

SUMMARY

The subject of the doctoral dissertation is the research on level of use and suitability of quality management methods and tools in medical devices industry. The main objective of the dissertation was to identify a set of quality management methods and tools used in the medical devices sector, taking into account their usefulness. A utilitarian objective was also defined, which is a recommendation regarding the possibility of using quality management methods and tools in terms of functionality for the medical sector. For the purpose of achieving the objectives, research tasks were defined:

- analysis of the literature relating to the methods and tools of quality management used and usefulness in the medical devices sector,
- identification of a set of quality management methods and tools (broken down into functions) selected to conduct the research,
- a survey of manufacturers of medical devices (small, medium, large enterprises with PKD number 32.50 Z) in terms of the use and usefulness of quality management methods and tools,
- defining the quality management methods and tools recommended for the medical devices sector.

As a result of the research, data was obtained that was subjected to statistical analysis, cluster analysis, Pearson's linear correlation coefficient and quality map methodology. As a result, a group of unused quality management methods and tools in the medical devices sector was identified. Similarities and differences in the level of application and usefulness of quality management methods and tools in relation to the size of the enterprise were determined. The main result of the analyzes in the dissertation is the classification of instruments, which include value assessment and recommendations of useful methods and tools for quality management for the medical devices sector. The dissertation ends with a discussion of further research directions.