INFORMATION SHEET

CLINICAL INVESTIGATION TO EVALUATE THE EFFICACY AND SAFETY OF EPILADY PROTOTYPE DEVICE FOLLOWED BY APPLICATION OF A TOPICAL FORMULA ON DEPIGMENTATION OF LENTIGO SPOTS IN HEALTHY WOMEN PARTICIPANTS

PHASE: II (FDA) AND IIB (EU)

Version 1.0 dated 04 November 2025 related to the Protocol 2425CMPH205 Version 1.0, dated 29/OCT/2025

Please complete in BLOCK LETTERS:

Name: _____

Family Name: _____

Dr _____ (Name, FAMILY NAME), on behalf of Centre International de Développement Pharmaceutique Ltée (CIDP Ltée), invites you to participate in a clinical study evaluating a laser medical device called Epilady used together with or without a cosmetic depigmenting formula for the treatment of benign skin pigmentation spots (lentigo) on the hands and forearms.

It is important that you read this document carefully before making your decision. Take your time and ask the investigator or study staff any questions you may have. You should only sign this form once you are sure you understand all the information presented in the following pages and are satisfied with the answers to your questions.

This study is organized and performed by CIDP Ltée, an independent Contract Research Organisation (CRO), located in the Biopark, Socota Phoenicia, Phoenix. CIDP has been conducting clinical research in Mauritius since 2004. For this study, Dr. Gitanjali Petkar, Dr. Ounisha Mungur, and Dr. Vedassen Jagabrun will act as the Clinical Investigators.

This study is sponsored and funded by L'Oreal EI- 100 Avenue de Stalingrad, 94550 Chevilly-Larue, FRANCE.

1. What is the purpose of this study?

The purpose of this study is to evaluate the safety and effectiveness of a laser medical device called Epilady, used with and without a cosmetic depigmenting serum (SERUM 2039125 10), for the treatment of benign pigmented skin spots called lentigines (also known as age spots or sunspots).

The Epilady device is a non-invasive handheld laser that emits pulses of light to target the dark pigment (melanin) in these spots. This process is expected to gradually lighten the appearance of the spots after several treatments, without damaging the surrounding skin.

In this study, the Epilady device will be applied once a week at the study center by trained clinical staff under the supervision of a doctor. On one hand or forearm, the device will be used alone, and on the other, it will be followed by the application of a cosmetic depigmenting serum (SERUM 2039125 10), to compare the results.

The serum, containing brightening agents such as Niacinamide, will be applied by you twice a day at home for the duration of the study (84 days), but only on the side (either your right or left hand/forearm) which will be chosen at random by the study team to receive both device and serum.

To support skin recovery and safety, the dermatologist will apply a healing cream to the treated areas 15 minutes after each laser session at the study center. You will be instructed to apply the sunscreen provided twice daily on both hands/forearms throughout the 84-day study period.

2. Why do we ask you to participate in the study and are you obliged to participate?

If you are seeking a treatment for benign pigmented spots (lentigines, commonly known as age spots or sun spots) on the hands or forearms, this study may be of interest to you. The study will help us to evaluate whether the Epilady laser device, with or without a cosmetic depigmenting serum, is effective and well tolerated in lightening these spots.

Your participation is completely voluntary. You are free to accept or refuse to participate in this study. If you agree to participate, the investigator will first carry out a clinical evaluation and physical examination to confirm that you are eligible.

However, you may not be included in the study if, for example:

- You are currently undergoing another treatment for pigmentation spots or other skin conditions on the hands/forearms.
- You are pregnant, breastfeeding, or planning to become pregnant during the study period.
- You have recently participated in another clinical study and are still within a "wash-out period" (the time needed to clear the effects of the previous treatment).
- You have certain medical conditions or contraindications (such as light sensitivity, recent cosmetic procedures, or dermatological diseases affecting the test area), which will be explained in detail by the investigator.

If you choose not to participate, please inform the investigator. You may also ask the investigator about **alternative available treatments** for pigmentation spots and their potential benefits and risks.

