EN 62366:2008 Checklist/检查表
Medical devices
Application of usability engineering to medical devices
可用性工程于医疗器械的应用

Product Name/产品名称
Report Reference No/编号. : Version/版本号： 验证人： Date of issue/发布日期:

版本修改记录：

日期	版本	说明	验证人	审批人

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Clause 条款	Requirement 要求	Remark 解释	Verdict 判定

4	**GENERAL REQUIREMENTS/总要求**		
4.1	General Requirements/总要求		
4.1.1	USABILITY ENGINEERING PROCESS/可用性工程过程		
	Has the MANUFACTURER established, documented and maintained a USABILITY ENGINEERING PROCESS to provide SAFETY for the PATIENT, USER and others related to USABILITY for the product? 制造商是否建立、记录并维持了一个可用性工程过程，以确保患者、用户和其它涉及产品适用性的人的安全?	User Manual; Quality manual, procedure document;	Compliance
	Does the PROCESS address USER INTERACtions with the MEDICAL DEVICE according to the ACCOMPANYING DOCUMENT including, but not limited to transport, storage, installation, operation, maintenance, repair and disposal? 该过程是否用于解决用户按随机文件与医疗器械的交互，如运输、存储、安装、操作、维护、维修和废弃？	User Manual	Compliance
4.1.2			
	Are RESIDUAL RISKS associated with USABILITY of the MEDICAL DEVICE presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary and documented? 关系医疗器械可用性的剩余风险是否推定可接受?	Risk analysis report ;	Compliance
4.1.3			
	MANUFACTURER SHALL subject the information for safety used as a RISK CONTROL to the USABILITY ENGINEERING PROCESS (e.g., warnings or limitation of use in the ACCOMPANYING DOCUMENTS, marking, etc.). 对于做为风险控制措施的安全信息，制造商应把它纳入可用性工程过程的控制	Risk analysis report ; User Manual;	Compliance
	Disregarding such information for SAFETY is considered beyond any further reasonable means of RISK CONTROL 忽视安全信息的行为应被认为是超出风险控制措施的（即非正常使用）	Risk analysis report	Compliance
4.2			
	The results of the USABILITY ENGINEERING PROCESS are recorded in the USABILITY ENGINEERING FILE 可用性工程过程的结果记录于可用性工程文档。	Quality manual, procedure document;	Compliance

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	The records and other documents that make up the USABILITY ENGINEERING FILE MAY form part of other documents and files (e.g., a MANUFACTURER'S product design file or RISK MANAGEMENT FILE), (SEE List of documents make up the UE file) 组成可用性工程文档的记录和其它文件可以是其它文档（如技术文档和风险管理文档）的一部分	Quality manual, procedure document	Compliance
4.3	Scaling of the USABILITY ENGINEERING effort/可用性工程的调整		
	The USABILITY ENGINEERING PROCESS is scaled based on the significance of any modifications depending on the results of the RISK ANALYSIS and documented 可用性工程调整取决于风险分析确认的设计更改的重要程度	Risk analysis report	Compliance
5	**USABILTY ENGINEERING PROCESS/可用性工程过程**		
5.1	Application specification/应用的规格		
	Application of MEDICAL DEVICE in the USABILITY ENGINEERING FILE is specified by the MANUFACTURER and includes 可用性工程文档中的医疗器械的应用由制造商决定，包括：	-	-
	– intended medical indication (e.g., conditions(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented); 预期医学用途，如预期要筛查、监护、治疗、诊断或预防的状态或疾病；	User Manual	Compliance
	– intended PATIENT population (e.g., age, weight, health, condition); 预期患者群，如年龄、体重、健康和社会条件；	User Manual	Compliance
	– intended part of the body or type of tissue applied to or interacted with; 预期使用的身体部位或组织；	User Manual	Compliance
	– intended conditions of use (e.g.. environment including hygienic requirements, frequency of use, location, mobility); and 预期的使用状态，如环境包括卫生要求、使用频度、地点和机动性；	User Manual	Compliance

