Medical devices issued by the State Food and Drug Administration Directory of Guidelines for Registration Technical Review		
#	Guiding Principle Name	Release Date
1	Guidelines for technical review of registration of single-use sterile closed clips (No. 30 of 2021)	2021
2	Guidelines for technical review of registration of dental glass ionomer cements (No. 30 of 2021)	2021
3	Guiding Principles for Technical Review of Needle Registration for Disposable Injection Pens (No. 30 of 2021)	2021
4	Guidelines for technical review of registration of citric acid disinfectants (No. 30 of 2021)	2021
5	Guidelines for the technical review of registration of human parvovirus B19 IgM/IgG antibody detection reagents (No. 24 of 2021)	2021
6	Guidelines for technical review of registration of group B streptococcal nucleic acid detection reagents (No. 24 of 2021)	2021
7	Guidelines for technical review of registration of rotavirus antigen detection reagents (No. 24 of 2021)	2021
8	Guidelines for update of instructions and technical review of tumor companion diagnostic reagents based on similar therapeutic drugs (No. 24 of 2021)	2021
9	Guidelines for registration technical review of real-time fluorescent PCR analyzers (No. 24 of 2021)	2021
10	Guidelines for Technical Review of Clinical Evaluation of the Same Type of Medical Magnetic Resonance Imaging System (Revised Edition in 2020) (No. 12 of 2021)	2021
11	Guidelines for technical review of registration of cryptococcal capsular polysaccharide antigen detection reagents (No. 4 of 2021)	2021
12	Guidelines for Technical Review of Registration of Genetic Deafness-related Gene Mutation Detection Reagents (No. 4 of 2021)	2021
13	Guidelines for technical review of registration of Mycoplasma pneumoniae IgM/IgG antibody detection reagents (No. 4 of 2021)	2021
14	Guidelines for Technical Review of Clinical Evaluation of Image-based Ultrasonic Diagnostic Equipment of the Same Variety (No. 2 of 2021)	2021

15	Guidelines for technical review of clinical evaluation of X-ray computed tomography equipment of the same type (No. 2 of 2021)	2021
16	Guidelines for the technical review of electronic upper gastrointestinal endoscopy registration (No. 87 of 2020)	2020
17	Guidelines for the Technical Review of Fundus Camera Registration (No. 87 of 2020)	2020
18	Guidelines for technical review of registration of specific protein immunoassay analyzers (No. 80 of 2020)	2020
19	Guidelines for technical review of registration of total triiodothyronine testing reagents (No. 80 of 2020)	2020
20	Guidelines for the technical review of the registration of prolactin test reagents (No. 80 of 2020)	2020
21	Guidelines for Technical Review of Registration of Rheumatoid Factor Detection Reagents (No. 80 of 2020)	2020
22	Guidelines for the technical review of the registration of serum amyloid A detection reagents (No. 80 of 2020)	2020
23	25-hydroxyvitamin D testing reagent registration technical review guidelines (No. 80 of 2020)	2020
24	Guidelines for the technical review of the registration of home in vitro diagnostic medical devices (No. 80 of 2020)	2020
25	Technical guidelines for the use of real-world data in the clinical evaluation of medical devices (for trial implementation) (No. 77 , 2020)	2020
26	Balloon dilatation catheter registered Technical Review Guidelines (2020 Year 62 No.)	2020
27	Guiding Principles for Evaluation of Fatigue Performance of Biological Femoral Stems (No. 62 , 2020)	2020
28	Allogeneic verification guidelines for implantable medical devices viral inactivation process (2020 revised edition) (2020 Year 62 No.)	2020
29	3D printing patient-matched body of the mandible false registration review guidelines (2020 Year 62 No.)	2020
30	Personalized matching bone implants and interactive quality control review of the guidelines for medical engineering tools (2020 Year 62 No.)	2020

