

# **Evaluation of the constructed device along with the software for digital archiving, sending the data and supporting the diagnosis of cervical cancer**

Jacek Gronwald<sup>1,2</sup>, Jakub Barbasz<sup>1,3</sup>, Łukasz Lasyk<sup>1</sup>, Paweł Żuk<sup>1,4</sup>, Artur Prusaczyk<sup>1,4</sup>, Tomasz Włodarczyk<sup>1, 4</sup>, Ewa Prokurat<sup>1,4</sup>, Wojciech Olszewski<sup>5</sup>, Mariusz Bidziński<sup>6</sup>

<sup>1</sup> Digitmed Sp. z o.o., Oleśnica, Poland

<sup>2</sup> Department of Genetics and Pathology, Pomeranian Medical University, Szczecin, Poland

<sup>3</sup> Institute of Catalysis and Surface Chemistry Polish Academy of Sciences, Cracow, Poland

<sup>4</sup> Centrum Medyczo-Diagnostyczne Sp. z o.o., Siedlce, Poland

<sup>5</sup> Department of Pathology, Maria Skłodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw, Poland

<sup>6</sup> Oncological Gynaecology Clinic, Maria Skłodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw, Poland

The incidence and mortality of cervical cancer are high in Poland. There are effective methods of the prevention and the early diagnosis, however those methods require well-trained medical professionals including cytologists.

Within this project we designed and built a prototype of a new device together with implemented software to convert the currently used optical microscopes to fully independent scanning systems for cytological samples. The use of the device is intended to improve the effectiveness of cytological screening, and registration of cytological tests' results. The features of the software include digital backup as well as transmission and telemedicine evaluation.

We proposed the use of a specific method to support diagnostics. The first goal was to decrease time of analysis in the entire process. The second goal was to achieve a quality of recognition of positive research results at least comparable with cytologists.

To evaluate the quality of the device we compared 8 000 conventional cervical cytology augmented by computer-assisted image analysis system vs. manually read as well as liquid based cytology augmented by computer-assisted image analysis system vs. manually read. The following and economic outcome measures were evaluated: clinical - detection rates, relative sensitivity, sensitivity difference, specificity difference; economic - cost per test, workload per test, acceptability of the computer-assisted image analysis system in the screening services, organizational and budget impact of computer-assisted image analysis system, as well as social and economic benefits (positive externalities).

*This project is co-financed with European Regional Development Fund within the Priority Axis I, Support for R&D activities for companies, Measure 1.2, Sectoral R&D Programmes, Sectoral Programme: "INNOMED – scientific research and development programme for innovative medicine economy sector".*