

Checklist: Software Release

Classes	IEC 62304:2006 Section	Document Section
A, B, C	5.8.1	(All)
A, B, C	5.8.2	(All)
A, B, C	5.8.3	(All)
A, B, C	5.8.4	(All)
B, C	5.8.5	(All)
B, C	5.8.6	(All)
A, B, C	5.8.7	(All)

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

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.

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
<p>All relevant functionalities of the software have been specified; the Software Requirement List is complete and has been reviewed.</p> <p>All relevant risks (including risks of known anomalies) have been evaluated; the Risk Management Report is complete.</p> <p>Verification (as software system testing) has been completed.</p>			

Item	Yes	No	Comment
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 control measures.			

Item	Yes	No	Comment
<p>A version number as defined in the Software Development Plan has been assigned and added as a tag to git.</p> <p>Software is registered with a Notified Body.</p> <p>If release includes substantial change: Notified Body has been informed.</p> <p>Label is applied correctly including CE marking.</p>			

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