3. What is the study design and timetable?

Approximately 44 participants will be included in this study. For each participant, the study will last about 84 days (12 weeks).

You will attend the study center once a week for laser treatment and follow-up. In total, you will have 13 or 14 visits, depending on whether the screening and baseline are done separately or combined:

- Visit 1: Screening visit (eligibility check, explanation of study, informed consent).
- Visit 2 (D0): Baseline visit – first laser session, randomization of right/left hand or forearm, photography, and distribution of the cosmetic serum (to be applied twice daily at home on the randomized side).
- Visits 3 to 13: Weekly laser treatment visits (D7, D14, D21, D28, D35, D42, D49, D56, D63, D70, D77).
    - At each of these visits, the investigator will apply a small amount of healing cream to the treated spots 15 minutes after the laser session.
- Key evaluation visits:
    - D28 (Week 4)
    - D56 (Week 8)
    - D84 (Week 12, end of study)

- At these time points, more detailed clinical evaluations, photographs, and questionnaires will be performed.

- Visit 14 (if screening and baseline are separate): Final assessment at D84 (end of study).

At each visit, the investigator will assess your skin, check for any reactions, perform the weekly laser application, and apply the healing cream to the treated spots. You will be reminded to continue applying the cosmetic serum at home from the day after the laser application (on the assigned side only) and to respect the study instructions.

Additional visits may be planned if required, and you will be informed accordingly.

Visit 1: Screening Visit/Baseline D0T0

Duration of visit: approximately 3 hours

- You will come to the investigational center without applying any cosmetic or other product on your hands or forearms since the previous evening.
- You will be asked to read this Informed Consent Form (ICF). The clinical investigator will explain the clinical investigation in detail and answer your questions. After this discussion, you will sign the consent form electronically or on paper. The form will also be signed and dated by the clinical investigator, and you will receive a signed copy.
- The investigator will check whether you meet all the inclusion and non-inclusion criteria for this study.
- Your demographic information (age, gender, skin type, ethnicity), medical history, and current medications will be recorded.
- If you are a female participant of childbearing potential, you will be required to undergo a urine pregnancy test (UPT) at the baseline visit before any study procedures are carried out.
- You will wash your hands or forearms with soapy water
- Before any clinical or imaging evaluations, you will sit in a room with controlled conditions (22 ± 2 °C temperature and 40–60% humidity) for about 15 minutes to allow your skin to acclimatize.
- The study zones (the spots to be treated) will be identified and marked using a repositioning mask, so that the same spots can be followed throughout the study.
- A clinical evaluation will be performed, including:
    - Assessment of the pigmentation spots and surrounding skin using a standardized Color Chart.
    - Photography of the spots with the VISIA® CR system for documentation.
    - Completion of a self-assessment questionnaire, where you will give your opinion on your skin condition.
- The Epilady laser device will then be applied to the selected lentigo spots on your hands or lower arms by trained study staff under medical supervision.
- Fifteen minutes after the laser session, the investigator will apply a healing cream to the treated areas to protect and support skin recovery.

Visit 1: D0 – Baseline visit (Timm)

Duration of visit: approximately 3 hours

- After the first laser session, the treated areas will be carefully checked by the investigator for any immediate skin reactions (for example: redness, swelling, blistering, or discomfort).
- The investigator will complete an Overall Tolerance Assessment to evaluate how your skin has reacted to the treatment.
- Fifteen minutes after the laser session, the investigator will apply a healing cream to the treated areas to protect and support skin recovery.
- You will then be provided with the topical depigmenting serum. You will be instructed to start using it 24 hours after the laser session, applying it twice daily at home on the randomized side (the side treated with both device + serum).
- You will also be given a sunscreen product (SPF 50+). You must apply this twice daily (morning and midday) on both hands and forearms for the entire 84-day study period, beginning on the day of your first laser treatment.
- A daily logbook will be provided to you. You should use it to record each serum application, sunscreen use, any observed skin reactions, and other relevant observations throughout the study.

