NOM :		*(première lettre)*	Prénom :		*(première lettre)*				
N° investigation clinique :	**22E0978**			**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 FILLGEL IN FACIAL AESTHETIC TREATMENT

Sponsor: KYLANE LABORATOIRES SA Chemin du Pré-Fleuri 1-3 CH-1228 Plan-les-Ouates SUISSE	Sponsor representant : 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
22E0978	Face

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)

his study is conducted for scientific purposes. It is experimental research compliant with national, European, and international regulations (legal texts available upon request).
The company KYLANE LABORATOIRES SA (study sponsor) has developed a range of injectable hyaluronic acid-based products for facial aesthetic treatments (wrinkle filling, volume restoration). The product range tested in this study (4 FILLGEL products) is not yet marketed and has not been tested on humans so far. However, these products are identical (except for the packaging) to another range already on the market (MaiLi® range).

The 4 medical devices differ by their respective hyaluronic acid concentrations, allowing the range to cover several indications in facial aesthetic treatments. The products also contain lidocaine, an anesthetic aimed at reducing discomfort during injection.
Hyaluronic acid is a molecule naturally present in the human body. It binds with water in the skin layers to smooth wrinkles and fill volume loss. In aesthetic medicine, it is widely used by injecting directly into the dermis or subcutaneous tissues.
This type of product is biodegradable and naturally dissipates within the body.
The objective of this study is to collect data on the efficacy and safety of this treatment range up to 12 months after injection.
Different scoring assessments will be conducted by physicians and yourself to evaluate:

- Aesthetic improvement
- Effectiveness on wrinkle filling or volume restoration
- Treatment safety

Photographs of your face will be taken to illustrate the treatment's effects.

The study will be divided into 4 groups. Each group will test one single product of the range, for one specific indication, on both sides of the face.
You will be assigned to one of the groups based on your needs and inclusion criteria:

- Group 1: Filling wrinkles around the mouth (i.e., around the lips)
- Group 2: Filling nasolabial folds (lines from the nose to the mouth) and/or lip augmentation (lower and/or upper lip)
- Group 3: Filling volume loss in the cheeks and cheekbones
- Group 4: Filling volume loss in the cheeks and cheekbones and/or the chin

The study will involve 68 subjects, divided into 4 groups of 17.
Your full participation is expected over a 12-month period (plus a pre-inclusion period).

2. STUDY DEVICES

The FILLGEL products will be injected on Day 0 into the treatment area(s):

- Group 1: FILLGEL 0 – Wrinkles around the mouth
- Group 2: FILLGEL 1 – Nasolabial folds and/or lips
- Group 3: FILLGEL 2 – Cheeks and cheekbones
- Group 4: FILLGEL 3 – Cheeks, cheekbones, and/or chin

For Groups 2 and 4, you may be injected into one or both of the indicated zones.
Injections will be performed by a trained, specialized physician after disinfection of the area.
The volume injected will be determined by the injector to achieve the best aesthetic result (maximum 2ml per zone per side of the face).
The injection procedure takes about 15 to 30 minutes.
No touch-ups are planned; this is a single injection performed on Day 0.

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.
- -Photos of your face (front and both profiles) will be taken.
- -The investigator will score the treatment area.
- After disinfecting the area and applying a local anesthetic cream (if requested), the specialized doctor will inject the product according to your group assignment:
- Group 1: FILLGEL 0 – Wrinkles around the mouth
- Group 2: FILLGEL 1 – Nasolabial folds and/or lips
- Group 3: FILLGEL 2 – Cheeks and cheekbones
- Group 4: FILLGEL 3 – Cheeks, cheekbones, and/or chin
- -The injector will evaluate the quality of the injection via a questionnaire.
- -The investigator will assess aesthetic improvement and skin reactions at the injection site.
- -You will receive instructions for the following days (explained later).
- -You will be given a daily monitoring sheet to record, for the first month, any reactions at the injection sites (redness, bruises, swelling, etc.). You must also record any medications or 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, 4, and 5 – Months 1, 6, and 12 (Approx. 30 min each):

