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*The names of those Members present on the 291<sup>th</sup> NMEC session of 10<sup>th</sup> December 2019 & 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



REPUBLIKA SLOVENIJA  
MINISTRSTVO ZA ZDRAVJE

Komisija Republike Slovenije za medicinsko etiko

Date: 10<sup>th</sup> December 2019

**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

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<sup>1</sup> The NMEC's remit is based on the Ministerial Decree of 24 April 1995, published in Uradni list RS (Official Gazette of the Republic of Slovenia) No. 30 of 2 June 1995 (pp. 2149-50), and its amendments, dated 20 August 2009 and 14 April 2018, published in Uradni list RS No. 69 of 4 September 2009 (p. 9539) and of 30 March 2018 (p. 3056), respectively.

<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 04/19/2021.