CLINICAL STUDY PROTOCOL

STUDY TITLE

CLINICAL TRIAL FOR THE ASSESSMENT OF THE EFFICACY OF COSMETIC PRODUCT IN IMPROVING HAIR CONDITIONS
A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

PROTOCOL REFERENCES
Clinical Study Protocol Number:
EC_ 0000200/26
Clinical Study Protocol Version and Date of issue:
Ver. 00 of 13/03/2026
Concept Protocol:
P0000200/26 by 23/02/2026
Study Code_Order:
H.E.HU.MP.NHL00.040.02.00_IT0001994/26

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

Centro di Saggio operante in BPL | Sistema di gestione qualità certificato **ISO 9001** e **ISO 13485** | Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N. 030015309008)

GENERAL INFORMATION

SPONSOR

Name and Address:
SKIN FIRST COSMETICS S.R.L, via Lorenzo Mascheroni 14, 20145 Milano – Italia
Authorized Signatory:
Maria Pia Priore, CEO

INVESTIGATORS AND SITES

Principal Investigator:
Dr. Enza Cestone, Specialist in dermatology
Co-Investigators:
Dr. Arianna Ottone, Efficacy Clinical Trial Technician

Principal Study center:
Complife Italia S.r.l. - Via Monsignor Angelini 21, San Martino Siccomario (PV) 27028 – Italy

Other Study Centers and Associated Co-Investigators:
The number of study sites and associated co-investigators will be defined, as appropriate to ensure the proper conduct of the study, during the study start-up phase and documented in a separate document, subject to review and approval by the Sponsor, the Principal Investigator, the Project Specilist, and the Ethics Committe (see Annex 1 for the list of potential study centers).

MANAGEMENT

Responsible Person:
Dr. Anna Pelizzola, Clinical trial project specialist
Facility Name and address:
Complife Italia S.r.l.; office in Viale Indipendenza, 11 - 27100 Pavia (PV), Italy
Headquarters: Via Guido Rossa, 1 - 20024 Garbagnate Milanese (MI), Italy

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

Centro di Saggio operante in BPL | Sistema di gestione qualità certificato **ISO 9001** e **ISO 13485** | Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N. 030015309008)

PROTOCOL APPROVAL

The undersigned acknowledge having read and understood the Clinical Study Protocol **EC_ 0000200/26 Ver. 00 of 13/03/2026**. They hereby agree to its content and commit to conduct or oversee the study in full compliance with this Protocol, the Declaration of Helsinki, Good Clinical Practice (GCP), and applicable regulatory requirements.

AUTHORIZED SIGNATORY OF THE SPONSOR
Maria Pia Priore, CEO
Date and Signature:

Firmato da:
Maria Pia Priore
9E73129BD11A479...

12/3/2026 | 17:10:46 CET

PRINCIPAL INVESTIGATOR
Dr. Enza Cestone, Specialist in dermatology
Date and Signature:

DOTT.SSA ENZA CESTONE
Digitally signed by Enza Cestone
Date: 2026.03.12 18:19:11 +01'00'

RESPONSIBLE FOR STUDY MANAGEMENT
Dr. Anna Pelizzola, Clinical trial project specialist
Date and Signature:

Digitally signed by Anna Pelizzola
Date: 2026.03.12 17:32:53 +01'00'

PROTOCOL AMENDMENTS

All protocol amendments must be jointly approved and signed by the Sponsor, the Principal Investigator, and the Project Manager of the study.
Deviations during the study will be reviewed to determine whether they require a formal amendment or justify study termination.

AMENDMENTS HISTORY

Clinical Study Protocol Version and Date of issue:
00, 13/03/2026
Description:
First release

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

Centro di Saggio operante in BPL | Sistema di gestione qualità certificato **ISO 9001** e **ISO 13485** | Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N. 030015309008)

SUMMARY

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

1. PROTOCOL SUMMARY

The aim of this study is to evaluate the efficacy of a cosmetic product (scalp serum) in improving hair conditions, in particular in reducing hair shedding.
To reach this goal, a double-blind, randomized, placebo-controlled clinical study is planned to be performed on forty-four (N = 44) healthy female (60%) and male (40%) subjects, aged between 18 and 60 years old with transient acute telogen effluvium (duration less than 6 months, due to fatigue, seasonal change, deficiency of vitamins and minerals, stress, change or imbalance of normal daily routing, or emotional stress) who are enrolled under the supervision of a board-certified Dermatologist. Twenty-two (N = 22) subjects (13 female subjects and 9 male subjects), will use the active product and twenty-two (N = 22) subjects (13 female subjects and 9 male subjects) the placebo product for 3 months (84 days) according to the instruction for use. Specific assessments will be carried out before and after 2 months (56 days) and 3 months (84 days) of product use. The occurrence of adverse events will be also recorded.