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	– operating principle(s) 操作原理	User Manual	Compliance
5.2	Frequently used functions/常用功能		
	Are frequently used functions that involve USER interaction with the MEDICAL DEVICE are determined and recorded in the USABILITY ENGINEERING FILE? 在可用性工程文档中是否确定并记录了涉及用户与医疗器械交互的常用功能？	User Manual	Compliance
5.3	Identification of HAZARDS and HAZARDOUS SITUATIONS related to USABILITY/识别可用性相关的危害和危害处境		
5.3.1	Identification of characteristics to SAFETY/识别安全特征		
	Identification of characteristics related to SAFETY (part of a RISK ANALYSIS) that focuses on USABILITY performed according to ISO 14971:2007, 4.2. 应按ISO 14971:2007, 4.2的要求识别专注于可用性的安全特征	Risk analysis report	Compliance
	During the identification characteristics related to SAFETY, the following are considered: 在识别安全特征时，要考虑下列因素： – application specification, including USER PROFILE(S); and 应用的规格，包括用户特征； –frequently used functions. 常用功能。	User Manual	Compliance
	Results of this identification characteristics related to SAFETY recorded in the USABILITY ENGINEERING FILE 安全特征识别的结果应记录于可用性工程文档	User Manual	Compliance
5.3.2	Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS/识别已知的或可预见的危害和危害处境		
	MANUFACTURER has identified known or foreseeable HAZARDS (part of a RISK ANALYSIS) related to USABILITY according to ISO 14971:2007, 4.3. 制造商要按ISO 14971:2007, 4.3的要求识别可用性相关的已知的或可预见的危害	Risk analysis report	Compliance
	Identification of HAZARDS considered HAZARDS to PATIENTS, USERS and other persons 识别危害时要考虑对患者、操作者和其他人员的危害	Risk analysis report	Compliance

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	Reasonably foreseeable sequences or combinations of events involving the USER INTERFACE that can result in a HAZARDOUS SITUATION associated with the MEDICAL DEVICE were identified. The SEVERITY of the resulting possible HARM is determined. 包括可能导致危害处境的医疗器械用户界面的合理可预见的事件的次序和组合已经被识别。导致的可能的危害的严重程度已确定。	Risk analysis report	Compliance
	During the identification of HAZARDS and HAZARDOUS SITUATIONS, the following was considered: 在识别危害和危害处境时，下列需要考虑： – application specification, including USER ROFILE(S); 应用的规格，包括用户特征； – task related requirements; 任务相关的要求； – context of use; 使用的背景； – information on HAZARDS and HAZARDOUS SITUATIONS known for existing USER INTERFACES of MEDICAL DEVICES of a similar type, if available; 对于现存的类似的医疗器械用户界面的已知的危害和危害处境信息； – preliminary USE SCENARIOS; 初步的使用情景； – possible USE ERRORS; 可能的使用错误； – if an incorrect mental model of the operation of the MEDICAL DEVICE can cause a USE ERROR resulting in a HAZARDOUS SITUATION; and 操作医疗器械的错误精神模型是否会引起导致危害处境的使用错误； – results of the review of the USER INTERFACE 用户界面的评审结果。	Risk analysis report User Manual	Compliance
	The results of this identification of HAZARDS, HAZARDOUS SITUATIONS and SEVERITY are recorded in the USABILITY ENGINEERING FILE. 识别危害、危害处境和严重程度的结果要记录在可用性工程文档里。	Risk analysis report	Compliance
5.4	PRIMARY OPERATING FUNCTIONS/主要操作功能		
	The manufacturer has determined the PRIMARY OPERATING FUNCTIONS and recorded in the USABILITY ENGINEERING FILE 制造商已经确定了主要操作功能并记录在可用性工程文档里。	User Manual	Compliance

