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Abstract

The ISO/IEC 17025 accreditation journey for additive manufacturing in medical engineering

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Over the recent years, additive manufacturing has undergone rapid development towards industrial application, so that more and more products and components can be manufactured additively. However, since critical properties of printed parts are strongly influenced by complex interdependencies among process parameters, quality control is facing different challenges as with other, more traditional, means of fabrication. This opens a wide field of new needs for testing standards and procedures for the application and material specific manufacturing of parts, especially in the highly regulated domain of medical engineering.

In order to address this need, we have set up a testing laboratory for additively manufactured parts (metals and polymers) according to ISO/IEC 17025, which has its accreditation certificate by the German accreditation body (DAkkS) since the end of February 2025. The particular challenge for research in the section of medical engineering is to integrate the regulatory requirements right into the development of new devices, to avoid additional development loops. Therefore, a quality management system, to be applied in the testing laboratory as defined by ISO/IEC 17025, had to be implemented. In addition, the necessary operating and work instructions were defined for the testing procedures of geometrical and defect analysis, both based on high resolution (for small parts up to 150nm) computed tomography. This includes the development of a supporting document that covers the entire testing process from the customer inquiry to the submission of the test report, ensuring that every testing laboratory employee can be sure that they have completed all steps of the testing process. Among other things, it is now possible to make 3D print circuit boards, where special care must be taken, to ensure that the conductor tracks are not interrupted by printing errors. This is an example for the development of new testing methods and quality standards, that can be realized within the testing laboratory, to address the specific requirements of additively manufactured medical devices that have not yet been defined in detail.

We are happy to share the experience which we have gained through the implementation so far, with the community.

AUTHOR'S STATEMENT
Conflict of interest: Authors state no conflict of interest.

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