INFORMED CONSENT FORM

Official title: Evaluation of the effects of taking bicarbonate-calcium water in premenopausal and postmenopausal women as prevention of osteoporosis

Date of Document: January 27th, 2021

Study investigator: Prof. Luca Rastrelli, Full Professor of Food Chemistry, Department of Pharmacy, University of Salerno, Via Giovanni Paolo II, 132, 84084 Fisciano SA- Nutritional research laboratory Nutriketo_Lab, San Giuseppe hospital Moscati, Contrada Amoretta, 83100 Avellino AV

Doctor: Dr. Giuseppe Castaldo, Scientific Director of the Research Laboratory nutritional Nutriketo_Lab, San Giuseppe Moscati hospital, Contrada Amoretta, 83100Avellino Av

Address: Nutritional research laboratory Nutriketo_Lab, CompanySan Giuseppe Moscati hospital, Contrada Amoretta, 83100 Avellino AV

Protocol date:

Study code: NKCL2101

Study sponsor: SGAM SpA

1. I confirm that I have read and understood the Information Note regarding the study above mentioned, that I received a copy and was given the opportunity to ask questions and to ask for explanations and received satisfactory answers;
2. I am aware that my participation is voluntary and that I am free to withdraw in any time without giving any explanation and without prejudice to my own medical treatment or my legal rights;
3. the nature, purpose, duration of the study, procedures were clearly explained to me that will be performed, the treatment envisaged for the participants and the type of collaboration that they will be required;
4. to have had all the necessary time before deciding whether to participate or not;
5. I am aware that some parts of my medical records may be examined by responsible parties conducting this research. I authorize them to access it;
6. on the basis of art. 13 of Legislative Decree 196/2003 and art. 13 GDPR 679/16, I agree to the treatment of my personal and sensitive data collected as part of this study;
7. with reference to the photographs and videos collected during the research, I express my consent to dissemination for research purposes (meetings, conferences and scientific publications);

Subject's surname and first name Signature

_____

Place and date of birth of the subject

Place and date

I subscribed _____ I confirm that I have explained to the patient the nature, purpose and terms of adherence to research, as regards the rights of the patient in terms of protection of personal data, the possibility of the patient to withdraw consent previously agreed, and I believe that these concepts were understood by the interested party. I declare that you have given the patient the necessary time and opportunity to ask questions about the study and that you have not exercised any coercion or undue influence in requesting Consent.

I confirm that the patient has freely agreed to participate in the study by signing this form consent form and that this form will be archived at our operating unit, and to have it delivered a signed and dated copy to the patient.

Surname and first name of the head of the study Signature

Place and date _____

NB *Deliver a copy to the participant; a copy will be archived*