NOM :		*(première lettre)*	Prénom :		*(première lettre)*				
N° investigation clinique :	**23E1077**			**N°PI sujet :** (*à remplir par l'investigateur*)	**S**	5			

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INFORMATION SHEET FOR THE STUDY PARTICIPANT

SAFETY AND EFFECTIVENESS CLINICAL EVALUATION OF THE RANGE OF INJECTABLE MEDICAL DEVICES VISCOL IN AESTHETIC TREATMENT

Sponsor:	Sponsor representant :
KYLANE LABORATOIRES SA Chemin du Pré-Fleuri 1-3 CH-1228 Plan-les-Ouates SUISSE	Eurofins Dermscan Pharmascan 114 Boulevard du 11 Novembre 1918 69100 Villeurbanne - France 04.72.82.36.59

Important information to remind us of during your visits to the laboratory or during your telephone contacts

N° of the study	Measure area
23E1077	Face or Body

For any questions regarding your appointments and/or the study process, please contact EUROFINS Dermscan Pharmascan at +33 4 72 82 51 00. For medical emergencies only, please call +33 4 72 82 36 59 or 15. No other information will be provided to you.

Dear Sir or Madam,
You are invited to take part in a clinical investigation, also known as a clinical study. You are free to accept or refuse to participate, and this will in no way affect your relationship with us.
This information notice regarding the study was sent to you by email a few days ago. Additionally, a member of Eurofins Dermscan Pharmascan's recruitment team explained the study to you over the phone.
This notice is intended to explain the objectives, methodology, constraints, and risks associated with the study. Please read it carefully.
After taking the time to think it over, if you agree to participate, please complete and sign the attached consent form in duplicate:

- One copy will be given to the investigator (the doctor in charge),
- The other is for you.

No tests or analyses not described in this notice will be conducted without obtaining your renewed consent.
Also, you may withdraw your consent at any time without affecting your relationship with us.
Please feel free to ask any questions you consider necessary, before signing the consent form and throughout the study.

1. STUDY OBJECTIVE(S)

This study is conducted for scientific purposes. This experimental research complies with current national, European, and international regulations (legal texts available upon request).
KYLANE LABORATOIRES SA (study sponsor) has developed a range of injectable products based on sodium hyaluronate (a component of hyaluronic acid) for the aesthetic treatment of aging skin on the face and body (improving skin quality). The product range tested in this study (two VISCOL products) is not yet commercially available and has not yet been tested on humans, but the sponsor has all the data to prove the products' effectiveness. The two medical devices tested are identical.

Sodium hyaluronate is a component of hyaluronic acid. It is a molecule naturally present in the human body. In aesthetic medicine, this molecule is widely used directly on the areas to be treated, via injection into the dermis or subcutaneous tissue. This type of product is biodegradable and will be naturally depleted in the body.

The objective of this study is to collect data regarding the efficacy and safety of this treatment range up to 6 months after injection.

The VISCOL range aims to improve the quality of your skin, particularly in terms of elasticity and hydration, by filling the skin tissue.

The study will be divided into two groups. Each group will test a single product from the range, for a single indication (face or body). You will be included in one or the other group depending on your needs and the inclusion criteria:
- Group 1: injection in the malar area (cheekbone) and submalar area (cheek), as well as, if necessary, in the optional areas: the mandible and/or chin. - Group 2: Injections in the neck/décolleté and, if necessary, in an optional area: the abdomen or the inner arms.

Scoring will be performed by physicians and yourself to assess the aesthetic improvement. You will also be asked to complete a subjective assessment questionnaire, and photographs of your face or the injected areas of the body will be taken to illustrate the treatment's effectiveness.
If you are included in Group 1 (face), skin hydration and elasticity measurements will be taken using non-invasive measuring devices.

This study will be conducted on 86 subjects, divided into two groups. 64 subjects will be included in Group 1 and 22 subjects will be included in Group 2.

