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## **Master's Thesis**

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### **Titel**

Medical Electrical Device Registration according to IEC 60601-1 and development of a quality assuring test setup

### **Keywords**

IEC 60601-1, medical electrical device, safety, air clearance, creepage distance, means of protection, isolation, DC Impulse<sup>®</sup>, DC Cutter<sup>®</sup>, current, removal, Over the Scope Clip (OTSC<sup>®</sup>), clip, quality assuring test setup

### **Abstract**

This thesis is embedded into the development of a completely novel medical electrical device for the use in endoscopy with the intended use to cut Nitinol<sup>®</sup> clips by a short DC impulse. For the market approval, this system has to be safe with regard to the requirements from IEC 60601 series. The scope of this thesis is the guidance of the development team with special respect to IEC 60601-1 and a verification of the safety of the system in accordance with its classification. Furthermore a quality assuring test setup is developed within this thesis. With this test board the implemented error messaging system of the device can be checked. Additionally it provides a means to simulate the most important situations during use. Moreover all essential functional signals can be observed with it.