Weekly Follow-up Visits (Day 0, Day 7 ± 2 days, Day 14 ± 2 days, Day 21 ± 2 days, Day 28 ± 2 days, Day 35 ± 2 days, Day 42 ± 2 days, Day 49 ± 2 days, Day 56 ± 2 days, Day 63 ± 2 days, Day 70 ± 2 days, Day 77 ± 2 days, and Day 84 ± 2 days.)

After your first treatment, you will return to the study center once a week for laser sessions. These visits will take place over about 12 weeks (84 days). The planned treatment days are Day 0, Day 7, Day 14, Day 21, Day 28, Day 35, Day 42, Day 49, Day 56, Day 63, Day 70, Day 77, and Day 84 (with a margin of ±2 days if needed).

At each visit:

- Washing of the treated areas with soapy water.
- You will rest for about 15 minutes in a controlled room (temperature 22 ± 2 °C, humidity 40–60%) so that your skin adapts before the treatment.
- The Epilady laser device will be applied to the selected spots on your hands or forearms by trained staff.
- If needed, the dermatologist may adjust the laser intensity (for safety reasons) or skip a session if your skin is not ready for treatment.
- After the laser session the dermatologist will examine the treated skin for any reactions (e.g., redness, swelling, blistering, color changes, or discomfort). At the end of the 15-minute observation period, the dermatologist will apply a small amount of the healing cream to each treated spot.
- You will then stay at the centre for about 15 minutes of observation to make sure it is safe for you to leave.

Attendance: ***You are expected to attend all weekly visits. You may miss up to two sessions during the study, but they should not be consecutive. Missing more than two sessions, or two in a row, could mean that you may have to stop participating in the study.***

Participant responsibilities between visits:

- continue the depigmenting serum twice daily on the randomized side only (device + serum).*(on laser days, don't apply the serum in the morning; resume 24 hours after that session.)*
- apply the provided sunscreen (SPF 50+) twice daily (morning and midday) on both hands and/or forearms for the entire study.
- use your daily log to record serum/sunscreen use and any skin reactions or comments.

Visit 5 &9: D28 ± 2 & D56± 2
Duration of visit: Minimum 3h

- You will come to the study center without applying any cosmetic or other product on your hands or forearms since the evening before.
- The investigator will check your skin for local reactions or intolerance, ask about any adverse events, and record any new medications or procedures.
- Washing of the treated areas with soapy water.
- You will rest for about 15 minutes in a controlled room (22 ± 2 °C, 40–60% humidity) before measurements.
- The treatment spots will be identified using repositioning masks so the same areas are always evaluated.
- The investigator will perform a clinical evaluation:
    - The intensity of your pigmentation spots and the nearby skin will be assessed using a Color Chart.
    - Standardized photographs of your hands/forearms will be taken using the VISIA® CR system.
- You will complete a self-assessment questionnaire about your perception of the treatment effect.
- A laser session will be performed on the selected spots by trained staff.
- **Immediately after the laser session:**
    - The investigator will examine the treated areas for any reactions (such as redness, swelling, blistering, pigmentation changes, or discomfort).
    - You will remain under observation for at least 15 minutes to ensure your safety.
    - At the end of the observation period, the dermatologist will apply a small amount of healing cream to the treated spots.
- The investigator will complete an Overall Tolerance Assessment.
- Your serum and sunscreen use as well as your daily logbook will be checked to confirm compliance.
- You will be reminded to continue applying the serum at home twice daily on the randomized side, starting 24 hours after the session, and to keep using the sunscreen twice daily on both hands/forearms throughout the study.