31	Infusion needle stick injuries guard product requirements and technical review guidelines evaluation (2020 Year 62 No.)	2020
32	Guidelines for technical review of registration of nitrous oxide inhalation sedative and analgesic devices (No. 49 of 2020)	2020
33	Guidelines for technical review of registration of dural (spinal) membrane patch (No. 48 , 2020)	2020
34	Guiding Principles for Animal Experimental Research on Bioabsorbable Coronary Artery Drug-Eluting Stents (No. 48 , 2020)	2020
35	Guiding Principles for Technical Review of Customized and Personalized Bone Implant Equivalence Model Registration (No. 48 , 2020)	2020
36	Guidelines for the technical review of registration of finite element analysis data for orthopedic metal implants (No. 48 of 2020)	2020
37	Guidelines for clinical trials of hernia repair patches (No. 48 , 2020)	2020
38	Guidelines for the technical review of registration of single-use breast positioning wires (No. 48 of 2020)	2020
39	Guidelines for Compiling Instructions for Rigid Air-permeable Contact Lenses for Orthokeratology (2020 Revised Edition) (No. 47 , 2020)	2020
40	In vitro synchronized cardioversion product registration Technical Review Guidelines (2020 Year 42 No.)	2020
41	Pacing in vitro skin products registered by the Technical Review Guidelines (2020 Year 42 No.)	2020
42	Sign up low-frequency electrotherapy Technical Review Guidelines (2020 Year 39 No.)	2020
43	Sign up technical review guidelines heat and moisture exchanger (2020 Year 39 No.)	2020
44	Audiometer registered Technical Review Guidelines (2020 Year 39 No.)	2020
45	Ventilatory function test product registration Technical Review Guidelines lung (2020 Year 39 No.)	2020
46	Medical technology incubator registration review guidelines for carbon dioxide (2020 Year 39 No.)	2020
47	Shock wave therapy device registration Technical Review Guidelines (2020 Year 39 No.)	2020
48	Hot paste (bags) product registration Technical Review Guidelines (2020 Year 39 No.)	2020
49	Electric pressure bleeding device registration Technical Review Guidelines (2020 Year 39 No.)	2020

50	Guidelines for technical review of registration of tendon-ligament fixation system (No. 36, 2020)	2020
51	3D printed acetabular cup product registration technical review guidelines (No. 36, 2020)	2020
52	3D Printing Artificial Vertebral Body Registration Technical Review Guidelines (No. 36, 2020)	2020
53	Guidelines for the Technical Review of the Registration of Facial Implants for Plastic Surgery (No. 36, 2020)	2020
54	Guidelines for Technical Review of Product Registration of Total Knee Prosthesis System (No. 36, 2020)	2020
55	Guidelines for the Evaluation of Changes in Raw Materials of Passive Medical Device Products (No. 33, 2020)	2020
56	Guidelines for technical review of registration of dengue virus nucleic acid detection reagents (No. 32 of 2020)	2020
57	Guidelines for Technical Review of Metal Intramedullary Nail System Product Registration (No. 31, 2020)	2020
58	Guidelines for the technical review of registration of vertebroplasty balloon dilatation catheters (No. 31 of 2020)	2020
59	Guidelines for technical review of registration quality control for clinical evaluation of spinal implants (No. 31 of 2020)	2020
60	Guidelines for the technical review of registration of needles for assisted reproduction (No. 31 of 2020)	2020
61	Guidelines for technical review of hydrocolloid dressing product registration (No. 31, 2020)	2020
62	Guiding Principles for Technical Review of Vaseline Gauze Product Registration (No. 31, 2020)	2020
63	Guidelines for technical review of registration of acrylic resin bone cement for artificial joint replacement (No. 31 of 2020)	2020
64	Guidelines for Technical Review of Registration of Implantable Left Ventricular Assist System (No. 17, 2020)	2020
65	Guidelines for technical review of registration of semiconductor laser hair removal machines (No. 15 of 2020)	2020
66	Basic principles of medical device safety and performance (No. 18, 2020)	2020

67	Guidelines for the technical review of registration of X-ray image guidance systems for radiotherapy (No. 13 of 2020)	2020
68	Guidelines for Technical Review of Registration of Positron Emission /X-ray Computed Tomography System (No. 13 of 2020)	2020
69	Sign up technical review guidelines detection reagents hepatitis B virus drug resistance-associated mutations (2020 Year 16 Hao)	2020
70	EB registered technical review guidelines virus nucleic acid detection reagents (2020 Year 16 Hao)	2020
71	Sign up technical review guidelines related thalassemia gene detection reagents (2020 Year 16 Hao)	2020
72	HBV e antigen, e registered technical review guidelines Antibody Test (2020 Year 16 Hao)	2020
73	Guidelines for technical review of registration of creatinine determination reagents (No. 14 of 2020)	2020
74	Guidelines for technical review of registration of antinuclear antibody detection reagents (No. 14 of 2020)	2020
75	Guidelines for the technical review of registration of anti-thyroid peroxidase antibody assay reagents (No. 14 of 2020)	2020
76	Guidelines for technical review of registration of glycated albumin determination reagents (No. 14 of 2020)	2020
77	Guidelines for technical review of registration of reagents for total bile acid determination (No. 14 of 2020)	2020
78	Guiding Principles for Technical Review of Follicle Stimulating Hormone Test Reagent Registration (No. 14 of 2020)	2020
79	Guidelines for registration technical review of colloidal gold immunochromatographic analyzers (No. 14 of 2020)	2020
80	Medical Devices named after General Guidelines (2019 Year 99 No.)	2019
81	Medical Devices conditional approval guidelines listed (2019 Year 93 No.)	2019
82	Technical Review Guidelines tumor-associated gene mutation detection reagent (high-throughput sequencing) performance evaluation common registered (2019 Year 83 No.)	2019