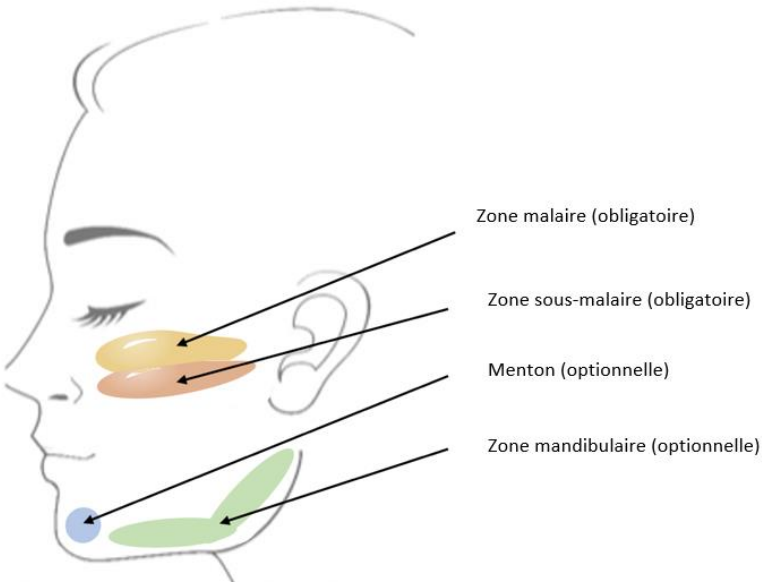
Your full participation is requested for a period of 4 months (plus the pre-inclusion period).

2. STUDY DEVICES

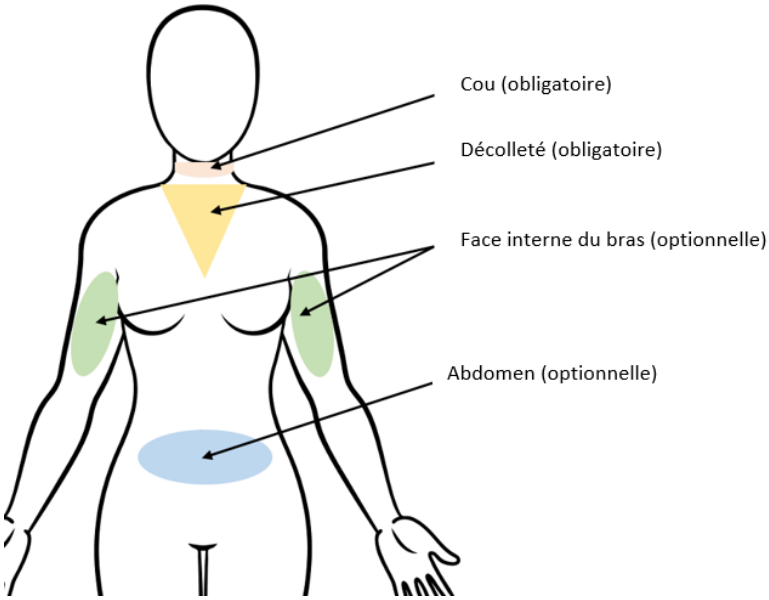
cThe VISCOL range of products will be injected on Day 0 into the treated area(s):

- Group 1, VISCOL Face product: Injections will be performed in the areas shown in the diagram below and on both sides of the face:
  Required areas: malar and submalar;

Optional areas: mandibular and chin areas



- Group 2, VISCOL Body product: injections will be performed in the neck and décolleté and, if necessary, in an optional area: the inner side of the arms or the abdomen.



The injections will be performed by a specialized and trained physician after prior disinfection of the injected areas. The physician may use a simple needle or a cannula depending on the injected area and the chosen technique. The injected volume will be determined by the injector to achieve an optimal aesthetic result (a maximum of 8 ml of product will be injected in total).
The injection lasts on average 15 to 30 minutes.

For this study, no touch-ups are planned, as the single injection will be performed on day 0.

These products do not contain anesthetic. If you feel the need, the physician may apply an anesthetic cream to the area to be injected before beginning the procedure.

3. STUDY PROCEDURE

Le déroulement de l'étude est le suivant :

Screening Visit – Day -X (Approx. 1 hour at the lab):

-You will come to the laboratory without having applied any product on your face since the night before (no makeup, no cream) and clean-shaven if applicable.

