表 2：医疗器械软件描述文档申报要求
Table 2: Submission Requirements for Medical Device Software Products

描述文档		A 级（轻微） Level A (Slight)	B 级（中等） Level B (Medium)	C 级（严重） Level C (Serious)
基本信息 Basic Information	产品标识 Product marking	描述软件名称、型号、版本号、制造商和生产地址 Describe software name, model, revision no., manufacturer and product location		
	安全性级别 Safety Level	描述软件安全性级别，并详述安全性级别确定理由 Describe software's safety level and reasons for determining such level 对于 B 级和 C 级的医疗器械软件，软件描述文档的部分内容应提供原始文件。 Provide original documents for Class B and C.		
		A 级：不可能对健康有伤害和损坏； Level A: Not possible to cause any injury or harm	B 级：可能有不严重的伤害 Level B: Possible to cause non-severe harm or injury	C 级：可能死亡或严重伤害。 Level C: Possible to cause death or sever injury or ham.
	结构功能 Function and structure	依据体系结构图，描述软件的组成模块、模块功能、模块关系、外部接口和用户界面 According to Design specification (SDS), using system block diagram, describe software modules, functions of each module, relationship between modules, connection with outside and user interface screens. Modules should be noted if it is optional, its revision no. and module name, revision, manufacturer and type (outsourced, off the shelf or TBD)		
	硬件关系 Hardware relationship	依据物理拓扑图，描述软件、通用计算机和医疗器械硬件的物理连接关系 According to SDS to provide the physical topology, describe with illustration the physical connection relationship among software modules, computer and medical device		
	运行环境 Operational environment	描述软件运行所需的硬件配置、软件环境和网络条件 Describe hardware configuration (such as processor, hard drive, external devices and IO device), software environment (system software, mandatory software, optional software and anti virus software) and network conditions (network connector, network type – LAN or WAN and network structure – CS or BS) for the software to function properly.		
	适应范围 Application	描述软件的适用范围和适用人群 Describe software application and applicable patient types. It should describe the software application range and the medical device's application range and patient types.		
	禁忌症 Contradiction	描述软件的禁忌症和不适用人群 Describe software contradiction and inapplicable patient types		
	上市历史 Market History	描述软件在中国、原产国等主要国家地区的上市时间、版本号和管理类别 Describe the time, revision and management class of the software in China, in the country of origin and other key international markets. New registration in China should list risk level based on SFDA regulation. For renewal registration, list all products already		

		on the market, revision numbers and registration numbers. Also list the initial market release of the product in country of origin, US, Japan and EU, including the revisions and management class. Describe the market history of the medical device.		
实现过程 **Realization Process**	开发综述 Description of software development	描述开发语言、工具、方法、模型、人员、时间、工作量、代码行数和控制文档数 Describe the language used to develop the software product, the tools (including supportive software, source software and 3rd party application software name, revision, manufacturer), methods, modules, personnel, time, work load, lines of codes and number of control documents. Also include number of developers, development time, work load (man month), number of lines of codes and total number of control documents.		
	风险管理 Risk management	提供风险管理资料 Provide risk management documents, including document name, seriousness, reasons, solutions and results.		
	需求规格 Specification	需求规格的功能、性能要求 Functions and feature requirements 描述软件需求规格（SRS）关于功能和性能的要求。	需求规格全文，包含硬件、功能、性能、输入输出、接口界面、警示信息、保密安全、数据与数据库、文档和法规的要求 Specifications, including hardware, functions, features, input/output ports, interface screen, warnings, security, data or database, documents and regulations. If using off the shelf software, the medical device software should provide relevant information.	
	生存周期 Life cycle Please reference YY/T0664-2008 or YY/T0708/2009	开发生存周期计划摘要 Plan for Life cycle of the development, describe objectives, contents and results of each segment. 生存周期实施情况应另附原始文件。YY/T0664-2008 或 YY/T0708-2009 核查表可以提供作为参考。当组成模块采用现有软件时，B 急和 C 级医疗器械软件应再开发生存周期计划、配置管理计划和维护计划中说明相应要求。	开发生存周期计划、配置管理计划和维护计划的摘要 Synapsis of Life cycle plan, synapsis of configuration management plan and service plan, describe relevant tools, flow plan and requirements. If using off the shelf software, B and C software should describe relevant requirements for product cycle, configuration and maintenance plans.	开发生存周期计划、配置管理计划和维护计划的摘要，列明各阶段输入输出文档 Abbreviations of Life cycle plan, configuration management plan and service plan. List input/output documents for each segment
	验证与确认 Validation and Confirmation	系统测试和用户测试的计划与报告摘要 Abbreviations of System testing plan and user testing plan and reports, describe testing conditions, tools, methods, standards and results.	概述开发各阶段的验证活动，提供系统测试和用户测试的计划与报告摘要 Describe the validation activities during each stage of development, provide Abbreviations of system testing and user testing plan and reports. In additional to Level A requirements, introduce validation activities in each development stage, tools, methods, content and results. For module testing, describe requirement of coverage. If using concentrated testing method, describe strategy.	概述开发各阶段的验证活动，提供系统测试和用户测试的计划与报告 Describe the validation activities during each stage of development, provide system testing and user testing plan and reports. System testing and user testing should be separate original documents. Please include traceability analysis report as reference. If a module uses off the shelf software, all levels of software need to be validated and confirmed.

