

# Medical Device Design Review Checklist

Project Name

Device Name

Design Review Date

Location

Review Leader

Attendees

Checklist Item	Yes/No	Comments
User Needs Defined and Addressed	<input type="text"/>	<input type="text"/>
Design Inputs Reviewed	<input type="text"/>	<input type="text"/>
Design Outputs Verified	<input type="text"/>	<input type="text"/>
Risk Analysis Performed	<input type="text"/>	<input type="text"/>
Regulatory Requirements Considered	<input type="text"/>	<input type="text"/>
Verification and Validation Plans	<input type="text"/>	<input type="text"/>

Design Changes Documented	<div><div></div></div>	<div></div>
Action Items Identified	<div><div></div></div>	<div></div>

General Comments

Action Items (if any)

Review Leader Signature

Date