Checklist: Software Requirements Review

Classes	IEC 62304:2006 Section	Document Section
A, B, C	5.2.6	(All)

ISO 13485:2016 Section	Document Section
7.3.3	(All)
7.3.5	(All)

1. Summary

This checklist is used to review (verify) software requirements prior to implementation.

> As with all regulatory documents, it's more about the content than about the tool. You don't have to fill this checklist out every time in Word / GDocs / etc., but could embed it in your Jira / GitHub workflow. The main point is that, at minimum, the items below should be filled out before you start implementing software requirements.

> Feel free to add further rows in the checklist if they make sense for your company. This template is pretty much the bare minimum to be 62304-compliant.

2. Checklist

Software Requirements. . .	Yes	No	Comment
are traceable to design input or risk control measures.			
are complete.			
are understandable, uniquely identifiable and do not contradict each other.			
include user interface requirements (mockups, wireframes, etc.), if relevant.			
include IT security requirements, if relevant.			
are testable and include acceptance criteria.			

3. Comments

<Insert comments if applicable>

4. Result

[ ] Software Requirements passed
[ ] Software Requirements not passed
[ ] Software Requirements passed with the following obligations: <Insert if applicable>