-Each time, arrive without makeup, cosmetics, or creams applied since the night before, clean-shaven if applicable, and bring your monitoring sheet.
-The investigator will record any adverse events and current treatments.
-Photos of your face (front and profiles) will be taken.
-The physician will score the treated area.
-They will evaluate aesthetic improvement and skin reactions.
-You will fill out a self-assessment questionnaire on the aesthetic improvement of your face.
-A new diary will be given for the next period to record:

- Medication intake
- Any adverse events
  (You will be guided on how to complete it.)

4. STUDY REQUIREMENTS AND CONSTRAINTS

To participate, you must agree to:

-Attend all 5 mandatory visits at the lab (Screening, Day 0, Month 1, Month 6, Month 12).

-Fully inform the investigator about:

- Your medical and surgical history
- Any current medical conditions
- All current or past treatments (oral or topical)

-Report any previous cosmetic surgery or aesthetic medicine procedures (Botox, hyaluronic acid, permanent or semi-permanent fillers, threads, etc.), either on the face or elsewhere. Some aesthetic treatments are incompatible — the investigator must know your entire history, even old procedures, to check compatibility.

-Report any medical consultation or intervention within the last 6 months, and any planned procedures during the study period.

For women of childbearing potential:
-Use an effective contraceptive method (pill, IUD, implant, condom) for at least 4 weeks before the study and throughout its duration.
-Do not start, stop, or change your contraceptive method during the study.

5. You must immediately inform the investigator of any new event during the study:

- Intolerance reactions to the product(s) (persistent discomfort or unusual signs)
- New illness, hospitalization, or accident
- Taking new medications or changing doses
- Pregnancy (this will result in your withdrawal from the study, but follow-up will continue until the pregnancy ends)

You cannot participate in another human research study simultaneously.

- Specific Visit Instructions:
- -Be clean-shaven (if applicable).
- -No cosmetics or makeup on your face (daily hygiene is fine).

One week before the injection:

Avoid taking Aspirin, anti-inflammatories (Ibuprofen, Ketoprofen, Naproxen, etc.), or any blood thinners, antiplatelet, or thrombolytic medication — to reduce the risk of bleeding or bruising.

Post-Injection Guidelines (Day 0):

-No cosmetics or makeup for 12 hours after injection.

-Avoid:

- Prolonged sun or UV exposure
- Temperatures below 0°C
- Sauna or hammam (for 2 weeks after injection)

-If sun exposure is unavoidable, use high SPF sunscreen.

-Do not massage or apply pressure to the treated area for several days.

COVID-19 Specific Requirements:

-Notify the investigator immediately if:

- You contract COVID-19
- You develop symptoms
- Someone close to you tests positive within 10 days prior or during the study

-Follow all protective measures explained by the lab (also displayed on-site and online) — including barrier gestures and safety protocols.

6. POTENTIEL BENEFIT(S)

he expected benefit of participating in this study is aesthetic improvement through:

- Wrinkle filling
- Restoring facial volume

However, the result is not guaranteed.

7. POSSIBLE RISKS AND SIDE EFFECTS

Side Effects Related to the Device and/or Injection Procedure:
Some side effects may occur immediately or later after the injection. These include, but are not limited to:

- -Common and usually resolve within a week:
- Injection-related effects or inflammatory reactions such as:
  - Bleeding
  - Bruising
  - Redness (erythema)
  - Hematoma
  - Skin discoloration
  - Swelling / Edema
  - Local infection
  - Pain or itching at the injection site
- Tenderness at the injection site
- Hardening (induration), bump, or nodule at the injection site
- Skin pigmentation changes (coloration or discoloration)

- -Possible delayed effects after injection:
- Hypersensitivity reactions to hyaluronic acid or lidocaine, immediate or delayed
- Nodule, abscess, or granuloma formation
- Vascular injury caused by:
  - Accidental injection into a blood vessel
  - Vascular compression by the injected filler