Visit 13: D84 ±2 days _ Final Visit
Duration of visit: Minimum 3h

- You will come to the study center without applying any cosmetic or other product on your hands or forearms since the previous evening.
- The investigator will check your skin for any reactions or intolerance, ask about adverse events, and record any medications or treatments you may have used during the study.
- If you are a female participant of childbearing potential, you will be required to undergo a urine pregnancy test (UPT) before any study procedures are carried out.
- Washing of the treated areas with soapy water.
- You will rest for about 15 minutes in a controlled room (22 ± 2 °C, 40–60% humidity) before the evaluations.
- The treatment zones will be identified using repositioning masks to ensure the same areas are assessed.
- A clinical evaluation will be carried out:
    - The intensity of the pigmentation spots and the surrounding skin will be measured using a Color Chart.
    - Standardized photographs will be taken with the VISIA® CR system.
- You will complete a self-assessment questionnaire to share your opinion about the treatment effect.
- A final laser session will be performed on the selected spots.
- **Immediately after the laser session:**
    - The investigator will examine the treated areas for any reactions (such as redness, swelling, blistering, pigmentation changes, or discomfort).
    - You will remain under observation for at least 15 minutes to ensure your safety.
    - At the end of the observation period, the dermatologist will apply a small amount of healing cream to the treated spots.
- The investigator will complete an Overall Tolerance Assessment of your skin's response.
- The study team will check your depigmenting serum, sunscreen use, and daily logbook to confirm compliance.
- End-of-study procedures will be completed, including returning any remaining study products, final instructions, and closing discussions with the investigator.

Note :

- *Adverse Device Event/ Adverse Event and All concomitant medications will be tracked, documented, and reported throughout the study from screening to the end of study visit.*

4. Will everyone get the same study treatment (medical device)?

Yes. All participants will receive treatment with the Epilady laser device.

However, to compare the effect of the device used alone versus the device combined with the cosmetic depigmenting serum, your right or left hand/forearm will be randomly assigned:

- One side will receive weekly Epilady laser treatments only,
- The other side will receive weekly Epilady laser treatments followed by twice-daily application of the depigmenting serum at home.

This type of design (called "split-body" or intra-individual randomization) allows each participant to act as her own control, which helps the investigators clearly see the difference between the two approaches.

Your participant number will be assigned in the order you are included in the study.

5. What are the possible benefits and possible constraints of participating in the study?

Possible Benefits:

The Epilady device works by targeting and reducing the dark pigment in lentigo spots (age spots or sun spots). With repeated treatments, the spots are expected to gradually become lighter and less visible.

The anticipated benefits are:

- A visible reduction in the intensity of pigmentation spots,
- Improved evenness of skin tone on the hands and forearms,
- A non-invasive treatment approach, without surgery or injections,
- Good cosmetic outcomes, with minimal risk of scarring.

Possible constraints:

- You cannot participate in this study if you are still in the wash-out* period of a previous clinical study or if you are currently participating in another clinical study.
- Except in case of emergency, if you take any medication during the study, you must inform the investigator and note it in your study diary so that your participation remains safe and valid.
- You are not allowed to use any other product or treatment with similar effects on the areas being studied (hands and forearms) during the study.
- You must not apply any product on the study areas (hands or forearms) the day before each visit at the study center.
- You must not use any skincare products on the study areas during the 24 hours before your baseline visit.
- You must avoid intentional sun exposure and not use artificial UV sources (such as tanning salons or phototherapy) on the study areas for the entire duration of the study.
- You must not use self-tanners, whitening agents, or pigment-altering cosmetics on the study areas.
- You must not use scrubs, exfoliants, or astringent products on your hands or forearms during the study.
- You must keep your usual skincare routine the same (such as moisturizers or cleansers) for at least 2 weeks before the baseline visit and throughout the study, unless the investigator tells you otherwise.

- You must apply the investigational serum exactly as instructed (twice daily, only on the study-assigned side).
- You must attend all scheduled visits unless prevented by medical or logistical reasons. If you miss a visit, you should reschedule it as soon as possible.
- You will need to attend the study center once a week for 12 weeks (about 3 months), with visits lasting around 2–3 hours.
- At home, you must apply the depigmenting serum twice a day on the randomized side, and the sunscreen twice a day on both hands and forearms throughout the study.
- You may experience temporary skin reactions such as redness, swelling, mild scabbing, or discomfort after laser treatment.
- You will be asked to avoid direct sun exposure to your hands and forearms during the study, which may require lifestyle adjustments (e.g., avoiding outdoor activities without protection).

