

Bsure Medical B.V. (Bsure Medical) INFORMATION SHEET

BSure Medical would like to inform you about the complete process of collecting your DNA sample and the services offered by BSure Medical. Our goal is to provide you with accurate and sufficient information so that you can assess and decide whether or not to request this service. Therefore, we kindly ask you to read this information sheet carefully and we will be happy to clarify any doubts you may have after reading it.

By signing this document, you confirm that you have understood the scope and objectives pursued in obtaining your DNA sample.

DNA samples are a valuable tool for detecting, preventing, or treating diseases. Specifically, the analysis of DNA samples provides highly relevant data to assess the risk or predisposition for diseases with a moderate or high genetic component.

The Bsure Medical DNA test for fillers shows whether you have a genetic predisposition to an increased risk of late-onset immune-mediated side effects to fillers. The test is based on current knowledge of genetics. This knowledge changes over time as we learn more through research. BSure Medical is a social enterprise and reinvests earnings in further research into genetic predisposition to side effects on fillers and other implants. This allows us to constantly improve and generate different and more interpretations in the future.

The Bsure Medical DNA test for fillers is based on scientific research. An abstract of this study can be found at PUBMED: <https://onlinelibrary.wiley.com/doi/10.1111/dth.14644> This study is based on a specific sample of patients which resulted in a positive predictive value of 84%. This means a very high chance of getting late-onset immune-mediated side effects if the test result is positive. However, it does NOT mean that a negative result excludes the chance of getting late-onset immune-mediated side effects to fillers; the chance will then be very low. It should be noted that these are scientific findings from the study of this sample of patients. Bsure Medical will conduct ongoing research that, together with the aggregated data obtained from all DNA testing, will contribute to an even better understanding of the genetic predisposition to late-onset immune-mediated side effects to fillers.

Bsure Medical collects, analyses and stores only the data necessary to determine your genetic predisposition to late-onset immune-mediated side effects to fillers. Your sample will be sent to and analysed by the Fagron Genomics laboratory in Terrassa, Barcelona (Spain). Fagron Genomics (<https://www.fagrongenomics.com/>) is part of the multinational FAGRON B.V., a pharmaceutical company headquartered in Rotterdam, the Netherlands. Your DNA sample will be analysed solely to determine the presence of two specific genes that - according to the scientific research and patent on which the Bsure DNA test is based - may lead to the above-mentioned filler side effects. Genetic advice is expressly excluded from the scope of the Services provided by BSure Medical.

Bsure Medical only determines the presence of the two genes but does not diagnose or interpret them. This is provided by your current medical professional if you purchase the test there. Therefore, you acknowledge that Bsure Medical is neither responsible nor liable for the content, quality, interpretations or recommendations of medical professionals.

By signing the consent form, you expressly declare that (i) you have read and understood this information sheet and consent form; (ii) all your questions have been answered; and (iii) you have been informed of:

- i. The advantages and disadvantages of the Services provided by Bsure Medical.
- ii. The purpose of obtaining and collecting the DNA sample by Bsure Medical and the procedures that will be performed on it.
- iii. The place where the DNA sample will be analysed and the details of the laboratory.
- iv. Your right to withdraw consent at any time and choose to destroy or anonymize the DNA sample.
- v. The fact that all information obtained will be treated as strictly confidential.
- vi. The fact that Bsure Medical may contact you or the person you designate for this purpose.

CONSENT FORM: PATIENT INFORMED CONSENT

Bsure Medical B.V. needs your written consent to conduct the genetic testing and process the results and your data to prepare your report.

Processing of your personal data

By signing this form, you authorize Bsure Medical B.V. to use your personal data according to the following principles:

Personal data: Bsure Medical B.V. processes your DNA sample, your personal information and your contact details.

Data Controller: BSure Medical B.V., - Achillesstraat 85, 1076 PX, Amsterdam, The Netherlands. email: info@bsuremedical.com

Purpose: BSure Medical B.V. processes your personal data to perform the requested genetic test and to prepare a personal report.

Identification: your written consent.

Storage of personal data: Once the process is completed, your data will be stored in accordance with GDPR regulations to ensure optimal privacy and protection. Your data will not be kept longer than necessary for the above purpose, unless this is required by law.

Sharing your information with third parties: To serve the above purpose, your personal information may be shared with your treating physician to provide the results of the test. Furthermore, your data will not be shared with third parties unless required by legislation, Fagron UK and Fagron Genomics excluded.

In all cases, we will collect, process, handle and/or store all your personal data in accordance with the GDPR requirements.

Rights: You have the right to access, correct and delete your personal data or to object to its processing at any time and in any form. In addition, you can ask us to make your data available for data transfer and you can request a restriction of data processing. To do this, you must send a written request to BSure Medical, B.V., the data controller as indicated above. If you are not satisfied, you can file a complaint with the ICO.

Your data:

First name:
Last name:
E-mail address:.....
Phone number:

By signing this document, you consent to the processing of your personal data. If the patient is not allowed to sign, this document must be signed by the legal guardian. In both cases you declare by signing this consent that the sample was taken from the patient as stated in this statement.

Venue:
Date:
Signature patient (or guardian):

Read the instructions carefully before starting to collect the sample.

The swab for sampling is for single use only for the patient as stated in this statement.

The kit contains an in vitro diagnostic test for topical use.

In accordance with current regulations, all components are destroyed after use.

Send the sample immediately after taking the sample.

If the sample was collected in a clinic, please complete and sign the following:

Name of the physician who collected the sample:
Name of clinic:
Signature of the physician who collected the sample: