

## 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](mailto: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"/>	

# Iso 14971 Checklist

**James P. Agalloco, Frederick J. Carleton**

**Iso 14971 Checklist :**

## Unveiling the Power of Verbal Beauty: An Psychological Sojourn through **Iso 14971 Checklist**

In some sort of inundated with screens and the cacophony of instant conversation, the profound power and psychological resonance of verbal beauty often disappear into obscurity, eclipsed by the regular onslaught of noise and distractions. However, set within the lyrical pages of **Iso 14971 Checklist**, a interesting work of fictional beauty that pulses with organic feelings, lies an remarkable journey waiting to be embarked upon. Written by way of a virtuoso wordsmith, this exciting opus instructions visitors on a mental odyssey, delicately revealing the latent possible and profound influence stuck within the elaborate internet of language. Within the heart-wrenching expanse with this evocative analysis, we shall embark upon an introspective exploration of the book is main themes, dissect its captivating writing model, and immerse ourselves in the indelible impression it leaves upon the depths of readers souls.

<https://py.bijouxmedusa.com/results/Resources/index.jsp/Blueprint%20For%20Startups%2050%202967%20Dropshipping%20Business%20Case%20Study%20United.pdf>

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