



Checklist :
Software Release


PROTOCOL NO. :

EFFECTIVE DATE :

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Checklist: Software Release

TITLE:	
AUTHORING GROUP:	
DATE:	
SUPERSEDE PROTOCOL NO.:	

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Summary

This checklist is used to verify that documentation and activities are complete before releasing a new version of the product.

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/GDcos/ etc, but could embed it in your Jira / GitHub workflow. The main point is that, at minimum, the items below should be checked (and document) before you release a new version of your software.

Checklist

The following documents are up to date:

The table below shows examples only. Add or reference- a list of all your required TechDoc records.

Item	Yes	No	Comment
Device Description			
Clinical Evaluation			
Declaration of Conformity			
(...)			

The following activities have been performed:

Item	Yes	No	Comment
All relevant functionalities of the software have been specified; the Software Requirement List is complete and has been reviewed.			
All relevant risks (including risks of known anomalies) have been evaluated; the Risk Management Report is complete.			
Verification (as software system testing) has been completed.			
Design control traceability is ensured: Stakeholder requirements can be traced to software requirements. Software requirements can be traced to system tests. Software requirements can be traced to software code implementation / software code reviews. Software requirements can be traced to risks and risk control measures. Stakeholder requirements can be traced to usability tests. Hazard-related use scenarios can be traced to usability tests. Hazard-related use scenarios can be traced to risks and risk			



CYCLONE
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control measures.

A version number as defined in the Software Development Plan has been assigned and added as a tag to git.

Software is registered with a Notified Body.

If release includes substantial change: Notified Body has been informed.

Label is applied correctly including CE marking.