

Checklist ISO 14971:2007 to ISO 14971:2019

This checklist has been created to facilitate updating relevant processes, procedures, templates and risk management plans and records from ISO 14971:2007/EN ISO 14971:2012 to ISO 14971:2019.

References have been made to the "old" clauses on the left-most column and the relevant clause in 2019.

Did you find other things that need updating in your documentation? Do let us know by writing to us on support@medicaldevicehq.com

| Clause in 2007/2012 | Clause in 2019 | Change | Appl. | Done | Notes |
|---------------------|----------------|--|--------------------------|--------------------------|-------|
| - | 3.2 | Add the definition of benefit to your procedure. | <input type="checkbox"/> | <input type="checkbox"/> | |
| 2.2 | 3.3 | Update to the new definition of harm (remove "Physical"). | <input type="checkbox"/> | <input type="checkbox"/> | |
| - | - | Check that cybersecurity risks are included in your risk analysis when applicable. | <input type="checkbox"/> | <input type="checkbox"/> | |
| - | 3.15 | Add the definition of reasonably foreseeable misuse to your procedure. | <input type="checkbox"/> | <input type="checkbox"/> | |
| 2.15 | 3.17 | Update definition of residual risk in your procedure (replace "taken" with "implemented"). | <input type="checkbox"/> | <input type="checkbox"/> | |
| - | 3.28 | Add definition of state-of-the-art to your procedure. | <input type="checkbox"/> | <input type="checkbox"/> | |
| - | 4.1 | Add risk management plan to the figure 1 flowchart. | <input type="checkbox"/> | <input type="checkbox"/> | |
| 4.2 | 4.2 | Define and document the policy for establishing criteria for risk acceptability in the risk management procedure. See ISO/TR 24971:2020 for guidance. | <input type="checkbox"/> | <input type="checkbox"/> | |
| 3.4 | 4.4 e) | Add "method to evaluate the overall residual risk..." to your risk management plan or risk management plan template. | <input type="checkbox"/> | <input type="checkbox"/> | |
| 4.2 | 5.2 | Replace reference to Annex C with questions relating to the safety of the medical device, with a reference to ISO/TR 24971 | <input type="checkbox"/> | <input type="checkbox"/> | |
| 5 | 6 | Update the wording relating to risk evaluation. The standard no longer says "decide...if risk reduction is required", but instead "evaluate the estimated risks and determine if the risk is acceptable or not". | <input type="checkbox"/> | <input type="checkbox"/> | |

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**Thirumalaisamy P.
Velavancorresponding**



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