

Biomedical Device Prototype Review Checklist

Device Name:

Project/Version:

Date:

Reviewer(s):

Checklist

Item	Check	Comments
Design complies with intended use and requirements	<input type="checkbox"/>	<input type="text"/>
Mechanical integrity and construction verified	<input type="checkbox"/>	<input type="text"/>
Materials are biocompatible and safe	<input type="checkbox"/>	<input type="text"/>
Electrical safety (if applicable)	<input type="checkbox"/>	<input type="text"/>
Device labeling and instructions are clear	<input type="checkbox"/>	<input type="text"/>
Usability/user interface validated	<input type="checkbox"/>	<input type="text"/>
Risk assessment reviewed	<input type="checkbox"/>	<input type="text"/>
Sterilization/cleanability evaluated	<input type="checkbox"/>	<input type="text"/>
Functionality and performance tested	<input type="checkbox"/>	<input type="text"/>

Regulatory requirements considered (e.g. FDA, CE)

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Documentation complete and accurate

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Additional Comments