-You will receive oral information about the objectives, constraints, and risks of the study, followed by this written information notice.

-If you agree to participate, you will sign two copies of the consent form.

-The investigator will perform a general medical examination to ensure your health allows participation. They will collect your medical history, current/past treatments, and assess all body systems.

-The investigator will check your eligibility based on inclusion and exclusion criteria and assign you to one of the four groups.

-If eligible, you will receive your schedule of appointments and a study diary to record:

-Any adverse events

-Medication intake

-Any medical procedure performed during the study

Visit 2 – Day 0 (Approx. 1.5 hours):

- -Arrive without applying any product on your face since the night before (no makeup, no cream), clean-shaven if needed, and bring your diary.
- -The investigator will record any adverse events and current treatments.
- -If you are a woman of childbearing age, you will take a urine pregnancy test to confirm you are not pregnant.
- -The investigator will confirm your eligibility.
- Depending on the study group you are included in, the following measurements will be taken:
  For Group 1:
  o Photos of your face (front and both profiles) will be taken.
  o Two measurements using non-invasive devices will be taken on your cheekbone to assess your skin's hydration and elasticity.
  For Group 2:
  o Photos of your neck and décolleté will be taken. If applicable, photos of the inner side of your arms or abdomen, depending on the area treated with the product, will also be taken.
- After local disinfection and the application of a local anesthetic cream if requested, the specialized injecting physician will inject you with the study product:
  - Group 1, VISCOL Face product in the malar (cheekbone) and submalar (cheek) areas, as well as, if applicable, in the mandible and chin areas;
  - Group 2, VISCOL Body product on the neck and décolleté, as well as, if applicable, in one of the optional areas, either the inner arms or the abdomen.
- The injecting physician will assess your reactions at the injection site.
- The injecting physician will evaluate the quality of the injection using a questionnaire.
- You will be given a daily monitoring sheet on which you will be asked to record any reactions at the injection sites (redness, bruising, swelling, etc.) during the first month. The investigating physician will explain how to complete this sheet. You will also be asked to record any medication taken or any adverse events until your next visit.

Phone Call – Day 7 (Approx. 10 min):

-The investigator will check tolerance to the injection.
-They will record any adverse events or new medications.

Visits 3 and 4 – Months 1 and 4 (Approx. 40 min each):

For each of these visits:
• You will arrive at the laboratory without having applied any product to your face since the previous evening (no makeup, no cream, etc.), having been clean-shaven in the treated areas (face or neck/décolleté) if applicable, and having brought your daily monitoring sheet.
• The investigator will record any adverse events and concomitant treatments;
• Depending on the study group in which you are included, the following measurements will be taken:
For Group 1:
o Photos of your face (front and both sides) will be taken.
o Two measurements using non-invasive devices will be taken on your cheekbone to assess your skin hydration and elasticity.
For Group 2:
o Photos of your neck and décolleté will be taken. If applicable, photos of the inner side of your arms or abdomen, depending on the area treated with the product, will also be taken. • The investigating physician will assess the cosmetic improvement brought about by the treatment and any skin reactions at the injection site.
• You will be asked to complete a subjective assessment questionnaire and assess the overall cosmetic improvement of the treated area(s).
• You will be given a follow-up logbook in which you will be asked to record any medication taken or any adverse events until the next visit. The physician will explain how to complete this document (only for Visit 3 – Month 1).

Phone Call – Month 6 (Approx. 10 min):

• The investigator will verify the injection's tolerance.
• They will record any adverse events and concomitant treatments.
• End of study

4. STUDY REQUIREMENTS AND CONSTRAINTS

The requirements and constraints for participating in this study are:
• to comply with the four mandatory laboratory visits (screening visit, Days 0, 1, and 4) and to be available for follow-up phone calls on Day 7 and Month 6;
• to inform the investigator of your entire medical and surgical history, any current illness, and any ongoing medical treatment (oral or topical) before your possible selection into the study;
• to inform the investigator of your history of cosmetic surgery or aesthetic medicine (Botox injections, hyaluronic acid injections, permanent or semi-permanent products, thread lifts, etc.), whether in the study area or elsewhere on the body. Indeed, some cosmetic treatments are incompatible, so it is important for the physician to be aware of your entire history, even the oldest, to verify the absence of incompatibilities with the device(s) under study. • Also report any medical procedures/consultations you may have had in the past 6 months and any procedures/consultations planned during the study period.

