EU MDR Checklist and Audit Template

10 Jan 2024

Complete

Score	1 / 1 (100%)	Flagged items	3	Actions	2

Conducted on	10 Jan 2024 13:05 PST
Location	Los Angeles, CA, USA (34.0549076, -118.242643)

Flagged items & Actions

3 flagged, 2 actions

Flagged items

3 flagged, 2 actions

Section II: Compliance with Requirements

Is there a safety plan in place? And has it been communicated effectively to workers?

No

Safety plan is not properly communicated. Not all employees know of them.

To do | Priority: High | Due: 17 Jan 2024 13:06 PST | Created by: SafetyCulture Staff

Conduct training on safety plans

Section II: Compliance with Requirements

Are there existing risk management and mitigation systems in place? And have they been communicated effectively to workers?

No

Risk systems are not properly communicated. Not all employees know of them.

To do | Assignee: SafetyCulture Staff | Priority: Low | Due: 17 Jan 2024 13:06 PST | Created by: SafetyCulture Staff

Conduct training on risk management

Section III: Auditing / Audit / Audit 2

Is this item, process, or activity working or performing as intended?

No

Other actions

0 actions

Section I: Information	1 / 1 (100%)
Document number	23432
Audit type	Internal Audit
Conducted by	Morgen Ciara

Section II: Compliance with Requirements	2 flagged, 2 actions
Are all processes documented properly?	Yes
Are all documents easily accessible?	Yes
Are technical documents easily understandable and accessible?	Yes
Is there a safety plan in place? And has it been communicated effectively to workers?	No

Safety plan is not properly communicated. Not all employees know of them.

To do | Priority: High | Due: 17 Jan 2024 13:06 PST | Created by: SafetyCulture Staff

Conduct training on safety plans

Is the existing quality management system still applicable to the organization's current needs?	Yes
Are there existing risk management and mitigation systems in place? And have they been communicated effectively to workers?	No

Risk systems are not properly communicated. Not all employees know of them.

To do | Assignee: SafetyCulture Staff | Priority: Low | Due: 17 Jan 2024 13:06 PST | Created by: SafetyCulture Staff

Conduct training on risk management

Are the parts for the medical devices sourced from credible providers?	Yes
Is there a clinical evaluation and management plan in place? And has it been communicated effectively to workers?	Yes
Is there a post-market surveillance system in place? And has it been communicated effectively to workers?	Yes

Section III: Auditing

1 flagged

Perform an audit on specific parts of your medical device production, sale, and distribution as needed with this section. Reproduce the next section for each audit.

Audit

1 flagged

Audit 1

Item, process, or activity to audit

Assembly line for nebulizer assembly

Is this item, process, or activity working or performing as intended?

Yes

Audit 2

1 flagged

Item, process, or activity to audit

Nebulizer cords

Is this item, process, or activity working or performing as intended?

No

Failure investigation (reference all potential root causes, records, and evidence; including tools and period for the investigation)

Some cords are coming in with holes. Possible faulty items from supplier, if not due to transit.

Corrective actions to be taken (ensure actions are aligned with investigation results)

- Check with supplier
- If it is found that these cords were damaged in transit, we might have to change transport providers

Preventive actions to be taken (ensure actions are aligned with investigation results)

Double-check cords with suppliers and transport providers before shipment

Audit 3

Item, process, or activity to audit

Post-market support for nebulizers, particularly in hospitals

Is this item, process, or activity working or performing as intended?

Yes

Audit 4

Item, process, or activity to audit

Clinical trials for nebulizers

Is this item, process, or activity working or performing as intended?	Yes

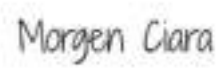
Section IV: Signature

Other notes and suggestions

We might need to look into new suppliers or transport providers

Lead Auditor Name Morgen Ciara

Signature



Morgen Ciara
10 Jan 2024 13:57 PST