sample Collection and Quantitative Chloride Analysis; Approved Guideline - Third Edition.	CLSI C34-A3 (Replaces C34-A2)	025	7-211
American National Standard for Wheelchairs - Volume 1: Requirements and Test Methods for Wheels chairs (including Scooters) Section 22: Set-up Procedures	ANSI RESNA WC-1:2009 Section 22	034	16-184
American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Electromagnetic Immunity of Medical Devices to Radiated Radio-Frequency (R...	ANSI IEEE C63.18-2014	041	19-17
Implants for surgery - Wear of total hip-joint prostheses - Part 4: Testing hip prostheses under variations in component positioning which results in direct edge loading	ISO 14242-4 First edition 2018-05	052	11-358
Ophthalmic optics - Contact lens care products - Antimicrobial preservative efficacy testing and guidance on determining discard date	ISO 14730 Second edition 2014-10-01	040	10-94
Standard Guide for Characterization and Testing of Chitosan Salts as Starting Materials Intended for use in Biomedical and Tissue-Engineered Medical Product Applications	ASTM F2103-11	028	15-28
Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard-Eighth Edition.	CLSI M11 9th Edition	051	7-286
Supplemental Tables for Interference Testing in Clinical Chemistry	CLSI EP37 1st Edition	050	7-284
Standard Specification for Polysulfone Resin for Medical Applications	ASTM F702-18	052	8-509
Wheelchairs - Part 16: Resistance to ignition of postural support devices	ISO 7176-16 Second edition 2012-1...	031	16-191