# Translated CFDA Documents

**General Documents**

| File # | Name | Issued Date |
|---|---|---|
| Amendment to 650 | Amended Regulation on Supervisory Management of Medical Devices (Draft) | 2018.06.25 |
| 650 | Regulation on Supervisory Management of Medical Devices | 2014.03.07 |
| 4 | Provisions for Medical Device Registration | 2014.07.30 |

**GMP/ QMS**

| File # | Name | Issued Date |
|---|---|---|
| 103 | Good Manufactureing Practices on In Vitro Diagostic Reagents | 2015.07.10 |
| 101 | Good Manufacturing Practice for Sterile Medical Devices | 2015.07.10 |
| 102 | Good Manufacturing Practice for Implantable Medical Devices | 2015.07.10 |
| 19 | Quality Mnagement System for Class III Medical Device Manufacturers | 2016.02.03 |
| 64 | Good Manufacturing Practice for Medical Devices | 2014.12.29 |
| Annex 1 to 218 | Good Manufacturing Practice Guidelines for Onsite Inspection | 2015.09.05 |
| Annex 2 to 218 | Good Manufacturing Practice Guidelines for Onsite Inspection of Sterile Medical Devices | 2015.09.05 |

| | | |
|---|---|---|
| Annex 3 to 218 | Good Manufacturing Practice Guidelines for Onsite Inspection of Implantable Medical Devices | 2015.09.05 |

**Labeling**

| File # | Name | Issued Date |
|---|---|---|
| 131 | CFDA Announcement on Using Chinese Name for Registrant or File Submitter of Imported Medical Devices | 2017.10.31 |

**Distribution**

| File # | Name | Issued Date |
|---|---|---|
| 239 | Good Supply Practice Guidelines for Onsite Inspection of Medical Device | 2015.10.15 |

**Clinical Trial**

| File # | Name | Issued Date |
|---|---|---|
| 6 | Medical Device Clinical Trial Design Guideline | 2018.01.04 |

**Other Important Documents**

| File # | Name | Issued Date |
|---|---|---|
| NA | Customized Additive Manufactured Medical Device Submission Technical Review Guidance Outline | 2018.02.06 |
| NA | Innovation Device Approval Procedure (draft) | 2018.05.07 |
| NA | Unique Device Itentification (UDI) Implementation Plan (draft) | 2018.02.09 |

**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.