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***The names of those Members present on the 276<sup>th</sup> NMEC session of 18<sup>th</sup> September 2018 & 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*



Date: 18<sup>th</sup> September 2018

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.