2. BACKGROUND AND RATIONALE

SKIN FIRST COSMETICS S.R.L, the Sponsor of the study, is interested in investigating the efficacy of the cosmetic product in improving hair conditions, in particular in reducing hair shedding.

2.1. Introduction

2.1.1. Clinical Context and Treatment Relevance

Diffuse hair loss is one of the most common causes of non-scarring alopecia. Telogen Effluvium (TE) is a scalp disorder characterized by diffuse, non-scarring shedding. Pathophysiologically, TE is driven by an alteration in the normal follicular cycle.
The hair follicle transitions through three primary phases:

- Anagen: The growth phase.
- Catagen: The involution phase.
- Telogen: The resting phase.

Physiologically, approximately 10% of scalp hair is in the telogen phase. An increase in this percentage leads to an increase in clinical shedding. A key mechanism is "immediate anagen release," where follicles prematurely exit the anagen phase to enter telogen, resulting in visible hair loss two to three months after the trigger. Acute effluvium is defined as shedding lasting less than six months and is generally self-limiting once the trigger is addressed.

2.1.2. Triggers and Clinical Variability

Systemic and environmental factors often trigger TE. These include:

- Significant physical or emotional stress, high fever, and acute infections.
- Surgery, systemic diseases, and thyroid dysfunction.
- Nutritional deficiencies, particularly iron and ferritin.
- Specific medications (e.g., retinoids, anticoagulants, beta-blockers, antidepressants).

Furthermore, seasonal modulation affects the human hair cycle. Research indicates a peak in the telogen percentage during July. Given the ~100-day duration of the telogen phase, this manifests as increased shedding in late summer and autumn.

2.1.3. Rationale for a Targeted Therapeutic Approach

The hair follicle is a cyclic "mini-organ" regulated by interactions between the stem cell compartment, dermal papilla, extracellular matrix, and local endocrine signals. While androgenic modulation via 5α-reductase is the primary driver of androgenetic alopecia, mixed clinical presentations (TE associated with subclinical androgenetic alopecia) are common. In these cases, individual follicular susceptibility can prolong the recovery phase.

2.2. Formulation Rationale of the Skin First Serum

Skin First has developed a multi-active topical serum to intervene simultaneously across different regulatory levels of the follicular cycle. The formulation focuses on three pillars: androgenic modulation, anagen phase support, and optimization of the follicular microenvironment.

2.2.1. Actives for Androgenic Modulation

To address follicular vulnerability and reduced anagen duration, the serum includes a combined anti-DHT system:

- Procapil®: Contains Biotinyl-GHK (for anchoring and metabolism), apigenin, and oleanolic acid (for 5α-reductase modulation).
- Capixyl™: A synergy of Acetyl Tetrapeptide-3 and *Trifolium pratense* (Biochanin A) to provide androgenic modulation and extracellular matrix support.

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

- Serenoa serrulata: A botanical extract used to modulate the conversion of testosterone to DHT.

2.2.2. Support for Anagen Phase and Vitality

- Redensyl®: Formulated with DHQG, EGCG2, glycine, and zinc to support the activity of the follicular compartment and dermal papilla.
- Capilia Longa™: Derived from *Curcuma longa*, it supports follicular homeostasis and modulates pro-inflammatory mediators.
- CapilMax NG: Provides structural amino acids and metabolic support to maintain hair shaft integrity.

2.2.3. Optimization of the Scalp Microenvironment

To maintain scalp homeostasis, the formula includes:

- Niacinamide: Supports barrier function and sebum regulation.
- Caffeine: Aids follicular vitality and microcirculation.
- Panthenol: Hydrating and soothing properties.
- Seascalp™: A marine active that rebalances the scalp ecosystem and reduces itching/flaking.

2.3. State of the Art and Study Justification

Current literature often lacks robust, placebo-controlled data on multi-active formulations at high functional concentrations. Given the multifactorial nature of TE, a controlled clinical evaluation is necessary to distinguish therapeutic effects from spontaneous recovery.

Skin First has initiated a 12-week, randomized, double-blind, placebo-controlled study. The study utilizes digital phototrichogram technology to provide objective, reproducible measurements of:

- Total hair density (hair/cm²).
- Anagen/Telogen distribution and ratio.
- Hair growth rate.

