China

Latest Updates

Software	
Embedded Software	Embedded software share the same classification as the device and should be registered with the device. Register according to the 1- "technical review guidance of medical device software registration"- C1 5th Jun 2020, NMPA publish the "technical review guidance of medical device software registration (2nd version) (exposure draft)" 2-"technical review guidance of mobile Medical Device registration" Classification according to 1- Medical Device Classification Rule [CFDA No.15] 2-"medical device classification catalog"-C3 3- Classification result on 2019 4- Classification result on 2020 5- AI Medical Device software Classification guidance 6- Medical Aid decision software Classification guidance (exposure draft） Need to comply with GB25000.51 Software Quality Requirement and Evaluation standard. -C2 YY/T 0664 （IEC 62304）Medical device software - Software life cycle processes do we need to list all related standard here? (quoted and list in guidance)
Software as Medical Device (SaMD)	Standalone software could be registered as separate license, or accessories to medical device if could be used with other devices. Register according to the: 1- Medical Device registration regulation (SMAR No.47] 2- Medical Device labelling regulation [NMPA No.6] 3- Medical Device Classification Rule [NMPA N0.15] 4- "technical review guidance of medical device software registration" 5th Jun 2020, NMPA publish the "technical review guidance of medical device software registration (2nd version) (exposure draft)" 5-"technical review guidance of mobile Medical Device registration" 6- "technical review guidance of PACS registration" 7- "technical review guidance of central monitoring software registration" Classification according to: 1- Medical Device Classification Rule [CFDA No.15] 2-""medical device classification catalog""-C3 3- Classification result on 2019 4- Classification result on 2020 5- AI Medical Device software Classification guidance 6- Medical Aid decision software Classification guidance (exposure draft）

	Need to comply with GB25000.51 Software Quality Requirement and Evaluation standard. YY/T 0664 （IEC 62304）Medical device software - Software life cycle processes do we need to list all related standard here? (quoted and list in guidance) 14 Jul 2022: NMPA published guidance document for recommended pathway for clinical evaluation of related products in sub-categories 21 "Medical Software" in "The Classification Catalogues of Medical Devices". This guidance document provides the recommendations on approaches to take in terms of clinical evaluation for medical software. Information on the product's description, intended use, device examples, regulatory classification, approaches for clinical evaluation on the same class products is listed with details.
Clinical Decision Support Software (CDS)	Based on the different situation to choose the clinical pass way: Register according to the 1- "technical review guidance of medical device Clinical evaluation " 2- Clinical exempt list 3- Clinical trial list 4- GCP regulation
Change Management Requirements for Software/SaMD	3- technical review guidance of AI medical device registration (exposure draft)
Quality Management System (QMS)	Follow all software guidance requirements
Post-Market Management	Regulations on Adverse Events Monitoring and Re-evaluation of Medical Device provisions for Medical Device Recall

Real World Data/Evidence

Announcement on the Publication of the Technical Guidelines for the Use of Real-World Data in Clinical Evaluation of Medical Devices (Trial)

22 April 2022: NMPA published Communication Procedure for Medical Device Real World Data Application Projects in Hainan Baoao Lecheng Medical Tourism Pilot Zone. NMPA will enhance the guide on medical device pilot program in Hainan to help apply Real World Data (RWD) for China registration.

Artificial Intelligence (SiMD & SaMD)

Machine Learning	Refer: SaMD systems based on Artificial Intelligence/Machine Learning 28 April 2022: NMPA announced the latest implementation and amendment plan for YY and YY/T industry standards in China, and among the list of 59 new YY/T standards, 2 standards covered are related to Artificial Intelligence (AI) medical device. (https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjylqx/20220428155347129.html)
Deep Learning	Refer: SaMD systems based on Artificial Intelligence/Machine Learning 28 April 2022: NMPA announced the latest implementation and

	amendment plan for YY and YY/T industry standards in China, and among the list of 59 new YY/T standards, 2 standards covered are related to Artificial Intelligence (AI) medical device. (https://www.nmpa.gov.cn/xxgk/fgwj/gzwj/gzwjylqx/20220428155347129.html)
Best Ethical Practices	No updates at present.
Generative AI	No updates at present.

