This thesis is focused on verifying of safety of medical devices. In theoretical part there are analyzed general certification principles both European and International. There is also described the task of institutions involved in process, methods and general terms used by medical device certification. In the end ot this part, there is elaborated the general scheme describing and leading to successfull CE certification.
In practical part there are described and elaborated basic stones of ECG Holter system documentation. There is accomplished analysis of requirements according to present standards and regulations. Safety attestation is verified through classification, validation and risk analysis. Output of the practical part is successfull ECG certification.