(*) Wash-out period: *A period in a clinical study during which participants receive no treatment for the condition under investigation, in order to allow the effects of any previous treatment to disappear (or be considered eliminated).*

6. What is the available information on the medical device Epilady and what do we know about side effects?

Available Information on the Epilady Device

The Epilady investigational device is a handheld, non-invasive laser system designed for the treatment of lentigo spots (also known as age spots or sun spots) on the hands and forearms.

- The device emits short pulses of light that are absorbed by the pigment (melanin) in the spots.
- This process is called selective photothermolysis and leads to a gradual lightening of the treated areas while leaving the surrounding skin intact.
- Two versions of the device exist:
- 660 nm wavelength (for lighter skin types I–IV),
- 808 nm wavelength (for darker skin types V–VI).
- The device includes safety sensors and skin tone checks to ensure it is used only under safe conditions.
- Treatments are performed by trained staff, once a week for 12 weeks.

Known or Expected Side Effects

Based on earlier feasibility testing and clinical experience, the following temporary skin reactions may occur after treatment:

a) **Immediate events** (during or right after treatment):

- Redness (erythema) or slight swelling (edema) around the treated spot.
- Mild to moderate pain or stinging during treatment (average pain score ~5.9 out of 10, often described as similar to waxing).

b) **Delayed events (hours to days after treatment):**

- Mild scabbing on the treated area, which is considered a normal part of the healing process.

- Temporary changes in skin color (lighter or darker) around the treated area, especially in darker skin types.
- Rarely, blistering or irritation can occur but usually heals on its own within a few days.

No serious or long-lasting side effects have been observed in preliminary clinical use of the device.

Precautions for Use

- After each laser session, a healing cream will be applied to the treated spots by the dermatologist at the study center, about 15 minutes after treatment, to support skin recovery
- You should avoid direct sun exposure on your hands and forearms throughout the study. Always apply the provided sunscreen (SPF 50+) twice daily.
- Do not use other cosmetic or dermatological treatments on the study areas during the investigation.
- You may notice small scabs — these should be left to fall off naturally. **Do not scratch or pick** at the treated areas.

In case of the occurrence of a health problem or unexpected event (including any study or non-study related health problems) during the study or following your participation in this study, you can contact CIDP on 4012600 available 24/7.
Useful numbers: - SAMU: 114.

7. How will you be compensated for your participation?

Different types of compensation are provided to compensate the costs incurred (trips, meals…) and the constraints of the study:

- **Compensation I:**

For your participation in this study, you will receive a total compensation of Rs 20,000. This amount is intended to cover the time and effort involved in attending all visits and following the study requirements. The payment will be made to you by internet transfer within three (3) working days after your final visit to the study center (excluding weekends and public holidays).

To receive the full amount, you must complete the entire study and attend all visits as scheduled. If you do not complete the full study or are unable to follow all the study requirements, you will still receive compensation based on the number of visits you have attended. The amounts for each visit are as follows:

- **Day 0 (D0): Rs 1,000**
- **Day 7 (D7): Rs 1,000**
- **Day 14 (D14): Rs 1,500**
- **Day 21 (D21): Rs 1,500**
- **Day 28 (D28): Rs 2,000**
- **Day 35 (D35): Rs 1,500**
- **Day 42 (D42): Rs 1,500**
- **Day 49 (D49): Rs 1,500**
- **Day 56 (D56): Rs 2,000**
- **Day 63 (D63): Rs 1,500**
- **Day 70 (D70): Rs 1,500**
- **Day 77 (D77): Rs 1,500**
- **Day 84 (D84): Rs 2,000**

- **Compensation II: Baseline Visit Non-Eligibility**

If you attend the **Baseline Visit (D0)** but are found not eligible to continue in the study, you will receive **Rs 500**. This amount is intended to cover your transportation and the costs of the medical examinations carried out during this visit.