• For women of childbearing potential:
- Have been using a recognized effective method of contraception (contraceptive pill, IUD, implants, condom) for at least 4 weeks and continue to do so for the duration of the study.
- not to start or stop using a contraceptive pill, or not to change contraceptive pills during the study.

• to inform the investigator as soon as possible of any new events occurring during the study:
• intolerance to the product(s) (unpleasant sensation and/or persistent abnormal signs, etc.),
• onset of an illness, hospitalization, or accident,
• taking new medications, changing dosage, etc.
• onset of pregnancy (in this case, you will be excluded from the study and follow-up will be carried out until its completion).

• Not to participate in any other clinical research.

On the day of the laboratory visits:
• Come to the laboratory with a beard or freshly shaved neck/décolleté hair, if applicable.
• Do not apply any cosmetics or makeup to your face (daily cleansing is permitted).
One week before the injection:
• To limit bleeding and bruising, do not take aspirin, anti-inflammatories (ibuprofen, ketoprofen, naproxen, etc.), or anticoagulant, antiplatelet, or thrombolytic medications one week before the injection.

Following the injections on Day 0, you will be advised to follow these instructions:

• Do not apply any cosmetics or makeup for 12 hours following the injection.
• Avoid prolonged exposure to the sun, UV rays, temperatures below 0°C, and saunas or steam rooms for two weeks following the injection. • If exposed to the sun in the two weeks following the injection, use a cream with a high sun protection factor.
• Avoid massaging the implantation site and/or applying pressure to it for several days afterward.
The study's requirements and constraints specific to COVID-19 are:
• To inform the investigator of any possible contamination or the appearance of any symptoms suggestive of COVID-19 in you or in a person with whom you have been in close contact, in the 7 days preceding the study and during it.
• To follow the instructions given by the laboratory regarding protective measures against COVID-19. These instructions were detailed to you by telephone and on the laboratory's voluntary website. This information is also available in the laboratory (displayed) to remind you of the barrier gestures and protective measures you must follow during your visit.

5. POTENTIEL BENEFIT(S)

The benefit you could gain from this study will be aesthetic with a potential improvement in the quality of your skin (hydration and elasticity) in the treated areas.

6. POSSIBLE RISKS AND SIDE EFFECTS

Adverse reactions related to the devices and/or the injection procedure:

Adverse reactions may occur immediately after the injection or with a delayed onset. These include, but are not limited to:

- Reactions that may occur within one month following the injection and resolve spontaneously within one week in the majority of cases:
• Injection-related reactions and/or inflammatory reactions such as bleeding, bruising, erythema, hematoma, skin reddening, contusion, swelling, edema, and infection, which may be accompanied by local pain or pruritus (itching) appearing after the injection.
• Tenderness at the injection site.
• Induration (hardening), lump, or nodule at the injection site.
• Skin discoloration or discoloration at the injection site.
• Immediate hypersensitivity reaction to any of the product's components.

- Delayed onset effects after injection:
• Delayed hypersensitivity reaction to one of the product's components.
• Nodule, abscess, or granuloma.
• Vascular involvement may occur due to accidental intravascular injection or as a result of vascular compression caused by the implantation of an injectable soft tissue filler. It may manifest as blanching, discoloration, necrosis, or ulceration at the implant site or in the area supplied by the affected blood vessels, or, in rare cases, ischemic events in other organs due to embolization.
Rare isolated cases of ischemic events involving the eye resulting in vision loss and involving the brain resulting in cerebral infarction after facial aesthetic procedures have been reported. In the event of a vascular accident, the injection would be stopped immediately and appropriate medical treatment could be initiated by a specialist physician. These rare cases of vascular events are observed mainly in the glabella (between the eyebrows), in and around the nose, in the forehead, and in the periorbital region (these areas are different from the study areas).

