



FACULTATEA DE ELECTRONICA, TELECOMUNICATIILE SI

TEHNOLOGIA INFORMATIEI

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PhD THESIS

***RESEARCH IN RISK ANALYSIS FOR MEDICAL
ELECTRONICS***

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Abstract

Risk analysis, part of risk management is becoming more and more important. Especially in the domain of medical devices, the present regulations require great effort in view of the development and the realization of the risk management. An important trend allotting more and more resources to the researches in this field is universally unfolding, risk analysis being considered a compulsory component of the management system and essential to a company manufacturing medical devices.

The transition undergone by Romania to join The European Union has a decisive impact on the economic, social and legal field. Due to the shortness of time the manufacturers of medical devices had to apply the new regulations, they were forced to stop the marketing of their products in spite of their competitiveness. The lack of proper council required by this transition has been successfully exploited by our present research, the results being used also as a consultative alternative.

The present thesis has several objectives, substantially differentiated. They are both scientific, theoretical, didactically, including prior researches and practically, implementable, valid; objectives for whose implementation the exterior pressure was special. Not fulfilling these objectives would have had harmful consequences for the beneficiary company.

Establishing the directing principles regarding “the organizational philosophy upon risk taking” has been a decisive stage of our approach. Eventually the common, correct and pragmatic principles enabled the existence of this thesis. Thus the essential achievements have been shared with all the participants.

The PHD thesis has an enhanced interdisciplinary character, including information ranging from electronics, physics, medicine, to management, human resources, culture and legislation. As far as the risk analyses approaches are concerned, there have been adopted five types of algorithms that are to be presented in the following chapters. A selection of the useful theory issues, achieved mostly in interdisciplinary collectives, is displayed in the first part of this thesis.

The second part of this thesis presents the approaches for the definition and implementation of the management system within SC Datronix Computer SRL , including the conception of the system procedures and the evaluation scale regularly used.

After proving the efficiency of the implemented system within SC Datronix Computer SRL , by its validation by the notified certification organizations, we have developed the theoretical components and their implementation in order to obtain an innovative management system, adjustable, functional and useful for other companies or organizations involved in medical electronics.

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