83	CYP2C19 registered technical review guidelines detection reagent drug metabolizing enzyme gene polymorphism (2019 Year 83 No.)	2019
84	Sign up technical review guidelines tip locator root (2019 Year 79 No.)	2019
85	Enteral nutrition pump registered Technical Review Guidelines (2019 Year 79 No.)	2019
86	Sign up technical review guidelines plasma freezer (2019 Year 79 No.)	2019
87	One-time use of live sampling clamp endoscope with a registered Technical Review Guidelines (2019 Year 79 No.)	2019
88	On lower limb active and passive movements registered a technical review of guidelines for rehabilitation training equipment (2019 Year 79 No.)	2019
89	Sign up technical review guidelines manual resuscitator (2019 Year 79 No.)	2019
90	Dental implant surgery Drill registered Technical Review Guidelines (2019 Year 79 No.)	2019
91	EMG bio-feedback Register Technical Review Guidelines therapeutic equipment (2019 Year 79 No.)	2019
92	Medical Diagnostic X-ray registration technology review guidelines tube assembly (2019 Year 79 No.)	2019
93	Direct ophthalmoscope registered Technical Review Guidelines (2019 Year 79 No.)	2019
94	Medical devices benefit -risk assessment registration Technical Review Guidelines (2019 Year 79 No.)	2019
95	Registration limb pressure Technical Review Guidelines physiotherapy equipment (2019 Year 79 No.)	2019
96	Sign up technical review guidelines urodynamic analyzer (2019 Year 79 No.)	2019
97	Based on human chromosome cell fluorescence in situ hybridization anomaly detection reagent registration Technical Review Guidelines (2019 Year 80 No.)	2019
98	Sign up technical review guidelines for respiratory virus multiplex nucleic acid detection reagents (2019 Year 80 No.)	2019
99	Chlamydia trachomatis and /or registered technical review guidelines Neisseria gonorrhoeae nucleic acid detection reagents (2019 Year 80 No.)	2019
100	Register technical review guidelines detection reagent aureus Staphylococcus aureus methicillin-resistant and nucleic acid-based detection methods (2019 Year 80 No.)	2019

101	Amino acids, carnitine and registered technical review guidelines detection reagent succinylacetone (2019 Year 80 No.)	2019
102	Guidelines for the technical review of registration of embryo transfer catheters for assisted reproduction (No. 78 of 2019)	2019
103	Guiding Principles for Technical Review of Registration and Application of Cardiopulmonary Bypass System Extracorporeal Circulation Pipeline (No. 78 of 2019)	2019
104	Guiding Principles for Technical Review of Registration and Verification of Known Leachable Substances of Medical Devices (No. 78 of 2019)	2019
105	Sign up technical review guidelines for total cholesterol assay reagent (2019 Year 74 No.)	2019
106	Sign up technical review guidelines uric acid reagent (2019 Year 74 No.)	2019
107	Determination of urea reagent registration Technical Review Guidelines (2019 Year 74 No.)	2019
108	Technical Review assay reagent registration guidelines aspartate aminotransferase (2019 Year 74 No.)	2019
109	Guidelines for the technical review of the registration of passive implantable bones, joints and oral hard tissues for personalized additive manufacturing medical devices (No. 70 of 2019)	2019
110	Guidelines for the Technical Review of Registration of Endometrial Radiofrequency Ablation Devices (No. 59 , 2019)	2019
111	Guidelines for the technical review of the registration of dental digital impression machines (No. 37 of 2019)	2019
112	Guidelines for the technical review of the registration of implantable drug delivery devices (No. 25 , 2019)	2019
113	Guidelines for the technical review of the registration of intrauterine contraceptive devices (No. 25 , 2019)	2019
114	Guidelines for technical review of synthetic resin dental registration (No. 25 , 2019)	2019
115	Guidelines for technical review of clinical evaluation registration of centrifugal blood component separation equipment (No. 24 of 2019)	2019
116	Guidelines for Technical Review of Registration of Active Medical Device Use Period (No. 23 of 2019)	2019