This may cause:

- Whitening or discoloration

- Skin necrosis or ulceration at the site or nearby areas
- Rare cases of ischemic events affecting:
  - The eye, leading to vision loss
  - The brain, causing a stroke (cerebral infarction)

These rare vascular complications mainly occur in:

- The glabella (between eyebrows)
- The nose and surrounding areas
- The forehead
- The periorbital region (around the eyes)

- Infection or reactivation of a previous infection
- Gel migration

- Device Safety Guarantee:

The sponsor guarantees that all tested devices:

- Contain only ingredients compliant with legal and regulatory standards
- Have sufficient data supporting their safety and effectiveness for human exposure

However, individual intolerance risks may still exist.
Any unusual symptoms must be reported to the investigator, who will decide whether to withdraw you from the study and ensure proper medical care.

- In Case of Adverse Reactions:
- Photographs may be taken (coded images, not identifiable)
- Additional follow-up (in person or remotely) may be required beyond the planned study visits

- Risks Linked to Study Procedures:
- The measurement methods used in this study pose no particular risk.

- Other Possible Discomforts:

Despite all precautions, unexpected risks may arise, as with any medical procedure of this kind.
Special COVID-19 safety measures (disinfection, protection) will be enforced, but cannot fully eliminate contamination risk.

8. ALTERNATIVE TREATMENTS

Improving wrinkles and soft tissue depressions can also be achieved through other treatments, such as (non-exhaustive list):

- Laser treatments
- Chemical peels
- Dermabrasion
- Other skin procedures
- Other filler products
- Surgery (like a facelift if necessary)

The investigator can discuss these alternative treatments and their risks with you, including the option of receiving no treatment at all.

9. CONDITIONS DE PARTICIPATION A L'ETUDE ET RESULTATS

Eligibility:
Your inclusion in the study depends on:

- **Meeting the inclusion and exclusion criteria**
- **Passing the medical exam**
- **Your willingness and ability to follow the study protocol**

-You must have valid health insurance coverage.
-Your participation is confidential.

Duration of Participation:
You are expected to complete the full study period. However, your participation may end early if:
-You decide to withdraw — You are free to stop at any time without justification.
All data collected up until your withdrawal will still be used by Eurofins Dermscan Pharmascan.
-The investigator decides due to:
Non-compliance with the study requirements
An exclusion criterion appearing during the study
An adverse event requiring your withdrawal for safety reasons
-The sponsor decides due to:
New urgent safety information
Regulatory authority requests
-Government decision (investigator center closure for administrative or health reasons)

You will be quickly informed of the reasons for any early termination, changes to the study plan, or any new information affecting your participation.

10. COMPENSATION

You will receive a compensation of €484 for the inconvenience and constraints related to your participation. Payment will be made starting from the 20th of the month following the end of your participation, provided that:

- All expected documents (questionnaires, daily monitoring sheets, etc.) are returned
- All visits, procedures, and assessments required by the protocol have been completed

-Travel expenses between your home and Eurofins Dermscan (strictly for study participation) will be reimbursed upon submission of supporting documents:

- Original invoices or
- Mileage expenses

These documents must be sent within 30 days of each visit to:
Eurofins Dermscan Pharmascan (Service Pharmascan – Study 22E0978)
114 Boulevard du 11 Novembre 1918
69100 Villeurbanne, France

11. n case of early withdrawal or study termination:
If you:

- Withdraw from the study
- Fail to comply with the study requirements
- The study ends early for health or administrative reasons

The compensation will be paid pro-rata based on:

- Days spent in the study
- Completed procedures
- Number of usable evaluations
  Subject to the return of the required materials

In case of an adverse event leading to your withdrawal:
-Full compensation will be paid.
-Additionally, any treatment and follow-up costs directly linked to a study-related adverse event will be covered.

For subjects not included in the study (screened but not selected):
An indemnity of €14 will be paid starting from the 20th of the month following your participation.

