Translation by Request

Classification

File #	Name	Issued Year
NA	Medical Device Classification Catalog	2017
Annex to No.133	Clinical Trial Exemption Catalog	2018

Clinical Trial

File #	Name	Issued Year
25	Quality Management Specification for Medical Device Clinical Trials	2016
58	Application Form of Ethical Review and Approval for Medical Device Clinical Trials	2016
87	Announcement on the Relevant Issues Concerning the Archival Filing of Medical Device Clinical Trials	2015
14	Guideline on Clinical Evaluation of Medical Devices	2015
16	Guideline on Clinical Trial of IVD Products	2014
14	Catalogue of Medical Devices of Class III Subject to Approval for Clinical Trials	2014

Good Manufacturing Practice

File #	Name	Issued Year
7	Measures for the Supervision and Administration of Medical Device Production	2015
NA	Supplier Verification Guideline for Medical Device Manufacturer	2015
Annex 4 to 218	Good Manufacturing Practice for Medical Device Guidelines for Onsite Inspection of In Vitro Diagnostic Reagent	2015

Adverse Events

File #	Name	Issued Year
766	Notice on Printing and Distributing the Management Measures for Monitoring and Re-evaluation of Medical Device Adverse Events (draft)	2008
650	Regulations on Supervisory Management of Medical Devices	2014
Annex to No.425	Guidelines for the Monitoring of Medical Devices Adverse Events	2011

Medical Device Recall

File#	Name	Issued Year
29	Measures of Medical Device Recall Supervision	2017
82	Measures of Administration of Medical Device Recall (Trial)	2011

IVD

File #	Name	Issued Year
5	Provisions for In-vitro Diagnostic Reagent Registration	2014
247	Measures for Registration and Administration of Medical Devices and In Vitro Diagnostic Reagents	2015
129	Announcement on issues concerning the registration of medical devices (including in vitro diagnostic reagents)	2014
17	CFDA issue notice on the guidelines for preparation of vitro diagnostic reagents IFU	2014

Other Important Documents

File #	Name	Issued Date
1	Decree of Medical Device Reporting and Evaluation	2018.08.31
NA	Regulation for Imported Medical Device Legal Agent (draft)	2018.08.03
NA	2018 Industry Standard Revision Plan	2018.08.07
NA	Regulation for Imported Medical Device Legal Agent	2018.08.03
NA	2018 Medical Device Inspection Plan	2018.05.30

About China Med Device, LLC

China Med Device, LLC (www.ChinaMedDevice.com), a Boston headquartered company, provides regulatory and commercialization turnkey solutions for western medical device, IVD and combination-product companies to enter China. Our NMPA (CFDA) regulatory services include: regulatory strategy, RA, clinical evaluation, clinical trial, QA, GMP and post-market compliance. Our commercialization services include: market assessment research, reimbursement, partnership, distribution qualification and management. We are a NMPA (CFDA) certified legal agent. With offices in U.S. (Boston) and China (Beijing), we can service our clients 24/7.