117	Guiding Principles for Technical Review of Medical Device Animal Experiment Research Part 1: Decision-Making Principles (No. 18, 2019)	2019
118	Guidelines for the review of animal experimental techniques for intra-abdominal hernia repair patches (No. 18, 2019)	2019
119	Guidelines for technical review of dental bur registration (No. 16 of 2019)	2019
120	Guidelines for the Technical Review of Registration of Disposable Syringes for Single Use (No. 16 of 2019)	2019
121	One-time use registration technical review guidelines skin stapler (2019 Revision) (2019 Year 16 number)	2019
122	Guidelines for the technical review of registration of ophthalmic high-frequency ultrasound diagnostic equipment (No. 10, 2019)	2019
123	Guidelines for the technical review of the registration of dual-energy X-ray bone densitometers (No. 10, 2019)	2019
124	Guiding Principles for Technical Review of Registration of Anesthesia Machines (No. 10, 2019)	2019
125	Guidelines for Clinical Evaluation of Oral and Maxillofacial Cone Beam Computed Tomography Equipment (No. 10, 2019)	2019
126	Guidelines for clinical trials of intraocular lenses (No. 13 of 2019)	2019
127	Guidelines for clinical trials of ophthalmic femtosecond laser treatment machines for corneal flaps (No. 13 of 2019)	2019
128	Guidelines for clinical trials of sodium hyaluronate-based facial injection fillers (No. 13 of 2019)	2019
129	Guidelines for Technical Review of Registration of Total Thyroxine Testing Reagents (No. 11, 2019)	2019
130	Guidelines for the technical review of registration of brain natriuretic peptide /amino-terminal pro-brain natriuretic peptide detection reagents (No. 11, 2019)	2019
131	Guidelines for the technical review of the registration of procalcitonin detection reagents (No. 11 of 2019)	2019
132	Guidelines for the technical review of the registration of progesterone testing reagents (No. 11 of 2019)	2019
133	Guidelines for clinical trials of bioabsorbable coronary drug-eluting stents (No. 8 of 2019)	2019

134	Guidelines for clinical trials of transcatheter implantable aortic valve prostheses (No. 8 of 2019)	2019
135	Guiding Principles for Clinical Trials of Aortic Stent Graft System (No. 8 of 2019)	2019
136	Guidelines for the technical review of the registration of medical laser fiber products (No. 130 of 2018)	2018
137	Guidelines for the technical review of registration of single-use biopsy needles (No. 126 of 2018)	2018
138	Guidelines for the technical review of registration of single-use bilirubin plasma adsorbers (No. 126 of 2018)	2018
139	Kiss (seam) combiner product registration Technical Review Guidelines (2018 Revision) (2018 Year 120 No.)	2018
140	Guidelines for the technical review of the registration of single-use sputum suction tubes (No. 120 of 2018)	2018
141	Surgical dressings registered technical review guidelines gauze (2018 Revision) (2018 Year 120 No.)	2018
142	All-ceramic dentures registered technical review guidelines zirconia ceramic blocks (2018 Revision) (2018 Year 116 No.)	2018
143	Umbilical cord care registration Technical Review Guidelines (2018 Revision) (2018 Year 116 No.)	2018
144	Guidelines for the technical review of manual wheelchair registration (No. 116 of 2018)	2018
145	One-time use registration technical review guidelines laryngeal mask Medical (2018 Revision) (2018 Year 107 No.)	2018
146	Guidelines for technical review of registration of bone cement casing components (No. 107 of 2018)	2018
147	Guidelines for the technical review of the registration of orthopedic external fixators (revised in 2018) (No. 107 of 2018)	2018
148	Guiding Principles for Registration and Review of Medical Devices for the Prevention and Treatment of Rare Diseases (No. 101 of 2018)	2018
149	Disposable sterile catheter registered Technical Review Guidelines (2018 Revision) (2018 Year 80 No.)	2018
150	Customized denture registered Technical Review Guidelines (2018 Revision) (2018 Year 80 No.)	2018

