# 软件的安全风险等级

**If the answer to any <u>one</u> question below is Yes, the Level of Concern for the Software Device is likely to be Major.**

1. Does the Software Device qualify as Blood Establishment Computer Software?

(Blood Establishment Computer Software is defined as software products intended for use in the manufacture of blood and blood components or for the maintenance of data that blood establishment personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture.)

2. Is the Software Device intended to be used in combination with a drug or biologic?

3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?

4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:

a. Does the Software Device control a life supporting or life sustaining function?

b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?

c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?

d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?

e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?

**If the Software Device is not Major Level of Concern and the answer to any <u>one</u> question below is Yes, the Level of Concern is likely to be Moderate.**

1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?

2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?

3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?

如果下面任何一个问题的答案是肯定的，那么对软件设备的关注程度可能是重要的C级。

1. 该软件器械是否为血液机构计算机软件？

2. 该软件器械是否可与药物或生物制品结合使用？

3. 该软件器械是否为具有C_高级关注程度 的医疗器械的配件？

4. 减缓危害之前，该软件器械的故障是否可对患者或对器械使用人员造成死亡或严重伤害？相关示例包括下列内容：

5. 该软件器械是否控制生命支持或生命维持功能？

6. 该软件器械是否控制可造成死亡或严重伤害的潜在有害能源，如放射治疗系统、除颤器和电切割系统？

7. 该软件器械是否影响治疗或疗效，从而差错或故障可能导致造成死亡或严重伤害？

8. 该软件器械是否提供可直接得出治疗或疗效决策的信息，这样如果使用不当可能会造成严重的伤害或死亡？

9. 该软件器械是否配有监测潜在生命威胁状况的重要指示信息和警报，其中这种生命威胁状况需要医疗干预？

如果软件设备不属于重要关注程度，并且下面任何一个问题的答案是肯定的，则问题的关注程度可能是中等的B级。

1. 该软件器械是否为具有B_中级关注程度医疗器械的配件？

2. 减缓危害之前，该软件器械的故障是否可对患者或对器械使用人员造成低级伤害？

3. 该软件器械的一项故障，或潜在的设计缺陷，是否能导致：错误诊断，或