12. NATURE AND SOURCE OF COLLECTED DATA

The investigator center will collect the following data during the study:
-Health data:

- Medical, surgical, allergic, and aesthetic history
- Prior and current medical procedures and treatments

- General physical exam data (pulse, blood pressure, weight, height)

-Pregnancy test result (if applicable)
-Demographic data:

- Marital and maiden name, first name
- Postal address, email
- Place and date of birth, age, sex
- Skin type, phototype

-Lifestyle data:

- Tobacco, drug, and alcohol use

-Efficacy and safety assessment data specifically designed to evaluate the product's effects in this study
-Questionnaires and daily monitoring sheets
-Data directly recorded by measuring devices, including photographs

Only pseudonymized data (non-directly identifying) will be transferred to the sponsor as described below.

13. DATA PROCESSING AND ACCESS RIGHTS

Your personal data will be processed by Eurofins Dermscan Pharmascan, on behalf of the study sponsor, in compliance with:

- The French Data Protection Law (Loi Informatique et Libertés - 1978, modified)
- The General Data Protection Regulation (GDPR - EU 2016/679)

These legal texts are available upon request.

Your data is collected to assess your eligibility, perform the study, and analyze the results.
-Legal basis: Article 6.1(f) and 9.2(i) of GDPR – legitimate interest and public health interest.
Data protection measures are in place to prevent:

- Distortion
- Damage
- Unauthorized access

-Your explicit written consent is required before processing any of your personal data.
Identifiable data is collected by the investigator and pseudonymized before being sent to the sponsor. The sponsor will not receive your name, first name, date of birth, or contact information.

Vos données personnelles font l'objet d'un traitement par Eurofins Dermscan Pharmascan, pour le compte du promoteur de l'étude, au sens de la Loi Informatique et Libertés (loi n° 78-17du 6 janvier 1978 dans sa version modifiée dite « Loi Informatique et Libertés ») et conformément aux dispositions du « Règlement (UE) n° 2016/679 relatif à la protection des personnes physiques à l'égard du traitement des données à caractère personnel et à la libre circulation de ces données (dit Règlement général sur la protection des données » ou « RGPD») (textes à disposition sur demande).

Vos données personnelles listées en paragraphe 11 seront collectées dans les conditions précisées ci-après. Leur collecte est nécessaire pour déterminer votre inclusion dans l'étude, pour la réalisation de l'étude et pour assurer l'exploitation des résultats dans le cadre de l'étude. Le traitement de ces données repose sur le fondement de l'article 6.1 (f) du RGPD à savoir que le traitement est nécessaire aux fins des intérêts légitimes du responsable de traitement et de l'article 9.2 (i) du RGPD aux termes duquel « le traitement est nécessaire pour des motifs d'intérêt public dans le domaine de la santé publique, […] aux fins de garantir des normes élevées de qualité et de sécurité des soins de santé et des médicaments ou des dispositifs médicaux ».

Who Has Access to Your Data?

Who?	Purpose	Data Access
Investigator's team, injectors, technicians	Perform the study, data collection, quality control	Identifiable data (including photos)
Sponsor's representatives	Monitor study compliance	Identifiable data
Regulatory authorities	Regulatory inspections	Identifiable data
Electronic CRF provider (DATACAPT)	Data collection/analysis	**Pseudonymized** data
Archiving provider (EVERIAL)	Archive paper data	Identifiable data
IT backup provider (JAGUAR NETWORK)	Backup digital data	Identifiable data
Study Sponsor and subcontractors	Analyze results, scientific use, publications, promotions	**Pseudonymized** data only

Everyone accessing your identifiable data is bound by professional secrecy.

Data Retention:

Your personal data will be:

- Kept by Eurofins Dermscan Pharmascan for the study duration
- Archived for 15 years (in compliance with regulations)

Subcontractors are prohibited from using your data for any purpose other than the study.

International Data Transfers:

Your pseudonymized data may be transferred outside the EU (e.g., to the sponsor in Switzerland).
-All transfers are secured and comply with GDPR requirements.