151	Catheter registered technical review guidelines nasogastric nutrition (2018 Revision) (2018 Year 80 No.)	2018
152	Guidelines for clinical trials of rigid breathable contact lenses for orthokeratology (No. 51 of 2018)	2018
153	Guidelines for clinical trials of soft contact lenses (No. 51 of 2018)	2018
154	Guidelines for the preparation of approval documents for clinical trials of passive implantable medical devices (No. 40 of 2018)	2018
155	Guidelines for the Technical Review of Registration of Endoscope Washing and Disinfecting Machines (No. 30 , 2018)	2018
156	Guidelines for technical review of registration of sleep breathing monitoring products (No. 30 of 2018)	2018
157	Guidelines for the technical review of registration of anesthesia laryngoscopy (No. 30 of 2018)	2018
158	Guidelines for technical review of registration of pulse wave velocity and ankle-brachial index testing products (No. 25 of 2018)	2018
159	Guidelines for the technical review of surgical microscope registration (No. 25 of 2018)	2018
160	Guidelines for the technical review of the registration of medical clean benches (No. 25 , 2018)	2018
161	Guidelines for technical review of tonometer registration (No. 25 of 2018)	2018
162	Guidelines for Preclinical Research of Coronary Artery Drug-Eluting Stents (No. 21 , 2018)	2018
163	Guidelines for clinical trials of coronary drug-eluting stents (No. 21 of 2018)	2018
164	Guidelines for the technical review of the registration of human in vitro assisted reproductive technology fluids (No. 18 of 2018)	2018
165	Guidelines for the Technical Review of Registration of Soft Contact Lenses (No. 18 of 2018)	2018
166	Guiding Principles for Technical Review of Registration of Medical Cryopreservation Boxes (No. 15 of 2018)	2018
167	Guiding Principles for the Technical Review of the Registration of Electronic Urine Meters (No. 15 of 2018)	2018
168	Guiding Principles for Technical Review of Insufflation Machine Registration (No. 15 of 2018)	2018

169	Guidelines for the technical review of electronic vaginal microscope registration (No. 15 of 2018)	2018
170	Guidelines for the Technical Review of the Registration of Oral Curved Body X-ray Machines (No. 9 of 2018)	2018
171	Guidelines for the technical review of the registration of rigid optical endoscopes (invasive) (No. 54 of 2018)	2018
172	Guidelines for Technical Review of Registration of Mycobacterium Tuberculosis Specific Cellular Immune Response Test Reagents (No. 57 of 2018)	2018
173	Guidelines for Technical Review of Registration of Continuous Glucose Monitoring System (No. 56 of 2018)	2018
174	Guidelines for the technical review of registration of ophthalmic ultrasound diagnostic equipment (No. 55 of 2018)	2018
175	Guidelines for the technical review of the registration of ophthalmological femtosecond laser treatment machines (No. 53 of 2018)	2018
176	Guidelines for the technical review of registration of ophthalmic optical coherence tomography scanners (No. 44 of 2018)	2018
177	Guiding Principles for Technical Review of Registration of Anti-Human Globulin Detection Reagents (No. 36 of 2018)	2018
178	Guidelines for the Technical Review of the Registration of Ultrasonic Soft Tissue Cutting Hemostasis System (No. 37 of 2018)	2018
179	Guidelines for the technical review of the registration of enterovirus nucleic acid detection reagents (No. 36 of 2018)	2018
180	Guidelines for technical review of registration of Helicobacter pylori antigen /antibody detection reagents (No. 36 of 2018)	2018
181	Human epidermal growth factor receptor (EGFR) mutation gene detection reagent (PCR method) registration technical review guidelines (No. 36 of 2018)	2018
182	Guidelines for the technical review of registration of X-ray computed tomography equipment (No. 26 of 2018)	2018
183	Guidelines for registration technical review of D-dimer assay reagents (immunoturbidimetric method) (No. 9 of 2018)	2018