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	The inputs to the PRIMARY OPERATING FUNCTIONS include frequently used functions and functions related to SAFETY of the MEDICAL DEVICE 主要操作功能的输入包括常用功能和关系医疗器械安全的功能。	User Manual	Compliance
5.5	USABILITY SPECIFICATION/可用性规范		
	MANUFACTURER developed a USABILITY SPECIFICATION recorded in the USABILITY ENGINEERING FILE as part of the USABILITY ENGINEERING PROCESS 制造商应制定可用性规范，记录于可用性工程文档里作为可用性工程过程的一部分。	Quality manual, procedure document	Compliance
	The USABILITY SPECIFICATION recorded in USABILITY ENGINEERING FILE. The USABILITY SPECIFICATION may be integrated into other specifications 可用性规范记录于可用性工程文档里。可用性规范可以整合于其它规范。	Quality manual, procedure document	Compliance
	The USABILITY SPECIFICATION includes: 可用性规范包括： – application specification; 应用的规格； – PRIMARY OPERATING FUNCTIONS 主要操作功能 – HAZARDS and HAZARDOUS SITUATIONS related to the USABILITY; and 关系可用性的危害和危害处境 – known or foreseeable USE ERRORS associated with the MEDICAL DEVICE 已知的或可预见的关系医疗器械的使用错误。	User Manual Risk analysis report	Compliance
	The USABILITY SPECIFICATION describes at least: 可用性规范至少要描述：		
	– USE SCENARIOS related to the PRIMARY OPERATING FUNCTIONS, including 关于主要操作功能的使用情景，包括： – frequent Use Scenarios, and 常见的使用情景 – reasonably foreseeable worst case USE SCENARIOS; 合理可预见的最坏使用情景；	User Manual Risk analysis report	Compliance

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	– USER INTERFACE requirements for the PRIMARY OPERATING FUNCTIONS, including those to mitigate RISK; 主要操作功能对于用户界面的要求，包括降低风险的那些；	Risk analysis report	Compliance
	– Requirements for determining whether PRIMARY OPERATING FUNCTIONS are easily recognizable by the USER. 用于决定主要操作功能是否易于被用户认知的要求	Risk analysis report	Compliance
5.6	USABILITY VALIDATION plan/可用性确认计划		
	The MANUFACTURER has developed and maintains a USABILITY VALIDATION plan specifying: 制造商需制定并维护可用性确认计划，以规定：	User Manual	Compliance
	– any method used for VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS; 对于主要操作功能的可用性的确认方法；	User Manual	Compliance
	– the criteria for determining successful VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS based on the USABILITY SPECIFICATION; and 基于可用性规范，对主要操作功能可用性的确认标准	User Manual	Compliance
	– the involvement of representative intended USERS 包含的预期用户代表	User Manual	Compliance
	USABILITY VALIDATION performed in a laboratory setting .....: 可用性确认实施的实验室设置：	Test report.	Compliance
	USABILITY VALIDATION performed in a simulated use environment .....: 可用性确认实施于模拟使用环境：	Test report	Compliance
	USABILITY VALIDATION performed in the actual use environment .....: 可用性确认实施于真实使用环境：	Test report	Compliance

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	The USABILITY VALIDATION plan addresses: 可用性确认计划包括： – frequent Use Scenarios, and 常见的使用情景； – reasonably foreseeable worst case USE SCENARIOS 合理可预见的最坏使用情景 that are identified in the USABILITY SPECIFICATION 都要在可用性规范中识别。	User Manual	Compliance
	The USABILITY VALIDATION plan recorded in the USABILITY ENGINEERING FILE 可用性确认计划应记录与可用性工程文档。	User Manual	Compliance
5.7	USER INTERFACE design and implementation/用户界面设计和实施		
	MANUFACTURER designed and implemented the USER INTERFACE as described in the USABILITY SPECIFICATION utilizing, as appropriate, USABILITY ENGINEERING methods and techniques 制造商应使用可用性工程的方法和技术来开发并实施可用性规范描述的用户界面。	Products do not have this requirement	non-compliance
5.8	USABILITY VERIFICATION /可用性验证		
	MANUFACTURER verified the implementation of the MEDICAL DEVICE USER INTERFACE design according to the USABILITY SPECIFICATION 制造商应根据可用性规范来验证医疗器械用户界面设计的实施。	Products do not have this requirement	non-compliance
	The results of the verification are recorded in USABILITY ENGINEERING FILE 验证的结果应记录于可用性工程文档。	Products do not have this requirement	non-compliance
5.9	USABILITY VALIDATION/可用性确认		
	The MANUFACTURER has validated the USABILITY of the MEDICAL DEVICE according to the USABILITY VALIDATION plan 制造商应根据可用性确认计划来确认医疗器械用户界面的可用性。	Products do not have this requirement	non-compliance
	The results are recorded in the USABILITY ENGINEERING FILE 确认的结果应记录于可用性工程文档。	Products do not have this requirement	non-compliance

