

Annex B (informative)

Overview of the risk management process for medical devices



Figure B.1 is provided to give the user of this International Standard an overview of the risk management process. It is for illustrative purposes only. As indicated in Figure B.1, the process needs to be iterative, covering each risk in turn, and returning to earlier steps if risk control measures introduce new hazards or if new information becomes available.

Figure B.1 — Overview of risk management activities as applied to medical devices