CE CERTIFICATE

EU DECLARATION OF CONFORMITY

according to the 98/79/EC In-Vitro Diagnostic medical devices Directive (IVD)

We hereby declare that the In-Vitro Diagnostic medical devices

AUMED test RT - LAMP Assay SARS-CoV-2

meets the basic requirements of the Regulation of the Government of the Czech Republic no. 56/2015 Coll., which lays down details on technical requirements and procedures for assessing the conformity of in vitro diagnostic medical devices, as amended.

Name and address of manufacturer:

AUMED, a.s., Komořanská 326, 14300 Praha, Czech Republic

Name of medical device:

AUMED test RT - LAMP Assay SARS-CoV-2

Classification of the In-Vitro Diagnostic medical devices:Other In-Vitro Diagnostic medical devicesProcedure used conformity assessment: According to the Regulation of the Government of the Slovak Republic no. 56/2015 Coll. Conformity with the requirements was assessed according to Annex 1 and 3 of the Regulation.

Used standards:

EN ISO 14791: 2019, EN ISO 18113-1: 2011, EN ISO 9001: 2015, EN ISO 15223-1: 2017

All documents, including technical documentation, are stored by the manufacturer. This in vitro diagnostic medical device is marked with the CE mark of conformity.

The vDetect COVID-19 RT-qPCR diagnostic kit is registered as a CE IVD with registration code 00912050.

In Prague on September 22, 2020

RNDr. Juraj Vronka
Member of the Board

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