Republic of Slovenia THE NATIONAL MEDICAL ETHICS COMMITTEE

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The names of those Members present on the continuation of the 270th NMEC session of 13th March 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,

Color Som

Chairman



THE REPUBLIC OF SLOVENIA NATIONAL MEDICAL ETHICS COMMITTEE

Date: 20th March 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. The NMEC's compliance with laws, regulations, policies, and guidelines is assured also by the *Federalwide Assurance for the Protection of Human Subjects* (FWA).

Dr. Božidar Voljč, M.D., D.Sc., Chairman

Color Som

¹ 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 amendment, dated 20 August 2009, published in Uradni list RS No. 69 of 4 September 2009 (p. 9539).

² 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 04/29/2018.