

Komisija Republike Slovenije za medicinsko etiko

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The names of those Members present on the 298th NMEC session of 14th july 2020 & taking decisions on ethical review of research are printed in italics.

Five Members constitute the quorum for ethical review of research. None of the Members had any conflict of interest in the matter on which they voted.

Signed:

Dr. Božidar Voljč, MD,

Chairman



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Date: 14th July 2020

Re: Compliance with Standards of Good Clinical Practice

#### TO WHOM IT MAY CONCERN

Herewith we confirm that the National Medical Ethics Committee of the Republic of Slovenia (NMEC) operates in compliance with the ICH/GCP requirements of good clinical practice and all the applicable regulations of the Republic of Slovenia and the EU<sup>1</sup>. The NMEC's compliance with laws, regulations, policies, and guidelines is assured also by the *Federalwide Assurance for the Protection of Human Subjects* (FWA)<sup>2</sup>.

Signed:

Dr. Božidar Voljč, MD,

Chairman



<sup>&</sup>lt;sup>1</sup> The NMEC's remit is based on the Ministerial Decree of 20 February 2020, published in Uradni list RS (Official Gazette of the Republic of Slovenia) No. 11 of 25 March (pp. 1047).

<sup>&</sup>lt;sup>2</sup> The NMEC is registered with the U.S. Department of Health and Human Services (DHHS), Office for Human Research Protections, as IRB Reg. No. 00002668. The registration is valid until 07/9/2023