Your Rights:

At any time, you can:

- Access your data
- Rectify inaccuracies
- Restrict or delete your data
- Object to the use of your health data

If you exercise your right to object, you will leave the study immediately, and no new data will be collected. However, the sponsor and Eurofins Dermscan may retain data already collected if deleting it jeopardizes the study's scientific validity.

You may exercise your rights by contacting the investigator: Eurofins Dermscan Pharmascan – Attn: Responsible Physician
114 Boulevard du 11 Novembre 1918

69100 Villeurbanne, France
investigateur@dermscan.com

In case of difficulties, you can also contact the Sponsor's Data Protection Officer (DPO):
compliance@kylane.com

 You may be asked to provide ID proof.

Right to File a Complaint:

You can lodge a complaint with the French CNIL (Commission Nationale de l'Informatique et des Libertés): 3 Place de Fontenoy, TSA 80715, 75334 PARIS CEDEX 07, France
https://www.cnil.fr/fr/adresser-une-plainte

Reuse of Data:

Your data may be reused for future scientific research in the same field.
You can object at any time by informing Eurofins Dermscan Pharmascan.

14. IMAGE RIGHTS

For the study purposes, your photographs will be taken by the center staff in compliance with legal regulations with your prior consent.

-Photos of your entire face will be taken at each evaluation visit.
-Additional photos may be taken if adverse reactions occur.

Your participation is NOT conditional on accepting the use of your photos for promotional or advertising purposes.

A specific section related to image rights is included in the consent form.

15. ETHICAL AND REGULATORY ASPECTS

This study is conducted in compliance with:

- Good Clinical Practices (ICH E6 R2)
- EN ISO 14155:2020 standard
- European Regulation (EU) 2017/745 on medical devices
- National regulations (French Public Health Code)

National Human Research Registry:
As required by French regulations, you will be registered in the national database of individuals participating in human research, managed by the Ministry of Health, for the following reasons:

- Safety: Prevent simultaneous participation in multiple studies
- Compensation cap: Ensure you do not exceed the legal limit of €4,500 over the past 12 months

Regulatory Approvals:
-The clinical investigation plan has been reviewed by the Ethics Committee (CPP Île de France I), which ensures your protection and rights.
-The CPP has issued a favorable opinion on [insert approval date].
-The plan has also been submitted to the Competent Authority (ANSM), which authorized it on [insert approval date].

Insurance and Liability:
The study sponsor, Kylane Laboratoires SA, has taken out civil liability insurance (CNA, policy no. 10477335) in accordance with French Law No. 2012-300 on human research.

Study Registration:
-This clinical study is registered in the ISRCTN database (publicly accessible).
-At the end of the study, results will also be posted in the database without disclosing your identity.

Sponsor Responsibilities:
The sponsor has delegated to Eurofins Dermscan Pharmascan:

- Document preparation
- Regulatory submissions
- Study conduct at the site

- Monitoring and analysis of study results in compliance with regulations

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

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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 FILLGEL IN FACIAL 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 :	@		

16. -Certify that:

- I have read and understood the information notice (Version 2.0 dated 05/10/2022)
- All my questions have been answered
- I understand the constraints and potential benefits of participating
- I know I can withdraw at any time without justification or consequences on my relationship with the team
- I understand that pseudonymized personal data will be processed and that I can exercise my data protection rights (GDPR and French law)

N° investigation clinique :	22E0978

- I accept that authorized individuals (sponsor reps, health authorities) may access my file for compliance checks

-Result Communication:

If I wish, I can request the study results, in accordance with the French Law of March 4, 2002.

-I freely agree to participate in this research as described.

-COVID-19 Specific Measures Acknowledgment:

I acknowledge that all necessary health precautions (barrier gestures, hydroalcoholic gel, etc.) are in place to protect my health during the study.
I have read and agree to the sanitary measures charter (available on www.dermscan.com/volontaire/ or on-site).

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: _____