- **Compensation III: Pre-selection Visit Non-Eligibility**

If you attend the **Pre-selection/Screening Visit** but are found not eligible to continue in the study, you will receive **Rs 300**. This amount is intended to cover your transportation and the costs of the medical examinations carried out during this visit.

- **Compensation IV: Study Termination**

If the study is **stopped early** by the investigator, the study center, or the sponsor, you will still receive the **full compensation of Rs 20,000**, even if the study is not completed

The compensation to which you are entitled will be given to you at the last study visit (Day 84 or earlier if applicable) (except in case of early termination).

8. What is the legal framework for this study?

This study will be conducted in compliance with the **Declaration of Helsinki**, **International Good Clinical Practice (GCP)** guidelines, and the standard **ISO 14155 (Clinical investigation of medical devices for human subjects — Good clinical practice)**.

The research has received a **favourable opinion from the Clinical Research Regulatory Council (CRRC)** on _____ (Trial Licence number: _____).

A description of this study will be available on the website **https://www.isrctn.com.** This public registry will not include any information that can personally identify you. It will only contain a short summary of the study procedures and, later on, a summary of the results. You can consult this website at any time.

The study is protected by **General Liability Insurance** contracted by the Sponsor (L'Oréal EI). In addition, CIDP has contracted a **Professional Liability Insurance** to cover the activities of the investigators and the study center.

9. Personal Data Processing

9.1. Defining Personal Data

By agreeing to participate in this study, you give your consent for the collection, storage, and processing of your personal data. This may include: your name and surname, sex, date of birth, nationality, signature, physical/anthropometric data, telephone/fax number, address, email, profession, ethnicity, social security number (if applicable), ID card/passport number, your health status, skin conditions, and any ongoing treatments.

A copy of your identity card may be kept by CIDP to confirm your identity.

CIDP will collect your personal data directly from you as a participant. Your data will be transmitted in a pseudonymized form (meaning your identity is replaced with a unique code) to CIDP's contractual partners or to authorities if required.

If CIDP receives personal data from third parties, those parties are obliged to inform you about how your personal data will be used.

Please note: if you refuse to provide your personal data, CIDP will not be able to include you in this clinical study or continue your participation.

9.2. Purpose and Legal basis Processing

Your personal data will be processed by CIDP during the study for the following purposes:

a. To conduct the clinical study, based on your explicit consent.

b. To contact your relatives in case of a medical emergency.

c. To manage the payment of compensation described in this document.

d. To support CIDP's legitimate interests (e.g., study management, handling complaints).

e. To comply with legal obligations (e.g., accounting, tax reporting).

f. For statistical analysis purposes.

Only authorised personnel will have access to your personal data, and they are required to maintain confidentiality. Any disclosure of your data to third parties will follow strict legal provisions. These third parties must also have appropriate safeguards in place to ensure your data is protected.

In certain cases, your personal data may be shared with other entities if required to establish or manage professional or contractual relationships.

In some cases, IT service providers may have access to your personal data, for example when providing hosting or technical maintenance services. Some of these providers may be located outside the European Union, including in the USA.

Your data may also be accessed by health authorities or auditors, if required by regulations.

In addition, to allow comparison and improvement of the study data, your information may be transferred to affiliated companies of the Sponsor in other countries.

The Sponsor and CIDP will ensure that, wherever your data is transferred, it is given a level of protection equivalent to that required under European Union law, and in compliance with local legal requirements.

9.3. Retention period

Your personal data will only be kept for as long as necessary for the purposes of this study and in line with legal requirements. In particular:

- For data collected as part of this clinical research, your information may be stored for **up to 15 years after the end of the study**, in accordance with legal and regulatory obligations.
- Certain documents, such as accounting records that may contain your personal data, must also be kept for **up to 15 years** after the end of the fiscal year, as required by law.

When these retention periods end, your personal data will be securely deleted, unless there is a valid legal reason to keep it longer, in line with the General Data Protection Regulation (GDPR).