• Infection or reactivation of a previous infection.
• Gel displacement.
• Inflammatory reactions and/or swelling may occur in patients who have previously received dermal fillers or who plan to receive them after receiving a COVID-19 vaccination.

The sponsor certifies that the devices tested contain only ingredients that comply with current legal and regulatory requirements and guarantees that there is sufficient data on their safety and efficacy to justify human exposure to these devices.

Depending on each individual's condition, however, there may be a risk of intolerance to the products. Any symptoms must be reported to the investigator, who will determine whether or not it is necessary to discontinue the study and will take the necessary and medically appropriate measures to address this intolerance.
In the event of an adverse reaction, photographs may be taken (these images do not allow for identification). Follow-up, in person and/or remotely (by telephone, video, etc.), may also be necessary beyond the schedule defined in the study.

Risk(s) related to the study techniques/procedures:

The measurement methods implemented in this study do not present any particular risks.

Other inconveniences that may be experienced during the study:

The sponsor has taken all necessary measures to limit the risks of this clinical study; however, unexpected risks may arise, as with any medical procedure of this type.

7. ALTERNATIVE TREATMENTS

The primary objective of this study is not to treat a pathology. Other products exist to improve skin quality and hydration: other injectable products (particularly those based on hyaluronic acid) or cosmetic products. The medical device being tested differs from cosmetic products in that the product is injected into the skin and not applied superficially, allowing for a more intense and lasting effect. The investigator may discuss alternative treatments (and the associated risks) with you, including the option of receiving no treatment.

8. CONDITIONS DE PARTICIPATION A L'ETUDE ET RESULTATS

Your inclusion in the study is conditional upon meeting the inclusion and exclusion criteria, as well as the results of the clinical examination and your willingness/ability to comply with the clinical investigation plan.

To participate in the study, you must be covered by a social security scheme.

Your participation in the study is confidential.

Your full participation throughout the study is desirable for the purposes of analyzing the results. However, it may end before the previously defined deadline:

- **At your own discretion: you are free to discontinue the study at any time. Your study data collected to date will be used by Eurofins Dermscan Pharmascan.**

- **At the investigator's discretion in the event of:**

- non-compliance with instructions,
- the occurrence of an exclusion criterion during the study,
- an adverse event requiring your withdrawal from the study for safety reasons.

- **Upon decision of the sponsor in the event of:**

- new information requiring urgent safety measures,
- request from regulatory authorities.

- **Upon government decision (closure of the investigational center) for administrative or health reasons.**

You will be promptly informed of the reasons for premature study termination, changes to the clinical investigation plan, or any new information that may affect your participation in the study.

In accordance with applicable regulations, you have the right to be informed of the overall results of this study as soon as they become available.

You can request this by mail addressed to:
Eurofins Dermscan Pharmascan – Study No. 23E1077 – Eurofins Pharmascan Department – 114 Boulevard du 11 Novembre 1918 / 69100 Villeurbanne.

In addition, the results of medical examinations performed and information about your health may be shared with you during or at the end of the study.

Your primary care physician may be informed of your participation in the study at your request. The investigator will then collect the name and address of your primary care physician in order to send them a letter informing them of your participation in this study.

9. COMPENSATION

A compensatory allowance of €339.00 for the constraints incurred will be paid starting on the 20th of the month following the end of your participation in the study, if the required information (questionnaires, daily monitoring, etc.) is reported to the center during the visits stipulated in the protocol and if all visits, procedures, and measurements have been completed.

Travel expenses between your home and Eurofins Dermscan (strictly related to your participation in the study) will be reimbursed upon presentation of supporting documentation (original invoices or mileage expenses). These supporting documents must be sent within 30 days of each visit by mail: To the attention of Eurofins Dermscan Pharmascan (Pharmascan Department - Study 23E1077 - 114 Boulevard du 11 Novembre 1918 - 69100 Villeurbanne.

In the event of withdrawal during the study, failure to comply with appointment times or days, failure to follow the instructions indicated in this information leaflet, or premature termination of the study for health or administrative reasons, the compensation will be paid to you pro rata temporis for the study days completed, the procedures performed and associated constraints, and the number of usable assessments.
In the event of an adverse event occurring during the study requiring your withdrawal from the study by decision of the investigator, the compensation will be paid to you in full.
In addition, and by decision of the investigator, the costs related to the Treatment and follow-up of a potential adverse event directly related to your participation in the study will be covered.

