# List of CAPAs

| ISO 13485:2016 Section | Document Section |
| --- | --- |
| 8.5.2 | (All) |
| 8.5.3 | (All) |

## Summary

This list contains all of our Corrective and Preventive Actions (CAPAs).

## List of CAPAs

* *“Adverse Implications”*: Verifying that the corrective / preventive action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device.
* *“Verification”*: Documenting proof of implementation of actions taken.
* *“Effectiveness”*: Review of the effectiveness of corrective / preventive actions taken.
* *“Root Cause”*: Analyzing the underlying cause that led to the event. Different methodologies can be used, e.g. *5 Why’s* (asking 5 times Why? in a row) or *Ishakawa/Fishbone Diagram* (identifying cause categories and sub-causes in a diagram).

| Input Category | CAPA ID | Date Created | CAPA Description | Root Cause | Date Root Cause Analysis Completed | Action (Corrective / Preventive) | Date Actions Defined | Potentially Adverse Implications | Verification | Date of Verification | Effectiveness Evaluation | Date Closed |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Usability feedback | 1 | 01-01-2022 | No contact details provided as part of product information | Missing Test Case for Product Information | 02-01-2022 | New product release incl. contact details; update test cases | 03-01-2022 |  | Release of product version and test case update |  | Number of future complaints related to this issue; review of technical information by Notified Body for completeness |  |

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