9.4. Your Rights Relating to Personal Data

Under both the Mauritius Data Protection Act 2017 and the European Union's General Data Protection Regulation 2016 you have certain right related to collection and use of your personal data. We have explained these rights with examples below to make it easier to understand.

1. ***Right to information***

You are allowed to know why CIDP is collecting your data and who will receive your data.

2. ***Right to access your personal data***

You can ask what data CIDP has collected about you.

3. ***Right to rectification***

If your data contains errors, you can ask CIDP to correct these errors.

4. ***Right to delete your data***

If the data is no longer required for a scientific purpose, then you can ask that we delete your data.

5. ***Right to portability***

If you need your data for medical reasons, you can ask CIDP to provide your data in a readable form.

6. ***Right to restrict the processing of your data***

This right may be applied after you have objected to the processing of your data. It applies temporarily while CIDP determines whether your objection is justified.

7. ***Right to object to processing of your data***

If your data has not yet been used for a scientific purpose, then you may object to the fact that CIDP uses your data.

8. ***Right related to automated decision making***

If CIDP uses your personal data to take a decision in an automated manner (without human intervention) then you will be informed in this document. This is not the case for this study.

9. ***Processing of special or consent-based data.***

If CIDP processes your Personal Data, you have the right to withdraw your consent at any time without affecting the lawfulness of the processing under consent prior to its withdrawal. You may change or withdraw your consent at any time, and CIDP will act immediately, unless there is a legal ground or legitimate interest in not doing so.

To exercise any of the rights above, please contact CIDP by sending a written request.

Contact details

The operator of personal data is CIDP Ltée, based in Biopark, Socota Phoenicia, Sayed Hossen Road, 73408, Phoenix, Mauritius, Telephone 4012600.

Data Protection Officer (C/o Mrs Rajini Naidoo-Cartier)

The Data Protection Officer can be contacted at the operator's premises, at CIDP Ltée, based in Biopark, Socota Phoenicia, Sayed Hossen Road, 73408, Phoenix, Mauritius, Telephone 4012600.Email: dpo@cidp-cro.com

According to the Mauritius Data Protection Act 2017, if you consider that your rights have not been respected, you may contact the Data Protection Commissioner of Mauritius.

9.5. **Confidentiality**

Your identity will never appear in any report or publication. Any information or data concerning you will be treated in a strictly confidential manner.

10. Photography authorization for scientific publication and commercial use

All photographs taken during this study will become the property of the Sponsor (L'Oréal EI) and its affiliated companies, without any time limit, and may be used worldwide. By agreeing to participate, you give the Sponsor the copyright to use these photographs, which may appear in scientific publications, presentations, or for commercial purposes. Your identity will always remain confidential, and the photographs will never be linked to your name. The Sponsor may publish the photographs in scientific journals, on the internet, or present them at scientific meetings, and may also reproduce, edit, reduce, or enlarge them, or allow other organizations to use them. You will not receive any payment for the use of these photographs.

11. What are your rights?

Your participation to this study is completely free and voluntary. Your decision will not cause any harm or change in the quality of care and treatment you are entitled to.

This aim of this information sheet is to give you all the information you need to take your decision. You can take the time you want to think about it, ask all your questions to the investigating physician or anyone in the research team, and discuss of the study with your close friends and family.

You can, at any time, ask for explanations on the conduct of the study or relative procedures to the investigator or any member of the research staff.

If you choose to participate in the study, you can change your mind at any time and withdraw your consent whatever your reasons are and without supporting any liability or responsibility. This will have no effect on the quality of care that will be provided to you, nor on the quality of your relationship with the doctor or any member of the staff.

Your participation in this study will not imply any personal expense. All the expenses related to the realization of this study (provisioning of medical device, expense of consultations and examination) will be borne by CIDP.

Any new important information concerning the medical device, which could influence your consent to participate in study, will be immediately communicated to you. In this case, you could be requested to sign an updated form of this document.

Your personal and medical information will remain confidential and can be consulted only under the medical investigator's responsibility.

