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### **Clinical validation of video-otoscopy based medical device for remote diagnosis of ear complains**

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Telemedicine refers to delivering remote clinical services over a distance, which offers increased access to health care, improved health care outcomes, reduced costs, and it is an emerging trend in many fields of health care specially, during or after a pandemic era. Sharing data, photos etc. can be useful among doctors (specialist – GP), between doctor and patient or for quick communication among other health care providers and all these aids fall under the regulation of medical devices [1].

Otoscopy is a routine methodology, and it is an essential step in clinical examination for ear complaints as the key step in diagnosis; while video-otoscopy shows potential as a safe and effective method for detecting the presence of ear disease in a wide range of healthcare settings [2,3].

Performance of video-otoscopy telemedicine application (software; classification based on the MDR is Class IIa) is evaluated in an opened randomized clinical trial; differences and similarities of the diagnosis and the treatment variables were studied depending on the type of diagnosis (remote or present).

Clinical evaluation is a central concept in Medical Device Regulation, in order to ensure that the medical device performs within its intended purpose and that it is safe and effective.

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