Cybersecurity

"1-""technical review guidance for medical device cybersecurity"" 2-""technical review guidance for medical device cybersecurity"" (2nd version) （exposure draft） 3- Beijing FDA--Guidelines for implementation of registration and Review guidelines for Medical Device Network Security ""China cybersecurity law""-C5 2-China Data security Law 3-China personal information protection Law 4-National Emergency Plan for Cyber Security Incidents 5-Measures for Assessment of Personal Information Exit Security (Draft) 6-Measures for Cybersecurity Review (Draft revision for public comments) 7-National Health and Medical Big Data Standards, Safety and Service Management Measures (Trial) under discussion: ""standard for medical device cybersecurity basic safety requirement"" 1-WS/T XXXX Internet Health and Medical Information Security Management Guideline 2-GB/T 20985.1-2017 信息技术 安全技术 信息安全事件管理 第1部分：事件管理原理[S] 3- GB/T 22080-2016 信息技术 安全技术 信息安全管理体系要求[S] 4- GB/T 22081-2016 信息技术 安全技术 信息安全管理实用规则[S] 5- GB/T 22239-2019 信息安全技术 网络安全等级保护基本要求[S] 6-GB/T 25000.51-2016 系统与软件工程 系统与软件质量要求和评价（SQuaRE） 第51部分：就绪可用软件产品（RUSP）的质量要求和测试细则[S] 7- GB/T 25070-2019 信息安全技术 网络安全等级保护安全设计技术要求[S] 8-GB/T 28448-2019 信息安全技术 网络安全等级保护测评要求[S] 9-GB/T 29246-2017 信息技术 安全技术 信息安全管理体系 概述和词汇[S] 10- GB/T 30276-2020 信息安全技术 网络安全漏洞管理规范[S] 11-GB/T 31167-2014 信息安全技术 云计算服务安全指南[S] [31] GB/T 31168-2014 信息安全技术 云计算服务安全能力要求[S] [32] GB/T 31722-2015 信息技术 安全技术 信息安全风险管理[S] [33] GB/T 35273-2020 信息安全技术 个人信息安全规范[S] [34] GB/T 35274-2017 信息安全技术 大数据服务安全能力要求[S] [35] GB/T 35278-2017 信息安全技术 移动终端安全保护技术要求[S] [36] GB/T 37964-2019 信息安全技术 个人信息去标识化指南[S] [37] GB/T 37973-2019 信息安全技术 大数据安全管理指南[S] [38] GB/T 37988-2019 信息安全技术 数据安全能力成熟度模型[S] [39] GB/T 39335-2020 信息安全技术 个人信息安全影响评估指南[S] [40] GB/T 39725-2020 信息安全技术 健康医疗数据安全指南[S] [41] YY/T 0287-2017 医疗器械 质量管理体系 用于法规的要求[S] [42] YY/T 0316-2016 医疗器械 风险管理对医疗器械的应用[S] [43] YY/T 0664-2020 医疗器械软件 软件生存周期过程[S] [44] YY/T 1406.1-2016 医疗器械软件 第1部分：YY/T 0316应用于医疗器械软件的指南[S] [45] YY/T 1708.1-2020 医用诊断X射线影像设备连通性符合性基本要求 第1部分：通用要求[S] [46] YY/T 1708.2-2020 医用诊断X射线影像设备连通性符合性基本要求 第2部分：X射线计算机体层摄影设备[S] [47] YY/T 1708.3 医用诊断X射线影像设备连通性符合性基本要求 第3部分：数字化摄影X射线机（DR）（报批稿）[S] [48] YY/T 1708.4 医用X射线影像设备连通性符合性基本要求 第4 部分：数字减影血管造影X射线机（DSA）（报批稿）[S] [49] YY/T 1708.5 医用诊断X射线影像设备连通性符合性基本要求 第5 部分：乳腺X射线机（报批稿）[S] [50] YY/T 1708.6 医用诊断X射线影像设备连通性符合性基本要求 第6 部分：口腔X射线机（报批稿）[S] [51] YY/T 医用电气设备网络安全基本要求（报批稿）[S] [52] DB32/T 3769-2020医疗器械网络连接通用技术规范[S]"

Data Privacy

No updates at present.

Labelling

UDI	No updates at present.
Specific Market Requirements	No updates at present.

Taiwan

Latest Updates

Software	
Embedded Software	Embedded software is not registered separately, but as part of the system.
Software as Medical device (SaMD)	Based on "Guidance of Classification of Medical Software"
Clinical Decision Support Software (CDS)	No updates at present.
Change Management Requirements for Software/SaMD	No updates at present.
Quality Management System (QMS)	Regulations of the Medical Device Quality Management System: https://law.moj.gov.tw/ENG/LawClass/LawAll.aspx?pcode=L0030116
Post-Market Management	Guidelines for Post-Market Change Application of Software as Medical Device: https://www.fda.gov.tw/TC/siteListContent.aspx?sid=310&id=39567 Guidance in terms of cybersecurity can be found in section VIII. Postmarket Cybersecurity Monitoring under the "Guidance for Industry on Management of Cybersecurity in Medical Devices" (Ref: https://www.fda.gov.tw/tc/includes/GetFile.ashx?id=f637558103530220620)

Real World Data/Evidence
No specific guidance.

Artificial Intelligence (SiMD & SaMD)	
Machine Learning	Guidance for Industry to Register Artificial Intelligence/Machine Learning-based Software as Medical Device (AI/ML-based SaMD) : https://www.fda.gov.tw/tc/includes/GetFile.ashx?id=f637648052118207932

Deep Learning	Guidance for Industry to Register Artificial Intelligence/Machine Learning-based Software as Medical Device (AI/ML-based SaMD) : https://www.fda.gov.tw/tc/includes/GetFile.ashx?id=f637648052118207932
Best Ethical Practices	No updates at present.
Generative AI	No updates at present.

Cybersecurity

Guidelines for Cybersecurity of Medical Devices for Manufacturers: https://www.fda.gov.tw/tc/includes/GetFile.ashx?id=f637558103530220620

Data Privacy

Implementation Regulations Governing Personal Information File Security Maintenance Plans in Wholesaling and Retailing Medical Devices: https://join.gov.tw/policies/detail/e0e0831f-73cc-4f07-95fd-361a73441fdb

Labelling

UDI	No updates at present.
Specific Market Requirements	No updates at present.