

中国法规

1. 国家药品监督管理局 www.nmpa.gov.cn

2. 国家药品监督管理局 数据查询

http://app1.nmpa.gov.cn/data_nmpa/face3/dir.html?CbSIDIH0=qGcbkAr_8vN_8vN_8jp1szy7ruD4OwTMgq0JwJJKdoQqqoL

3. 医疗器械标准查询

<http://app.nifdc.org.cn/biaogzx/qxqwk.do>

4. 医疗器械行业标准

http://app.nifdc.org.cn/jianybz/jybzTwoGj.do?formAction=listTsDalid&type=ylqx&page=list_ylqx

5. 医疗器械非采标推荐性行业标准

http://app.nifdc.org.cn/jianybz/jybzTwoGj.do?formAction=listTsDalid&type=qxtjbz&page=list_qxtjbz

6. 医疗器械分类目录查询

<http://app.nifdc.org.cn/biaogzx/dataGk.do>

7. 分类界定文件查询

<http://app.nifdc.org.cn/biaogzx/flmlbczlkd>

8. I 类产品补充分类信息

<http://app.nifdc.org.cn/biaogzx/flmlbczlkd>

9. 医疗器械标准与分类管理

<https://www.nifdc.org.cn/nifdc/bshff/ylqxbzhgl/index.html>

10. 医疗器械法规查询

<https://www.nmpa.gov.cn/xxgk/fgwj/index.html>

11. 国家标准全文公开系统

<http://openstd.samr.gov.cn/bzgk/gb/index>

12. 分类目录 指导原则 标准

<https://www.cmde.org.cn/CL0195/>

13. 审评论坛 <https://www.cmde.org.cn/CL0010/>

14. 器审云课堂 <https://www.cmde.org.cn/CL0279/>

15. 国家局器审中心 <https://www.cmde.org.cn/CL0001/>

16. 医疗器械 UDI 数据库 <https://udi.nmpa.gov.cn/>

17. 医疗器械不良事件通报

<https://www.nmpa.gov.cn/xxgk/yjjsh/ylqxbshjtb/index.html>

18. 医疗器械召回

<https://www.nmpa.gov.cn/xxgk/chpzhh/ylqxzh/index.html>

19. 国家局高级研修学院 <http://nmpaied.org.cn/>

20. 国家医疗器械不良事件监测信息系统

<https://maers.adrs.org.cn/console/login.ftl>

21. 国家局审核查验中心

<https://www.cfdi.org.cn/cfdi/index?module=A001&nty=A>

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美国法规

1. 美国 FDA <https://www.fda.gov/>

2. 美国联邦法规

https://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl

3. 医疗器械数据库

<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases>

4. CDRH Learn

<https://www.fda.gov/training-and-continuing-education/cdrh-learn>

5. 510K premarket notification

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>

6. 工厂注册和器械列名

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRRL/rl.cfm>

7. 产品分类数据库

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpccd/classification.cfm>

8. FDA 认可标准数据库

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

9. 审评指南数据库

<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>

10. FDA 账号注册与登录

<https://www.access.fda.gov/oaa/logonFlow.htm?execution=e1s1>

11. FDA 自由信息法案

<https://www.fda.gov/regulatory-information/freedom-information>

12. FDA 法规简介

<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>

13. FDA UDI

<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system#ruleguidance>

14. FDA MDSAP

<https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap>

15. MDR 上报

<https://www.fda.gov/medical-devices/medical-device-safety/reporting-allegations-regulatory-misconduct>

16. 召回数据库

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm>

17. GUDID 数据库 <https://accessgudid.nlm.nih.gov/>

18. OSHA's Nationally Recognized Testing Laboratory (NRTL)

<https://www.osha.gov/nationally-recognized-testing-laboratory-program>

欧盟法规

1. 欧盟医疗器械信息

https://ec.europa.eu/health/md_sector/overview_en

2. 欧盟医疗器械专家委员会

https://ec.europa.eu/health/md_expertpanels/overview_en

3. EUDAMED

https://ec.europa.eu/health/md_eudamed/overview_en

4. EUDAMED 数据库

<https://webgate.ec.europa.eu/eudamed/landing-page#/>

5. Medical Device Coordination Group Working Groups

https://ec.europa.eu/health/md_dialogue/mdcg_working_groups_en

6. MDCG 指南

https://ec.europa.eu/health/md_sector/new_regulations/guidance_en#sec10

7. 欧盟协调标准

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en

8. Basic UDI-DI 生成

<https://www.gs1.org/services/gmn-generator>

9. 公告机构 Nando EUROPA - European Commission -

Growth - Regulatory policy - NANDO

<https://ec.europa.eu/growth/toolsdatabases/nando/index.cfm?fuseaction=notifiedbody.main>

10. NB-MED 文件:

<https://www.team-nb.org/nb-med-documents/>



医课汇
公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



hlongmed.com
医疗器械咨询服务
MEDICAL DEVICE
CONSULTING
SERVICES



医课培训平台
医疗器械任职培训
WEB TRAINING
CENTER



医械宝
医疗器械知识平台
KNOWLEDG
ECENTEROF
MEDICAL DEVICE



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DEVICE