184	Guiding Principles for Technical Review of Registration of Apolipoprotein B Assay Reagents (No. 9 of 2018)	2018
185	Guiding Principles for Technical Review of Registration of Apolipoprotein A1 Assay Reagents (No. 9 of 2018)	2018
186	Guidelines for technical review of registration of C-peptide assay reagents (No. 8 of 2018)	2018
187	Guidelines for the technical review of registration of insulin determination reagents (No. 8 of 2018)	2018
188	Guiding Principles for Technical Review of Registration of Homocysteine Determination Reagents (No. 8 of 2018)	2018
189	Guidelines for technical review of registration of alanine aminotransferase assay reagents (No. 8 of 2018)	2018
190	Guidelines for Technical Review of Urinalysis Test Strip Registration (No. 8 of 2018)	2018
191	Technical Guidelines for Accepting Overseas Clinical Trial Data of Medical Devices (No. 13 of 2018)	2018
192	Guidelines for technical review of registration of single-use infusion pumps (non-electrically driven) (No. 3 of 2018)	2018
193	Guidelines for the technical review of registration of whole blood and blood component storage bags (No. 3 of 2018)	2018
194	Guidelines for technical review of registration of blood concentrators (No. 3 of 2018)	2018
195	Guiding Principles for the Design of Medical Device Clinical Trials (No. 6 of 2018)	2018
196	Guidelines for Technical Review of Clinical Evaluation of Proton Carbon Ion Therapy System (No. 4 of 2018)	2018
197	Guidelines for Technical Review of Registration of Mobile Medical Devices (No. 222 of 2017)	2017
198	Guiding Principles for the Technical Review of the Registration of Medical Devices of Animal Origin (2017 Revised Edition) (No. 224 of 2017)	2017
199	Guidelines for the registration technical review of luteinizing hormone detection reagent (colloidal gold immunochromatographic method) (No. 213 of 2017)	2017
200	Guidelines for registration technical review of cardiac troponin I/ myoglobin / creatine kinase isoenzyme MB detection reagent (colloidal gold immunochromatographic method) (2017 No. 213)	2017

201	Guidelines for registration technical review of cystatin C determination reagent (latex transmission immunoturbidimetric method) (No. 213 of 2017)	2017
202	Guidelines for technical review of registration of high-density lipoprotein cholesterol determination reagents (No. 213 of 2017)	2017
203	Guidelines for the technical review of registration of electrolyte potassium, sodium, chloride, and calcium determination reagents (No. 213 of 2017)	2017
204	Guidelines for registration technical review of human epidermal growth factor receptor 2 gene amplification detection kit (fluorescence in situ hybridization) (2017 No. 209)	2017
205	ABO , RhD blood group antigen test card (column agglutination method) registration technical review guidelines (No. 209 of 2017)	2017
206	Guidelines for registration technical review of automatic blood group analyzers (No. 209 of 2017)	2017
207	Guidelines for technical review of registration of hepatitis C virus nucleic acid genotyping test kits (No. 209 of 2017)	2017
208	Guidelines for technical review of clinical evaluation of endometrial removal (heat conduction, radiofrequency ablation) equipment (2017 No. 212)	2017
209	Guidelines for technical review of clinical evaluation of therapeutic ventilator (No. 212 of 2017)	2017
210	Technical guidelines for research and evaluation of cell therapy products (for trial implementation) (No. 216 of 2017)	2017
211	Guiding Principles for the Registration and Technical Review of Electric Gastric Lavage Machines (2017 Revised Edition) (No. 199 of 2017)	2017
212	Guiding Principles for Technical Review of Infusion Pump Registration (No. 199 of 2017)	2017
213	Guidelines for the technical review of the registration of slit lamp microscopes (No. 199 of 2017)	2017
214	Guiding Principles for Technical Review of Holter System Registration (No. 198 of 2017)	2017
215	Guidelines for Technical Review of Registration of Ultraviolet Therapy Equipment (No. 199 of 2017)	2017