For subjects not included in the study during the screening visit, a €14 compensation allowance will be paid starting on the 20th of the month following the end of your study participation.
For subjects not included in the study during the D0 visit, a €28 compensation allowance will be paid starting on the 20th of the month following the end of your study participation.

10. NATURE AND SOURCE OF COLLECTED DATA

The following data will be collected as part of this study by the investigating center:
- Health data including medical, surgical, allergy, and cosmetic history, previous medical procedures and procedures performed during the study, current and previous medical treatments, contraception, and data collected through a general physical examination (pulse, blood pressure, weight, height),
- Pregnancy test results,
- Demographic data (married and maiden name, first name, postal address, email address, place of birth, date of birth, age, gender, weight, etc.),
- Data relating to your lifestyle habits (tobacco, drug, and alcohol use),
- Data relating to efficacy and safety assessments specifically planned to evaluate the effects of the product in the study,
- Data collected through study-specific questionnaires and monitoring sheets,
- Data recorded directly on the measuring devices and photographs

Only indirectly identifying data will be transferred to the sponsor as described in the paragraph below..

11. DATA PROCESSING AND ACCESS RIGHTS

Your personal data is processed by Eurofins Dermscan Pharmascan, on behalf of the study sponsor, within the meaning of the French Data Protection Act (Act No. 78-17 of 6 January 1978, as amended, known as the "Data Protection Act") and in accordance with the provisions of Regulation (EU) No. 2016/679 on the

protection of natural persons with regard to the processing of personal data and on the free movement of such data (known as the General Data Protection Regulation or "GDPR") (texts available upon request).

Your personal data listed in paragraph 11 will be collected under the conditions specified below. Their collection is necessary to determine your inclusion in the study, to conduct the study, and to ensure the use of the results within the framework of the study. The processing of this data is based on Article 6.1 (f) of the GDPR, namely that the processing is necessary for the purposes of the legitimate interests of the controller, and Article 9.2 (i) of the GDPR, according to which "processing is necessary for reasons of public interest in the area of public health, […] to ensure high standards of quality and safety of healthcare and of medicinal products or medical devices."

Eurofins Dermscan Pharmascan implements all appropriate technical and organizational measures, taking into account the nature of the data and the risks posed by their processing, to preserve the security and confidentiality of the personal data you provide and, in particular, to prevent it from being distorted, damaged, or accessed by unauthorized third parties.

Your personal data may not be processed without your prior express written consent to participate in the study. Your data is collected in an identifiable manner by the investigator and will then be indirectly identified through the assignment of an alphanumeric code before being sent to the study sponsor. Therefore, your first name/last name/date of birth and contact details will not be shared with the Sponsor. Details of the people who may have access to your data are presented in the table below.

Eurofins Dermscan Pharmascan undertakes not to disclose, transfer, rent, or transmit your personal data to third parties other than those mentioned below and for the expressly provided purposes:

The parties with access to your identifying data are bound by professional secrecy.

Your personal data is retained by Eurofins Dermscan Pharmascan for the duration of the clinical study and then archived for a period of fifteen (15) years, in accordance with applicable regulations. The Eurofins Dermscan Pharmascan subcontractors responsible for this archiving (computer and paper), as listed above, implement appropriate security measures to ensure the confidentiality and integrity of your personal data. They have no right to use your personal data except for the purposes of performing the services entrusted to them by Eurofins Dermscan Pharmascan and under its control. For the purposes of this study, your personal data may be transferred outside the European Union to the study sponsor (based in Switzerland), one or more subsidiaries of Eurofins Dermscan Pharmascan participating in the study (Tunisia), and/or any other service provider acting on behalf of the sponsor. Eurofins Dermscan Pharmascan ensures at all times that these transfers are carried out under appropriate and appropriate security and confidentiality conditions to guarantee a level of protection of your personal data equivalent to the level required within the European Union, in accordance with the GDPR and the French Data Protection Act. Furthermore, such a transfer of your personal data may only take place if appropriate safeguards have been previously put in place, such as standard contractual clauses or binding corporate rules, or if an adequacy decision has been issued by the European Commission authorizing the free transfer of personal data to the recipient country. You have the right to access your personal data at any time, to rectify it when it is inaccurate or incomplete, as well as the right to limit its processing and to erase it. You also have the right to object to the transmission of data

covered by professional confidentiality that may be used and processed in the context of this research. If you exercise this right, you will be removed from the study, and no further data may be collected.

