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| |  |  |  |  |  | | --- | --- | --- | --- | --- | | **序号** | **区域** | **检索渠道** | **网站** | **关注模块** | | 1 | 国际标准 | ISO  标准 | https://www.iso.org/home.html | 每周更新适用的标准知识库清单 | | IEC 标准 | https://webstore.iec.ch/home | | ASTM 标准 | https://www.astm.org/Standard/index.html | | EN 标准 | https://www.cencenelec.eu/ | | ISO update | https://www.iso.org/iso-update.html | ISO标准每月发布的报告 | | 2 | IMDRF | IMDRF | https://www.imdrf.org/ | 国际医疗器械监管机构论坛(International  Medical Device Regulators Forum) | | 3 | 欧盟 | 欧盟官方公告-OJ | https://eur-lex.europa.eu/homepage.html | Access  to the Official Journal | | Medical Devices - Sector - Latest updates | https://ec.europa.eu/health/medical-devices-sector/latest-updates\_en | 医疗器械相关资讯的更新 | | Public Health-Latest updates | https://ec.europa.eu/health/latest-updates\_en | 公共健康模块的咨询更新 | | EUDAMED的概览 | https://health.ec.europa.eu/medical-devices-eudamed/overview\_en | EUDAMED模块公布的时间表 | | 通用规范、指南的征求意见稿 | https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives\_en | 征求意见 | | European Commission资讯更新 | https://ec.europa.eu/growth/news\_en | 通告、公告更新 | | Harmonised Standards | https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices\_en | MDR下的协调性标准 | | MDCG 指南 | https://ec.europa.eu/health/md\_sector/new\_regulations/guidance\_en | MDCG  所有模块下医疗器械的相关指南文件 | | EUDAMED数据库 | https://ec.europa.eu/health/md\_eudamed/actors\_registration\_en | 欧盟EUDAMED数据库 | | Team NB | https://www.team-nb.org/ | 公告机构组织发布的信息，会转载OJ、MDCG的资讯发布 | | CAMD | https://www.camd-europe.eu/news/ | 各主管当局的小组发布文章，如IVDR过渡期解答 | | Bfarm | https://www.bfarm.de/EN/News/News-from-the-divisions/Medical-devices-news/\_node.html | 德国主管当局信息更新 | | MDD下公告机构指导文件（NBOG） | https://www.nbog.eu/nbog-documents/ | MDD下公告机构指导文件 | | MEDDEV指南 | https://ec.europa.eu/health/md\_sector/current\_directives\_en | MEDDEV更新的医疗器械指南文件 | | 3 | 美国 | FDA近期发布的指南文件 | https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/recent-final-medical-device-guidance-documents | 关注最新的医疗器械指南文件 | | FDA历史发布的指南文件 | https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products | 关注医疗器械相关指南文件 | | 21 CFR Part 800-898 Medical Devices | https://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab\_02.tpl | 关注FDA医疗器械法规的变化 | | 4 | 加拿大 | 加拿大MDR | https://laws-lois.justice.gc.ca/eng/regulations/ | 关注加拿大MDR医疗器械法规的变化 | | 医疗器械最新消息     What's new: Medical devices | https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/what-new.html | 关注加拿大医疗器械相关的最新动态 | | 5 | 英国 | 英国医疗器械监管Medical  devices regulation and safety | https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety | 关注英国医疗器械相关的最新动态 | | 英国医疗器械指南 | https://www.gov.uk/government/collections/new-guidance-and-information-for-industry-from-the-mhra | 关注英国医疗器械相关的指南文件 | | 6 | MDSAP区域（日本、巴西、澳大利亚） | FDA官网 | https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/mdsap-international-regulations-english-australia-brazil-canada-japan-and-usa | 关注MDSAP五国的QMS相关法规 | | 7 | 澳大利亚 | Therapeutic Goods Administration (TGA) | https://www.legislation.gov.au/Search/Therapeutic%20Goods | 关注如下三个法规的变化：     1、Therapeutic Goods Act 1989     治疗产品法案，其他法规基础     2、Therapeutic Goods Regulations 1990 治疗产品法规     3、Therapeutic Goods (Medical Devices) Regulations 2002     治疗产品（医疗器械）法规，注册，符合性评估主要依据 | | TGA官网     What's New on the Federal Register of Legislation | https://www.legislation.gov.au/WhatsNew | 联邦立法纪事在最近21天内公布的材料清单，     关注澳大利亚医疗器械相关的最新动态 | | Therapeutic Goods Administration (TGA) | https://www.tga.gov.au/latest-news-updates | Latest  news & updates | | Guidance and resources | https://www.tga.gov.au/resources | 所有指南文件的检索 | | Publications | https://www.tga.gov.au/resources/publication/publications | 公告发布 | | Latest News | https://www.tga.gov.au/news/news | 最新资讯发布 | | Consultations | https://www.tga.gov.au/resources/consultation | 征求意见稿发布 | | 8 | 巴西 | ANVISA官网 | https://www.gov.br/anvisa/pt-br | 关注如下两个法规的变化：     1、Resolution RDC 185/2001     巴西ANVISA注册法规         2、RDC 40/2015 Defines the enrollment/ notification requirements of medical  products.     适用于Class I、II的登记备案要求 | | 第三方咨询机构Emergo | https://www.emergobyul.com/resources/regulations-brazil | Resolution-RDC-16-2013  （BGMP）     GMP要求 | | 9 | 日本 | 日本法规翻译网 | http://www.japaneselawtranslation.go.jp/law/list/?ft=2&re=2&dn=1&yo=medical+device&ia=03&ja=04&ph=&x=35&y=15 | 关注日本医疗器械法规的变化 | | 厚生劳动省官网 | https://www.mhlw.go.jp/english/index.html | 关注“Pharmaceuticals  and Medical Devices（药品和医疗器械）”模块的变化 | | 日本药品和医疗器械局（PMDA） 官网 | https://www.pmda.go.jp/english/index.html | 关注日本“Medical  devices”医疗器械模块的更新 | | 10 | 香港 | 卫生部-医疗器械官网 | https://www.mdd.gov.hk/tc/home/index.html | 关注香港医疗器械“醫療儀器行政管理制度” | | 11 | l  马来西亚 | 马来西亚-医疗器械管理局(MDA)官网 | https://www.mda.gov.my/ | 马来西亚医疗器械法规及指南文件 | | 12 | 韩国 | 韩国食品和药品安全部官网 | https://www.mfds.go.kr/eng/index.do | 关注韩国Medical  Devices 模块的变化 | | 13 | 瑞士 | 瑞士联邦法律 | https://www.fedlex.admin.ch/eli/cc/2020/552/en | 关注Medical  Devices Ordinance法规 | | 瑞士卫生部 | https://www.swissmedic.ch/swissmedic/en/home/news.html | 关注瑞士医疗器械法规的变化 | | 14 | 菲律宾 | 菲律宾FDA官网 | https://www.fda.gov.ph/ | 关注菲律宾医疗器械法规的变化（FDA  circular, FDA Memorandum, Memorandun circular板块） | | 15 | 东盟 | 东盟ASEAN官网 | https://asean.org/ | 关注医疗器械法规的变化 | | ASEAN DOCS | https://docs.asean.org/SitePages/DocumentSearch.aspx | 指南文件检索 | | 16 | WHO | WHO官网 | https://www.who.int/ | 关注医疗器械法规的变化 | | Emergency use listing (EUL) | https://www.who.int/teams/regulation-prequalification/eul/ | 白名单 | | Coronavirus disease (COVID-19) Pandemic —  Emergency Use Listing Procedure (EUL) open for IVDs | https://extranet.who.int/pqweb/vitro-diagnostics/coronavirus-disease-covid-19-pandemic-%E2%80%94-emergency-use-listing-procedure-eul-open | 新冠EU | |