216	Guidelines for the technical review of the registration of small steam sterilizers (No. 198 of 2017)	2017
217	Guidelines for the technical review of the registration of central monitoring software (No. 198 of 2017)	2017
218	Guiding Principles for Technical Review of Refractometer Registration (No. 198 of 2017)	2017
219	Guidelines for the technical review of registration of balloon inflation devices for intravascular balloon dilatation catheters (No. 198 of 2017)	2017
220	Guiding Principles for Technical Review of Registration of Biological Microscopes (No. 199 of 2017)	2017
221	Guiding Principles for the Division of Medical Device Registration Units (No. 187 of 2017)	2017
222	Guidelines for the technical review of dental handpiece registration (2017 revised edition) (No. 177 of 2017)	2017
223	Guiding Principles for the Technical Review of Registration of Pulse Oximeters (2017 Revised Edition) (No. 177 of 2017)	2017
224	Guiding Principles for Technical Review of Registration of Infrared Therapy Equipment (2017 Revised Edition) (No. 177 of 2017)	2017
225	Guiding Principles for the Technical Review of Registration of Medical Temperature Control Blankets (2017 Revised Edition) (No. 177 of 2017)	2017
226	Guidelines for Technical Review of Registration of Intermediate Frequency Electrotherapy Products (2017 Revised Edition) (No. 177 of 2017)	2017
227	Guidelines for Technical Review of Registration of Electric Wheelchairs (No. 180 of 2017)	2017
228	Guidelines for the technical review of registration of ultrasound bone densitometers (No. 180 of 2017)	2017
229	Guidelines for the technical review of registration of ear cavity medical infrared thermometers (No. 180 of 2017)	2017
230	Guidelines for the registration technical review of small molecular sieve oxygen generators (2017 revision) (2017 No. 180)	2017
231	Guidelines for the Technical Review of the Registration of Medical Attraction Equipment (2017 Revised Edition) (No. 180 of 2017)	2017

232	Guidelines for the Technical Review of the Registration of Doppler Ultrasound Fetal Monitors (2017 Revised Edition) (No. 177 of 2017)	2017
233	Guiding Principles for Technical Review of Registration of Anti-decubitus Air Mattresses (2017 Revised Edition) (No. 177 of 2017)	2017
234	Guiding Principles for Technical Review of Perimeter Registration (2017 Revised Edition) (No. 177 of 2017)	2017
235	Guidelines for the Technical Review of Registration of Ultrasonic Physical Therapy Equipment (2017 Revised Edition) (No. 177 of 2017)	2017
236	Guidelines for the Technical Review of Registration of Ultrasonic Dental Appliances (2017 Revised Edition) (No. 177 of 2017)	2017
237	Guidelines for technical review of registration of patient monitoring products (category 2) (No. 154 of 2017)	2017
238	Guidelines for technical review of registration of electrocardiographs (No. 154 of 2017)	2017
239	Guiding Principles for Technical Review of Microplate Reader Registration (No. 154 of 2017)	2017
240	Guidelines for the technical review of registration of single-use ECG electrodes (No. 154 of 2017)	2017
241	Guidelines for the technical review of the registration of ambulatory blood pressure measuring instruments (No. 154 of 2017)	2017
242	Guiding Principles for Technical Review of Registration of Infrared Breast Examers (2017 Revised Edition) (No. 146 of 2017)	2017
243	Guidelines for the Technical Review of Bone Tissue Surgical Equipment Registration (2017 Revised Edition) (No. 146 of 2017)	2017
244	Guidelines for the Technical Review of Registration of Medical Ozone Gynecological Therapy Apparatus (2017 Revised Edition) (No. 146 of 2017)	2017
245	Guiding Principles for Technical Review of Dental Implant Machine Registration (No. 124 of 2017)	2017
246	Guiding Principles for Registration and Application Data of Passive Implantable Medical Device Shelf Life Period (2017 Revised Edition) (2017 No. 75)	2017
247	Guiding Principles for Technical Review of Registration of Electric Traction Units (2017 Revised Edition) (No. 60 of 2017)	2017

248	Guiding Principles for the Technical Review of the Registration of Electric Operating Tables (2017 Revised Edition) (No. 60 of 2017)	2017
249	Guidelines for the technical review of registration of ultrasound Doppler fetal heart rate monitors (No. 60 , 2017)	2017
250	Guidelines for the Technical Review of Registration of Imaging Ultrasonic Diagnostic Equipment (Class 2) (No. 60 of 2017)	2017
251	Guidelines for registration technical review of fetal chromosomal aneuploidy (T21 , T18 , T13) detection kits (high-throughput sequencing method) (2017 No. 52)	2017
252	Guidelines for the technical review of the registration of artificial cervical intervertebral disc prostheses (No. 23 of 2017)	2017
253	Guidelines for Technical Review of Surgical Electrode Registration (2017 Revised Edition) (No. 41 of 2017)	2017
254	Guidelines for Technical Review of Registration of Polyurethane Foam Dressing Products (No. 44 of 2017)	2017
255	Guidelines for technical review of dental fiber post product registration (No. 44 of 2017)	2017
256	Guidelines for the technical review of the registration of hip prosthesis systems (No. 23 of 2017)	2017
257	Guidelines for technical review of registration of drug-resistant gene mutation detection reagents for Mycobacterium tuberculosis complex group (2017 No. 25)	2017
258	Guidelines for the technical review of the registration of surgical shadowless lamps (No. 30 of 2017)	2017
259	Guidelines for technical review of laparoscopic surgical instruments (No. 30 of 2017)	2017
260	Guiding Principles for the Technical Review of the Registration of Electric Hospital Beds (2017 Revised Edition) (No. 30 of 2017)	2017
261	Guiding Principles for Technical Review of Cochlear Implant System Registration (No. 35 of 2017)	2017
262	Guiding Principles for Technical Review of Product Registration for Endoscopic Staplers (No. 44 of 2017)	2017
263	Guiding Principles for Technical Review of Medical Device Cybersecurity Registration (No. 13 of 2017)	2017