You are informed that withdrawing your consent to participate in the study, as well as exercising your right to object and/or your right to erasure, will result in the end of your participation in the study. However, the sponsor and Eurofins Dermscan Pharmascan may use data collected prior to the withdrawal of your consent, to the extent that its deletion would likely make it impossible or seriously compromise the achievement of the study objectives. No new information will be collected and processed for the study database.

You can exercise your rights at any time with the Eurofins Dermscan Pharmascan physician:

- by post to the following address:

Eurofins Dermscan Pharmascan

To the attention of the physician in charge of the laboratory

114 boulevard du 11 novembre 1918

69100 VILLEURBANNE

- or by email to the following address: investigator@dermscan.com.

If you have difficulty asserting your rights with the investigator, you can contact the sponsor's Data Protection Officer (DPO) at the following email address: compliance@kylane.com. In this case, the sponsor's DPO will have access to your identity.

You may be asked to provide proof of identity. You have the right to file a complaint with the French Data Protection Authority (CNIL) if you believe that the processing carried out by Eurofins Dermscan Pharmascan constitutes a violation of your personal data. You can contact the CNIL by post at the following address: Commission nationale de l'informatique et des libertés, Service des plaintes, 3 Place de Fontenoy, TSA80715, 75334 PARIS CEDEX 07 or by visiting the website https://www.cnil.fr/fr/adresse-une-plainte.

In any event, you are hereby informed of the possible reuse of your personal data collected and processed as part of the study by the sponsor for secondary scientific research purposes in the same field as the study. You may, however, object to this secondary use of your data at any time by informing the Eurofins Dermscan Pharmascan physician. You will be informed of the conduct of such a research project. In the event of transfer to hospital or consultations outside Eurofins Dermscan Pharmascan, I designate, in accordance with Articles R. 1111-1 and R. 1112-6 of the French Public Health Code, the Eurofins Dermscan Pharmascan doctor, namely the investigator, the on-call doctor or the medical manager of Eurofins Dermscan Pharmascan, as my intermediary or referring doctor. As such, I authorize any reciprocal exchange of information concerning me, and in particular any medical information relating to my state of health, useful and relevant to my care, the continuity of care, and the safety of other subjects participating in the research, as well as any information concerning my medical history between the Eurofins Dermscan Pharmascan doctor and the doctors involved in my care in the event of hospitalization.

12. IMAGE RIGHTS

For the purposes of this study, you will be photographed by center staff in accordance with applicable legal requirements, subject to your prior consent.
Photographs of your full face and neck/décolleté, as well as one of the optional areas (inner arms or abdomen), will be taken at the assessment times specified in the clinical investigation plan. Additional photographs of the areas studied may also be taken in the event of an adverse reaction. These photographs will be anonymized afterward.
Your participation in the study is not conditional on your agreement to the use of the photographs for promotional or advertising purposes.
A specific section regarding image rights must be completed in the consent form.

13. ETHICAL AND REGULATORY ASPECTS

This study is conducted in accordance with Good Clinical Practice (ICH Topic E6 (R2)), EN ISO 14155:2020, and the European Medical Device Regulation 2017/745 of April 5, 2017.

In accordance with current regulations, you will be included in the national database of individuals participating in clinical research managed by the Ministry of Health, based on the information you provide in the attached consent form. This is for:
- safety reasons, to prevent you from participating simultaneously or within too short a period of time in another research study;
- to verify that the maximum amount you have received for your participation in clinical studies over the past 12 months does not exceed the legal limit of €6,000 (six thousand euros).

