ISO 14971 Checklist

21 Oct 2022 / Cora Lauma

Complete

Score	**0%**	Flagged items	**1**	Actions	**1**

Site conducted	Unanswered
Conducted on	21.10.2022 11:56 PST
Prepared by	Cora Lauma

Flagged items & Actions

1 flagged, 1 action

Flagged items

1 flagged, 1 action

ISO 14971 Checklist / Risk Management for Medical Device / Risk Management for Medical Device 1

What is its risk level? High

To Do | Priority **High** | Due **28.10.2022 11:57 PST** | Created by **SafetyCulture Staff**

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

Other actions

0 actions

ISO 14971 Checklist 1 flagged, 1 action

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

Repeat the following section per medical device to inspect.

Risk Management for Medical Device

1 flagged, 1 action

Risk Management for Medical Device 1

1 flagged, 1 action

What is the product or part being managed or questioned?

Blood chemistry analyzer - version 2

What hazard(s) or risk(s) can this product or part bring to the company or its intended user?

Version 2 is more prone to malfunctioning via overheating. Overheating has no known cause yet.

What is its risk level?

High

To Do | Priority High | Due 28.10.2022 11:57 PST | Created by SafetyCulture Staff

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

How can the identified hazard(s) or risk(s) harm the company or its users?

Overheating can lead to the machine malfunctioning, which can affect the results of samples.

What measures should be taken to reduce or eliminate these risks?

- Take apart the machine to identify the source of overheating
- Run more tests on machine and its individual parts

What other kinds of risks are left behind or can be left behind after implementing mitigation plans?

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

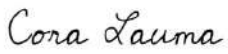
What conclusion can be drawn from after taking the necessary steps to reduce or eliminate risks and hazards?

- 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.

Recommendations

- Double-check suppliers and their quality of products
- Run more tests on the parts

Prepared by



Cora Lauma
21.10.2022 11:58 PST