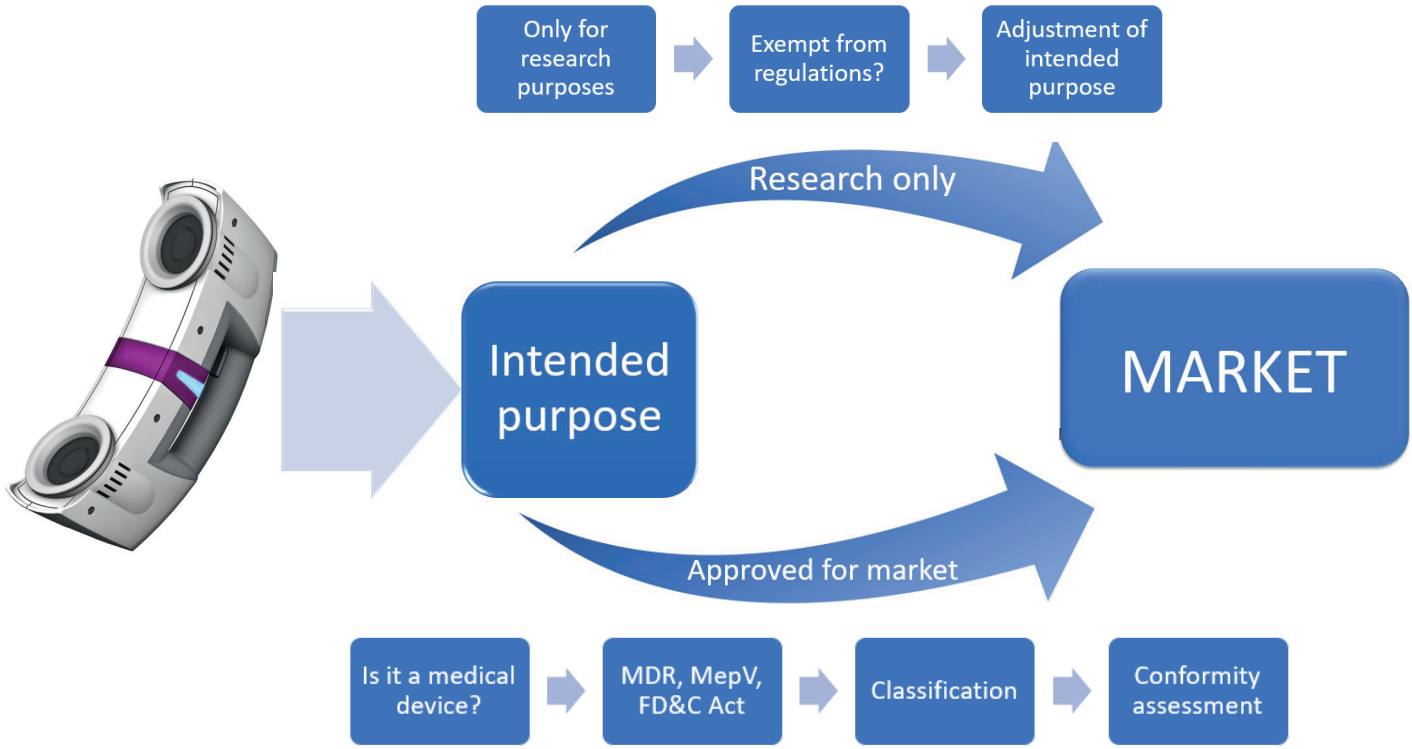
Lucerne University of
Applied Sciences and Arts
HOCHSCHULE
LUZERN
Technik & Architektur
FH Zentralschweiz

NEUROSPEC®
RESEARCH NEUROSCIENCES
NEUROSPEC AG
Stansstaderstrasse 10, 6370 Stans

Bachelor-Thesis Medizintechnik

Regulatory requirements for a research medical device



Introduction
Medical devices need to fulfil many requirements depending on their functionality, in order to be allowed onto the market. The requirements may also vary depending on which market the medical device will be launched on. On the 26 May 2021, the Medical Device Regulation (MDR) came into effect. The MDR replaced the old directives for medical devices. This new regulation sets new standards and requirements for any kind of medical device which is to be brought onto the EU or Swiss market. NEUROSPEC AG is a Swiss company, which globally supplies and distributes computer-based diagnostic and research equipment for neurology, audiology, neuropsychology and psychophysiology. They are currently developing a "3D-Digitizer for EEG" device which scans the positions of all the EEG-Electrodes (Electroencephalography) on an EEG cap. Now, NEUROSPEC AG desires to know what changes the new regulation will bring to research medical devices and what kind of requirements need to be fulfilled in order to launch a medical device on the Swiss, EU and US market.

Methods
This work mainly focuses on two procedures. The first one is the procedure to have the "3D-Digitizer for EEG" approved for the target markets and the second one is to treat the "3D-Digitizer for EEG" as a "research only" device which will only be made available for research purposes. It will be shown what the relevant regulations and who the respective authorities are on each market. Afterwards the device "3D-Digitizer for EEG" will be explained. This includes its "intended purpose" and classification. The classification process will be shown for each target market and the corresponding regulatory definitions and rules analysed.

Results
Through analysing the respective regulations, it is clear that no specific regulations or requirements apply to medical devices solely used for research purposes. They need to fulfil the same "general safety and performance requirements" as other medical devices. However, it could be possible to market the "3D-Digitizer for EEG" as a non-medical device by adjusting its intended purpose in a way that only defines non-medical, in this case the measuring functions. Nevertheless, this feasibility of this possibility should first be confirmed by the respective legal authorities.

Schumacher Oliver

Supervisors:
Prof. Dr. Roger Abächerli