The clinical investigation plan was reviewed by a Personal Protection Committee (CPP Ouest I, Tours), whose role is to ensure that the conditions required for your protection and respect for your rights are met. The CPP issued a favorable opinion on September 13, 2023. Similarly, the clinical investigation plan was submitted to the competent authority (ANSM), which authorized it on …….. / …… / ……..

The sponsor of this study (Kylane Laboratoires SA, Chemin du Pré-Fleuri 1-3, CH-1228 Plan-les-Ouates, SWITZERLAND) has taken the measures required by the European Medical Device Regulation 2017/745 of April 5, 2017, by taking out Civil Liability insurance (QBE Europe SA/NV INSURANCE, policy no. 064745/01/2023/0000).

The description of this clinical study has been registered in the following publicly available database: https://www.clinicaltrials.gov/. At the end of the study, the results will also be registered in this public database, without disclosing your identity.

The sponsor delegates the following tasks to a representative (Eurofins Dermscan Pharmascan): preparation of documentation, submission of the regulatory dossier to the authorities, implementation and conduct of the study at its site, and monitoring and analysis of the study results in compliance with applicable regulations.

N° investigation clinique :	22E0978	N°PI sujet : (*à remplir par l'investigateur*):	S	5		

eurofins | Dermscan Pharmascan

INFORMED CONSENT FORM For participants in the study:

N° of clinical investigation	22E0978

SAFETY AND EFFECTIVENESS CLINICAL EVALUATION OF THE RANGE OF INJECTABLE MEDICAL DEVICES VISCOL IN AESTHETIC TREATMENT

For any questions about your appointments or the study, contact EUROFINS Dermscan Pharmascan:
04.72.82.51.00
For MEDICAL EMERGENCIES ONLY:
04.72.82.36.59 or 15
No other information will be provided by phone.

I, the undersigned:

Last name :		First name :	
Maiden name :			
Born on :	__ / __ / ____ (day / month / year)	At :	
Address :	Road : Zip Code : _____ Town :		
Phone :	_____		
Email :	@		

- I certify that I have read and understood the information letter (Version 3.0 dated 10/26/2023) that was provided to me and that I have had the opportunity to ask any questions I may have.
- I understand the constraints and benefits associated with my participation in this trial.
- I am aware that I may discontinue my participation in this research at any time without having to justify my decision. This will not affect the quality of future relationships.
- I acknowledge that I have been informed that the indirectly identifying data recorded during this study may be subject to computer processing. I have noted that I may exercise my rights regarding my personal data as provided for by the regulations relating to the protection of personal data (GDPR and the French Data Protection Act). I also agree that the sponsor's representative or the

representative of the Health Authorities, bound by professional secrecy, may have access to my file for compliance checks.

- If I wish and at my request, the results of the test will be communicated to me directly.I accept that authorized individuals (sponsor reps, health authorities) may access my file for compliance checks
- I freely agree to participate in this research study under the conditions specified in the information letter. My consent in no way relieves the research organizers of their responsibilities; I retain all rights guaranteed by law.

IMAGE RIGHTS

By signing this form:

- I AUTHORIZE the capture and use of my identifiable image by the center or its providers for data collection, analysis, and archiving.
- I AUTHORIZE the transmission of my non-identifiable image (eyes and distinctive features masked) to the sponsor to illustrate the study results.

Additionally:
I AGREE or I REFUSE
to the use of my non-identifiable image (with masking) for:

- Scientific publications
- Promotional purposes
- On any media (print, digital) and distribution (TV, cinema, press, internet) worldwide for 15 years from the study end date, extended if necessary to cover product marketing, without financial compensation.

I understand that I can withdraw this authorization anytime, if my image has not yet been published, by writing to the center or via email.

I am informed that I may withdraw my consent at any time by contacting the center, provided that my image has not yet been published, either by mail at the following address: Eurofins Dermscan Pharmascan, Attn: Laboratory Responsible Physician, 114 Boulevard du 11 Novembre 1918, 69100 VILLEURBANNE, France, or by email at the following address: investigateur@dermscan.com. Acceptable proof of identity will be required.

Signed in two copies at: Villeurbanne

- Participant's Full Name, Date & Signature: _____
- Investigator's Full Name, Date & Signature: _____