The primary objective is to determine the formulation's ability to significantly modulate the anagen/telogen distribution compared to a placebo.

---

1. *Asghar F, Shamim N, Farooque U, Sheikh H, Aqeel R. Telogen Effluvium: A Review of the Literature. Cureus. 2020 May 27;12(5):e8320. doi: 10.7759/cureus.8320. PMID: 32607303; PMCID: PMC7320655.*
2. *Kunz M, Seifert B, Trüeb RM. Seasonality of hair shedding in healthy women complaining of hair loss. Dermatology. 2009;219(2):105-10. doi: 10.1159/000216832. Epub 2009 Apr 29. PMID: 19407435.*
3. *Stenn KS, Paus R. Controls of hair follicle cycling. Physiol Rev. 2001 Jan;81(1):449-494. doi: 10.1152/physrev.2001.81.1.449. PMID: 11152763.*
4. *Randall VA. Androgens and hair growth. Dermatol Ther. 2008 Sep-Oct;21(5):314-28. doi: 10.1111/j.1529-8019.2008.00214.x. PMID: 18844710.*
5. *Bikash C. Topical Alternatives for Hair Loss: Beyond the Conventional. Int J Trichology. 2025 Jan-Feb;17(1):13-19. doi: 10.4103/ijt.ijt_8_23. Epub 2025 Jun 23. PMID: 40654553; PMCID: PMC12251978.*

3. OBJECTIVES

3.1. Primary objective

The primary objective of this study is to evaluate the efficacy of the product in reducing hair shedding by phototricogram using TrichoScan in female and male subjects showing acute telogen effluvium, in particular, monitoring the efficacy of the tested product in modulating the anagen/telogen distribution compared to placebo.

Primary end-points:

- Analysis performed by Phototricogram:
  - Anagen hair density (number/cm^2)
  - Telogen hair density (number/cm^2)
  - Anagen hair (%)
  - Telogen hair (%)
  - Anagen/telogen ratio
  - Hair density (number/cm^2)

3.2. Secondary objectives

The secondary objectives of this study is to evaluate the efficacy of the product in improving hair conditions and investigate the pleasantness of the product perceived by the subjects.

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

Secondary end-points:
- Digital pictures acquisition of the hair to assess the improvement of hair density and overall conditions
- Self-evaluation questionnaire (questions with five possible answers: completely agree / agree / neither agree nor disagree / disagree / completely disagree)

4. STUDY DESIGN

The study will be double-blind, randomized, placebo-controlled: half of the subjects will be allocated to the active product and half of the subjects will be allocated to a placebo. Subjects will use the assigned product for 3 months (84 days) days according to the directions for use.

4.1. Randomization

A restricted randomization list will be generated by an independent technician using the appropriate algorithm ("Wei's urn") of the PASS 11 software (PASS, LLC. Kaysville, UT, USA) and stored in a secure location. The Principal Investigator or designated personnel will dispense the products according to the generated randomization list.

4.2. Blinding

The study will be double-blind, meaning that subjects, Principal Investigator and collaborators are kept masked to products assignment. The products will be supplied in the same packaging with no obvious differences between the products (see Annex 2).

5. INVESTIGATIONAL PRODUCTS

5.1. Composition

Active - Siero Anti Caduta con Attivi (Campione A): 260225/1

Ingredients: Aqua, Butylene Glycol, Glycerin, Pentylene Glycol, Polysorbate 20, Niacinamide, Propanediol, Pseudoalteromonas Ferment Extract, Biotinoyl Tripeptide-1, Acetyl Tetrapeptide-3, Oleanolic Acid, Apigenin, Caffeine, Salicylic Acid, Larix Europaea Wood Extract, Glycine, Serenoa Serrulata Fruit Extract, Medicago Sativa Extract, Humulus Lupulus Extract, Melilotus Officinalis Extract, Curcuma Longa Root Extract, Zingiber Officinale Root Extract, Rosmarinus Officinalis Leaf Extract, Trifolium Pratense Flower Extract, Camellia Sinensis Leaf Extract, Zinc Chloride, Panthenol, Sodium PCA, Arginine, Alanine, Serine, Valine, Proline, Threonine, Isoleucine, Histidine, Phenylalanine, Aspartic Acid, Sodium Lactate, Dextran, Parfum, PPG-26-Buteth-26, PEG-40 Hydrogenated Castor Oil, PCA, Phytic Acid, Potassium Sorbate, Sorbic Acid, Sodium Metabisulfite, Sodium Salicylate, Benzyl Alcohol, Dehydroacetic Acid, Phenoxyethanol, Ethylhexylglycerin, Tetrasodium Glutamate Diacetate.