264	Guiding Principles for Technical Review of Registration of Semiconductor Laser Therapy Machines (Class 2) (2017 Revised Edition) (No. 41 of 2017)	2017
265	Technical Guidelines for the Registration of Medical Electronic Thermometers (2017 Revised Edition) (No. 41 of 2017)	2017
266	Guiding Principles for Technical Review of Registration of Syringe Pumps (2017 Revised Edition) (No. 41 of 2017)	2017
267	Guiding Principles for the Technical Review of the Registration of Visible Spectrum Therapy Apparatus (No. 40 of 2017)	2017
268	Guiding Principles for Technical Review of Registration of Hard Tube Endoscopes (Class 2) (2017 Revised Edition) (No. 40 of 2017)	2017
269	Technical guidelines for the registration of flexible fiber endoscopes (category 2) (2017 revision) (2017 No. 40)	2017
270	Guiding Principles for Technical Review of Registration of Sock-Type Medical Pressure Belts (No. 14 of 2017)	2017
271	Guidelines for Technical Review of Registration of Central Venous Catheter Products (No. 14 of 2017)	2017
272	Guiding Principles for Technical Review of Registration of Calcium Phosphorus /Silicon Bone Filling Materials (No. 14 of 2017)	2017
273	Guiding Principles for Technical Review of Light Curing Machine Registration (No. 6 of 2017)	2017
274	Guidelines for the technical review of the registration of oral and maxillofacial cone-beam computed tomography equipment (No. 6 of 2017)	2017
275	Technical guidelines for the registration of external defibrillation products (No. 6 of 2017)	2017
276	Guidelines for Technical Review of Clinical Evaluation of Medical Magnetic Resonance Imaging System (No. 6 of 2017)	2017
277	Guidelines for clinical trials of cochlear implant systems (No. 3 , 2017)	2017
278	Guidelines for technical review of registration of ophthalmic phacoemulsification and anterior segment vitrectomy equipment and accessories (No. 162 of 2016)	2016
279	Guidelines for the technical review of registration of single-use hemodialysis tubing (No. 146 of 2016)	2016

280	Guidelines for the technical review of registration of human red blood cell anti-typing reagents (No. 131 of 2016)	2016
281	Guidelines for the technical review of the registration of intervertebral fusion cages (No. 70 of 2016)	2016
282	Guidelines for technical review of registration of dental base polymer materials (No. 70 of 2016)	2016
283	Guidelines for the technical review of the registration of absorbable surgical sutures (No. 70 of 2016)	2016
284	Guidelines for the technical review of registration of single-use hydrocephalus shunts (No. 70 of 2016)	2016
285	Guidelines for technical review of dental implant (system) registration (No. 70 of 2016)	2016
286	Guidelines for the technical review of registration of posterior spinal internal fixation systems (No. 70 of 2016)	2016
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296	Guidelines for the Technical Review of Registration of Medical Nebulizers (2016 Revised Edition) (No. 22 of 2016)	2016
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381	Guiding Principles for Technical Review of Registration of Disposable Surgical Gown Products (Food and Drug Administration Office [2011] No. 187)	2011
382	Guidelines for technical review of registration of single-use vacuum blood collection tube products (Food and Drug Administration Office Letter [2011] No. 187)	2011
383	Guidelines for Technical Review of Customized Denture Product Registration (Food and Drug Administration Office Letter [2011] No. 187)	2011
384	Guidelines for technical review of registration of natural rubber latex condoms (Food and Drug Administration Office [2011] No. 187)	2011
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390	Guidelines for Technical Review of Virus Inactivation Process Verification for Allogeneic Implantable Medical Devices (Food and Drug Administration Office Letter [2011] No. 116)	2011
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