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	For the acceptance criteria documented in the USABILITY VALIDATION plan that are not met: 对于没有可用性确认计划中制定的未被满足的接收准则： - further USER INTERFACE design and implementation activities are performed; or 需要进行进一步的用户界面设计和执行；或 - if further improvement is not practicable, the MANUFACTURER may gather and review data and literature to determine if the medical benefits of the INTENDED USE outweigh the RISK arising from USABILITY problems 如果进一步的改进不现实，制造商需要收集并评审数据和文献，以确定预期用途的医疗收益是否超过可用性问题带来的风险。 To perform this step, the MANUFACTURER needs to estimate the RISK arising from USABILITY problems. 为此，制造商需评估可用性问题带来的风险。	Products do not have this requirement	non-compliance
6	**ACCOMPANYING DOCUMENTS/随机文件**		
	The ACCOMPANYING DOCUMENT includes a summary of the MEDICAL DEVICE application specification 随机文件应包括医疗器械应用的规格的总结。	User Manual	Compliance
	A concise description of the MEDICAL DEVICE, its operating principles, significant physical and performance characteristics and intended USER PROFILE are included in the ACCOMPANYING DOCUMENT 随机文件包括医疗器械、工作原理、重要的物理和性能特性和预期用户的特征的简要描述。	User Manual	Compliance
	The ACCOMPANYING DOCUMENT is written at a level consistent with the intended OPERATOR PROFILE 随机文件的编写要与用户特征的水平相一致。	User Manual	Compliance
	The ACCOMPANYING DOCUMENT for equipment are, optionally, provided electronically 设备的随机文件或者可以电子文件提供。	User Manual	Compliance

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	USABILITY ENGINEERING PROCESS includes the information that will need to be provided as a hard copy or as markings on MEDICAL DEVICE when ACCOMPANYING DOCUMENTS are provided electronically 当随机文件是电子形式时，可用性工程过程应包括在医疗器械上需要以硬拷贝或标识提供的信息。	User Manual	Compliance

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7	**TRAINING AND MATERIALS FOR TRAINING/培训和培训材料**		
	The required training on the MEDICAL DEVICE for safe and effective use of PRIMARY OPERATING FUNCTIONS by the intended USER is given by: 由预期用户安全有效使用医疗器械主要操作功能的必须培训包括：	User Manual	Compliance
	– necessary training materials provided by the manufacturer; 制造商提供的必要的培训材料；	User Manual	Compliance
	– necessary training materials are available; or 必要培训材料的可获得性；	User Manual	Compliance
	– the manufacturer provides TRAINING 或制造商提供培训	User Manual	Compliance
	The ACCOMPANYING DOCUMENT describes the available training options (Recommendation: ACCOMPANYING DOCUMENT include the suggested duration and frequency of such training) 随机文件要描述可获得的培训选项 （推荐：随机文件包括此类培训时间和频度的建议）	User Manual	Compliance
	INTENDED USE AND USER PROFILE(S) are the basis for TRAINING and TRAINING material 预期用途和用户特征是培训和培训材料的基础。	User Manual	Compliance