Allergens

Benzyl Alcohol

Placebo – Siero Anti Caduta Placebo (Campione B): 260225/2

Ingredients: Aqua, Butylene Glycol, Pentylene Glycol, Glycerin, Polysorbate 20, Propanediol, Parfum, Phenoxyethanol, Ethylhexylglycerin.

Allergens

Not present

The products are complaint to the current national and international legislation (The sponsor is responsible for providing a statement to this regard).

5.2. Dosage and direction of use

Apply daily to dry or damp hair. Divide the hair into four sections and distribute one full dropper for each section directly onto the scalp. Gently massage until fully absorbed. Do not rinse.

5.3. Supply and storage

The products will be supplied by the Sponsor.

If shipped without a pallet, the delivery address is: Complife S.r.l., Via Monsignor Angelini, 21, 27028, S. Martino Siccomario (PV), Italy.

The contact person is Sabrina Martinazzo (@: segreteriapavia@complifegroup.com; T: +39 0382 25504)

Products will be stored at room temperature protected from direct light, heat and source of water safe place with restricted access OR reporting the specific conditions provided by the Sponsor.

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

Centro di Saggio operante in BPL | Sistema di gestione qualità certificato **ISO 9001** e **ISO 13485** | Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N. 030015309008)

6. STUDY POPULATION

6.1. Sample size

The study will be performed on 44 (40 + 4, considering a 10% drop-out) subjects.

6.1. Subjects' enrolment

Subjects are enrolled according to specific inclusion and exclusion criteria listed in the sections below.
All inclusion and exclusion criteria are checked by the Principal Investigator or designated personnel. The Principal Investigator maintains a record of all subjects who are enrolled and who are considered screen-failed (i.e., subject who signs the informed consent form and is not enrolled) and for each subject, the primary reason for not enrolling is recorded. Subjects enrolled are identified by a unique code that remains personal and cannot be associated to another subject during the study.

6.1.1. Inclusion criteria

1. Healthy female (60%) and male (40%) subjects
2. Subjects of Caucasian ethnicity
3. Subjects aged between 18 and 60 years (extremes included)
4. Subjects with transient acute telogen effluvium (duration less than 6 months) due to fatigue, seasonal change, deficiency of vitamins and minerals, stress, change or imbalance of normal daily routing, or emotional stress*
5. Subjects registered with the national public health system in the country where the study is conducted
6. Subjects certifying the truthfulness of the personal data disclosed to the Principal Investigator or designated personnel
7. Subjects able to understand the language used in the investigation centre and the information given by the Principal Investigator or designated personnel
8. Subjects able to respect the instructions given by the Principal Investigator or designated personnel as well as able to respect the study constraints and specific requirements
9. Subjects who commit not to change their daily routine or lifestyle during the study**
10. Subjects on stable pharmacological therapy (except for the pharmacological therapy in the non-inclusion criteria) for at least one month without any changes expected or planned during the study
11. Subjects informed about the test procedures who have signed a consent form and privacy agreement

*At the recruitment
** Subjects are asked not to change their usual hair hygiene and styling products (such as shampoo, conditioner, hair gel, hairspray, etc.) throughout the study

6.1.2. Exclusion criteria

1. Subjects who do not meet the inclusion criteria
2. Subjects with any acute, chronic, or progressive disease or condition that may interfere with the study data or that the Principal Investigator considers dangerous to the subject or incompatible with the requirements of the study***
3. Subjects participating or planning to participate in other clinical trials
4. Subjects who participated in a similar study without respecting an adequate washout period (at least one month)
5. Subjects that have intolerances or allergies to ingredients of the study product
6. Subjects under pharmacological treatments that are considered incompatible with the study requirement by the Principal Investigator ****
7. Subjects who are currently using food supplement(s) and/or products with the same activity as the study product, or who haven't observed an adequate washout period (at least one month)
8. Subjects admitted to a health or social facility
9. Subjects planning a hospitalization during the study
10. Subjects not able to be contacted in case of emergency
11. Subjects deprived of freedom by administrative or legal decision or under guardianship
12. Subjects who have or have had a history of alcohol or drug addiction
13. Subjects with eating disorders (i.e. bulimia, psychogenic eating disorders, etc.)
14. Subject breastfeeding, pregnant or not willing to take necessary precautions to avoid pregnancy during the study (for the women of childbearing potential).

