

Risk Management Exercise

Risk Analysis for an Electric Bike (ISO 14971 Approach)

Objective	Apply ISO 14971:2019 principles to identify, assess, and mitigate risks associated with an electric bike (e-bike) used for urban commuting. Your job is to analyze potential hazards, evaluate risks, and propose risk control measures.
Scenario	Your company is developing a new e-bike model designed for urban transport. The bike features: <ul style="list-style-type: none">- A battery-powered motor to assist pedaling.- An electronic braking system (EBS) for enhanced safety.- A mobile app for performance tracking and navigation.
Hazard domains	<ul style="list-style-type: none">- Electrical system failures (e.g., battery overheating, short circuits).- Mechanical failures (e.g., brake malfunction, structural failure of the frame).- Software issues (e.g., app connectivity loss affecting bike control settings).- User-related errors (e.g., incorrect usage of throttle or braking system).- Environmental factors (e.g., water ingress, reduced visibility in foggy conditions).
Risk Estimation	<ul style="list-style-type: none">- Severity (S): Impact on the user (1 = minor inconvenience, 5 = life-threatening).- Probability (P): Likelihood of occurrence (1 = rare, 5 = frequent).