



ISO 14971 Checklist

23 Feb 2026 / Cora Lauma

Complete

Score	0 / 0 (0%)	Flagged items	1	Actions	1
Site conducted					Unanswered
Conducted on					23.02.2026 10:00 PST
Prepared by					Cora Lauma

Before accomplishing this checklist, make sure you:

- Know the necessary risk management plans in place for a specific device, part, or product
- Remember to cross-reference all findings here with your risk management plans after
- Contact the necessary people to address any issues with risk management and compliance

Flagged items & Actions

1 flagged, 1 action

Flagged items

1 flagged, 0 actions

Risk Management for Medical Device / Table / Row 1

What is its risk level?

High

Other actions

1 action

Sign Off

Prepared by

Cora Lauma

Cora Lauma
24.02.2026 10:43 PST

To do | Priority: High | Due: 03.03.2026 10:43 PST | Created by: SafetyCulture Staff

Meeting on testing

Conduct a meeting on testing the blood chemistry analyzer with marketing and engineers

Risk Management for Medical Device

1 flagged

What is the product or part being managed or questioned?	What hazard(s) or risk(s) can this product or part bring to the company or its intended user?	What is its risk level?	How can the identified hazard(s) or risk(s) harm the company or its users?	What measures should be taken to reduce or eliminate these risks?	What other kinds of risks are left behind or can be left behind after implementing mitigation plans?	What conclusion can be drawn from after taking the necessary steps to reduce or eliminate risks and hazards?	Recommendations
1 Blood chemistry analyzer - version 2	Version 2 is more prone to malfunctioning via overheating. Overheating has no known cause yet.	High	Overheating can lead to the machine malfunctioning, which can affect the results of samples.	<ul style="list-style-type: none"> - Take apart the machine to identify the source of overheating - Run more tests on machine and its individual parts 	The process of disassembling and reassembling can make the blood chemistry analyzer prone to other issues, as the entire process can disrupt its functions in other ways	<ul style="list-style-type: none"> - There may be issues with the parts used for creating the blood chemistry analyzer - There may be a supplier issue - If the parts are the issue, then the whole product will be affected. Best practice should be to check the parts individually first. 	<ul style="list-style-type: none"> - Double-check suppliers and their quality of products - Run more tests on the parts

Sign Off

1 action

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