2.01.2022 INFORMED CONSENT TO PARTICIPATE IN A CLINICAL STUDY

Title of the Study: Assessment of the Impact of the Probiotic Limosilactobacillus Reuteri Prodentis (DSM 17938 and ATCC PTA 5289) on Clinical and Microbiological Parameters in Orthodontically Treated Patients with Concomitant Gingivitis

I, the undersigned
…… …… hereby declare that I have read and understood the information provided above concerning the described clinical study and that I have received comprehensive and satisfactory answers to all questions I asked. I voluntarily consent to participate in this clinical study and I am aware that I may withdraw my consent to participate in the study at any time and without giving any reason. By signing this consent form, I do not waive any rights to which I am legally entitled. I will receive a copy of this consent form signed and dated. I hereby consent to representatives of national, foreign, or international authorities supervising the conduct of the clinical study having access to my personal data and medical documentation (health-related data) for the purpose of verifying the proper conduct of the study, provided that such representatives are directly involved in the supervision of the study. By signing this document, I also confirm that I have been informed about the methods of data processing used in this study and that the collected data will be verified by comparison with my medical records. I understand that the data are collected solely for the purposes of scientific analysis related to the study.

I consent to the processing of my data in accordance with applicable Polish law and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (General Data Protection Regulation – GDPR) on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, repealing Directive 95/46/EC. I also consent to the transfer of my anonymized data to other countries, both within and outside the European Union.

Data analyzed by competent authorities, representatives of the Ministry of Health, governmental agencies, and Bioethics Committees will be made available exclusively in an anonymized form. I have been informed that in the event of withdrawal of my consent to participate in the study, the data collected up to that moment may still be used and processed as part of the study database. Information Clause pursuant to Article 13 of the General Data Protection Regulation (EU) 2016/679 In accordance with Article 13 of the General Data Protection Regulation of 27 April 2016, I am informed that: The controller of my personal data is UCS CM WUM, with its registered office in Warsaw, ul. Stanisława Binieckiego 6, 02-097 Warsaw, Poland. The Data Protection Officer at UCS CM WUM is Dr. Maciej Karwas, telephone: +48 503 824 905 or +48 (22) 57 20 320, e-mail: iod@cmwum.pl; iod@wum.edu.pl

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My personal data will be processed for the purpose of conducting the clinical study entitled: "Evaluation of the effect of dietary supplements containing probiotics on clinical and microbiological parameters in patients with gingivitis and periodontitis treated with fixed orthodontic appliances" at the Department of Dental Hygiene, UCS CM WUM, pursuant to Article 9(2)(a) of the GDPR. My personal data may be disclosed exclusively to: persons authorized by the data controller to process personal data, entities processing data under a data processing agreement, representatives of national, foreign, or international institutions supervising the clinical study, subject to compliance with the conditions specified in Chapter V of the GDPR, other entities authorized under applicable law. My personal data will be stored only for the period required by applicable legal regulations. I have the right to access my data, rectify them, request their erasure, restrict their processing, transfer my data, object to processing, and withdraw consent at any time. I have the right to lodge a complaint with the Polish Personal Data Protection Office if I believe that my personal data are being processed in violation of the GDPR. Providing personal data is voluntary. Decisions will not be made in an automated manner, and I will not be subject to profiling. Patient
…… Full name (in block letters) Signature:
_____ Date: _____ I declare that I have explained the above-described study to the patient using clear and comprehensible language and have provided information concerning the nature and significance of the study. Person obtaining consent
…… Full name (in block letters) Signature:
_____ Date: _____