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CARDIOLENS - PLATFORM FOR NON-INVASIVE CARDIAC DIAGNOSTICS

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Cardiovascular diseases are the leading cause of death in developed countries. The high incidence of these conditions, especially coronary artery disease (CAD), is a significant challenge for modern medicine. CAD is a disorder of the heart's arteries that supply blood to its muscles. Narrowing of these arteries can lead to impaired exercise tolerance, chest pain during exertion, and in the worst cases, myocardial infarction or death.

In recent years, advances have been made in the non-invasive diagnosis of CAD using computed tomography (CT). With CT scans, one can non-invasively obtain images of the coronary arteries and determine the stenosis degree. Guidelines from the *European Society of Cardiology* indicate that CT scanning is the preferred non-invasive test for diagnosing CAD.

Hemolens' platform, including products *Cardiolens Viewer* and *Cardiolens FFR-CT Pro®* (in development), is an innovative, non-invasive method of CAD diagnosis based on computational fluid dynamics (CFD) techniques, digital image processing (3D virtual twin of the heart) supported by Biomedical Engineering (BME) and Artificial Intelligence (AI) algorithms.

Coronary computed tomography angiography-derived fractional flow reserve (FFR-CT) diagnosis carries very low risk for the patient, while helping the cardiologist determine whether the patient would benefit from stenting or bypass surgery, or whether drug treatment is sufficient. Few similar solutions exist worldwide, but in 1-2 years, Hemolens' solution will also be available.

The expected advantages of the *Cardiolens FFR-CT Pro®* solution vs. the "gold standard" - invasive coronary angiography are the minimization of risks associated with invasive diagnosis and reduction of diagnostic invasive procedures (coronarography, catheterization with FFR measurement, etc.).

The *Cardiolens Platform* will be a solution to help diagnose patients, based on computer simulations at the stage of planning and conducting patient therapy. The final result will be a technology for non-invasive hemodynamic diagnostics functioning as a Software as a Medical Device (SaMD) model, containing new functionalities in the form of dedicated diagnostic tools for fully autonomous analysis of patient clinical data. The essence of the product innovation will be the ability to offer diagnostic tools for obtaining hemodynamic indices of coronary artery flow including assessment of myocardial ischemia deficits and an advanced coronary artery imaging tool dedicated to cardiologists based on computed tomography. The combination of the aforementioned elements represents a pioneering approach to coronary artery and myocardial diagnosis, which has not yet been used in available technical solutions.