If you agree to participate in this study after carefully reading this document, and after discussing all the study aspects with the medical investigator, kindly:

- write your initials at the end of each page of this document
- date and sign the informed consent form on the next page

INFORMED CONSENT FORM – FOR ADULTS' PARTICIPANTS

I, the undersigned, _____ (Name, FAMILY NAME), freely agree to participate in the study entitled **«Phase II / IIb Clinical Investigation to evaluate the efficacy and safety of epilady prototype device followed by application of a topical formula on depigmentation of lentigo spots in healthy women participants»**, organized by the **Centre International de Développement Pharmaceutique Ltée (CIDP Ltée)** on behalf of the **Sponsor, L'Oréal Recherche et Innovation (L'Oréal EI)**, and proposed to me by Dr _____ (Name, FAMILY NAME, phone number), Investigator of this study.

- I have carefully read the 16 pages information sheet version 1 dated 04 November 2025 explaining the objectives of this study, the way in which it will be conducted, the constraints and what my participation implies, the potential side effects of the medical device, and my rights.
- I have been given every opportunity to ask questions before making my decision. I may request additional information at any time from the investigator in charge of the study or any CIDP staff implicated in the clinical study.
- I have received clear answers to all my questions, and I have had sufficient time to make my decision.
- I keep a copy of the information sheet and of the signed informed consent form.
- I have understood that my participation will last 84 days and that I can't participate in any other interventional study during this time.
- I am aware that my participation in this study is free and that I can withdraw my consent of participation and at any time whatever are my reasons and without supporting any responsibility or prejudice to the Quality of care I will receive. If I stop my participation, I shall inform the investigator about it. I shall tell him/her if I accept that the data collected until my decision can be processed or not. A last medical examination will be performed for my safety.
- I am aware that my participation can also be interrupted by the sponsor or the investigator without my prior agreement, for example if I do not respect the terms of protocol that have been explained to me by the investigator.
- I will be informed if new details concerning the medical device become known, which might affect my consent to take part in this research.
- My consent does not discharge in any way the investigator, the sponsor and CIDP Ltée of their responsibility and I keep all my rights guaranteed by law.
- I agree that CIDP Ltée, registered as a personal data controller with the Data Protection Office, processes personal data that I have provided for this study. I declare the supply of these data is voluntary.
- I accept that data are transmitted to the sponsor and can be checked by a monitor, auditor, ethics committee and/or regulatory authority's representative in conditions guaranteeing their confidentiality, even if I withdraw my consent.
- I have understood that photos of lesions will taken. As all the study data, they will be anonymized.
- I authorized the use of any data or results that arise from this study for scientific purpose(s) by CIDP Ltée.
- I know that I benefit under the Data Protection Act 2017 on protection of individuals regarding the processing of personal data and free movement of such data, of the right to have access to data, of intervention on the data, the right to object, and the right to address to the justice.
- I certify not being deprived of freedom by a court or administrative order and not being under guardianship.
- I consent that CIDP contacts me for future studies and be registered on CIDP Participant Database.

☐ YES ☐ NO

Signature of the participant giving consent

Name: _____

*Please write in block letters "**READ AND APPROVED**"*

Date: _____/_____/_____ *DD/MMM/YYY)*

Signature: _____

Signature of the investigator

I undersigned, as the investigator/designee, confirm having entirely explained and discussed the study's nature, purpose and necessities with the participant.

Name: _____

Date: _____/_____/_____ *(DD/MMM/YYY)*

Signature: _____

If you have any questions about this document, the study, or your rights, please call CIDP on 4012600

Study number: 2425CMPH205

Signature of impartial witness (if needed)

*I, _____. (**Name, FAMILY NAME**) confirm that the information presented in that document, as well as all written information related to the study, has been precisely and accurately described to _____. (**Name, FAMILY NAME of the participant**), who freely consents to participate in this study.*

Date: _____/_____/_____*(DD/MMM/YY)*

Signature of the impartial witness:

_____

Name of the investigator:
_____

Date: _____/_____/_____ *(DD/MMM/YY)*

Signature of the investigator:

_____

12. History of Modifications

Not applicable