	缺陷管理 Defects Management	描述缺陷总数和剩余缺陷数 Describe total number of defects and remaining number of defects	描述缺陷总数和剩余缺陷数，列明剩余缺陷的严重度、处理措施和处理时间 Describe total number of defects and remaining number of defects. List seriousness of the defects, solutions and solution date. If using off the shelf software, Level B and C should list all remaining defects.	
	修订历史 Revision History	描述版本号命名规则，列明本次修订的版本号、类型和日期 Describe revision naming principle; list the revision number, type (perfect, adaptive, corrective) and date.	描述版本号命名规则，列明本次修订的版本号、类型（完善型、适应型、纠正型）和日期，详述本版与前版的变更内容 Describe revision naming principle; list this revision number, type and date. Describe in detail the changes in this revision vs. the earlier version. For Level B and C softwares, list each revision, type and date of each software versions since the original release in home market.	描述版本号命名规则，列明本次和以往修订的版本号、类型和日期，详述本版与前版的变更内容 Describe revision naming principle; list the revision number and previous revision numbers, type and date. Describe in detail the changes in this revision vs. the earlier version.
	临床评价 Clinical evaluation	提供临床评价资料 Provide clinical evaluation document, including white papers, clinical data, clinical evaluation reports.		
核心算法 **Core Algorithm** According to SDS and user manual, list core algorithm's name, theory, usage and type. Core Algorithm includes post process algorithm and human intelligence algorithm. The post process algorithm usually can change the original medical image or data, includes but not limited to compressed, segmentation, match and fusion, 3D reconstruction, Quantitative analysis and abnormal identification. Human intelligence algorithm is based on database analysis, including but not limited to module identification, neuro network and expert system. Type means public	公认成熟算法列明名称，全新算法列明名称、原理和用途 List the name of algorithm if it is publically considered as mature method. List the algorithm name, theory, application if it is a new algorithm	公认成熟算法列明名称、原理和用途，全新算法除列明名称、原理和用途外，还应提供安全性与有效性的验证资料 List the name of algorithm if it is publically considered as mature method. List the algorithm name, theory, application if it is a new algorithm. Provide validation document for safety and effectiveness.		

mature algorithm (white paper or patent standard, principle, no adverse event after 4 years since market release) or new algorithm (derived from scientific research and clinical data)		
附：部分现成软件 **Additional: Some available software** If the entire software package is developed by a third party, the registration should include: 1. contract with the outside developer and software description document. 2. off the shelf contract and software description (explain if some applications are not applicable). If the software has been registered in China, provide copy of the registration and other relevant documents. 3. remaining software should include product registration certificate and software description.	在结构功能、风险管理、验证与确认中有相应要求 Relevant requirements for configuration, features, risk management, validation and confirmation.	在结构功能、需求规格、风险管理、生存周期、验证与确认和缺陷管理中有相应要求 Relevant requirements for configuration, features, risk management, life cycle, validation and confirmation and defects.