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

*** Including oncological diseases, diabetes, autoimmune diseases, acute inflammatory diseases, ongoing infectious diseases, and alopecia areata.
**** Including corticosteroid drugs, biological drugs, and cytostatic drugs.

6.2. Subject withdrawal and discontinuation

In compliance with the Declaration of Helsinki, subjects have the right to withdraw from the study at any time and for any reason. In all cases, the Principal Investigator or designated personnel should try to contact the subject as soon as possible for a final assessment to: i) document the subject's decision on the informed consent form, ii) record the reason(s) for withdrawal on the data collection sheet, iii) evaluate the subject's clinical condition, if relevant iv) provide appropriate therapeutic measures if necessary (e.g., management of adverse events or concomitant conditions), v) collect any investigational product provided to the subject.
If a subject misses a scheduled visit, the Principal Investigator or designated personnel will attempt to contact the subject by phone on two separate occasions. If the subject cannot be reached after these attempts, they will be considered lost to follow-up. These contact attempts and their outcomes will be documented in the source document.
The Principal Investigator may also decide to withdraw a participant from the trial early if the subject no longer meets the eligibility criteria, fails to comply with the protocol, or is deemed unsuitable to continue the study. This may occur, for example, in the event of illness, pregnancy, or the occurrence of an Adverse Event (AE) or Serious Adverse Event (SAE), particularly if the Principal Investigator considers that the subject's health may be at risk or if concomitant treatments required are incompatible with the continuation of the trial. In such cases, the Sponsor will be notified immediately, and a detailed report explaining the reason for withdrawal will be forwarded as soon as possible. Any early termination related to an AE or SAE will be monitored until its resolution.
The sponsor has the right to exclude any subject from the trial for major protocol violations, administrative reasons, or other justifiable reasons.
However, a high dropout rate may compromise or invalidate the interpretability of the study. Therefore, premature exits without valid reasons should be minimized and carefully documented in the case report form, the final report, and, if applicable, in the AE form. Each premature exit will be categorized as follows: i) violation of inclusion and exclusion criteria, ii) occurrence of an AE, iii) occurrence of an SAE, iv) withdrawal of consent, v) lost to follow-up, vi) non-adherence to the protocol, vii) other reason (to be clearly specified).
Withdrawn/lost to follow-up/drop-out subjects will not be replaced.
Further details regarding safety reporting and management are provided in Paragraph 12.

6.3. Subject full participation

Study completion is achieved when a subject has completed all treatment and has attended all scheduled visits.

7. ETHICAL CONSIDERATIONS

7.1. Risk and benefit

The product administered in this study is in compliance with current cosmetic legislation and is composed of ingredients with a well-established history of safe use in humans.
No adverse effects are expected under the indication of use. However, as with any cosmetic product, the possibility of individual reactions cannot be completely excluded. If applicable, information regarding the presence of any substances that may cause hypersensitivity will be provided prior to participation.
The potential benefits associated with the use of the product are related to an improvement of hair conditions, in particular the reduction of hair shedding.

7.2. Compliance with the Declaration of Helsinki

The study will be conducted in accordance with the ethical principles for the medical research (Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th WMA General Assembly Helsinki, Finland, June 1964 and amendments).

7.3. Informed Consent

During the recruitment phase, the Principal Investigator or designated personnel will explain to each subject the nature, purpose, potential benefits, and possible risks of participation in the study. The investigator must ensure that the subject has understood all relevant aspects of the study. Sufficient time will be provided to allow questions to be asked and answered.

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

After this discussion, subjects will be asked to carefully read and sign the study information sheet and informed consent form, and the privacy agreement pursuant to art. 13 of EU Regulation 2016/679.
The informed consent form, approved by the Sponsor, will be prepared in two versions: a version in English and a version in the local language, written in terms readily understandable to the subject. Only the version in the local language will be presented to and signed by study participants.
The informed consent form, approved by the Sponsor, will contain all required elements in language that is readily understandable to the subject. Each original consent form, personally signed and dated by both the subject and the investigator conducting the consent discussion, will be retained by the investigator. A copy will be provided to the subject. Subjects will be informed that they have the right to withdraw their consent.
The consent form may need to be revised during the study, either because important new information has become available that may be relevant to the safety of the subjects, or because of protocol amendments. It is the investigator's responsibility to ensure that the amended form is signed by all subjects who are subsequently entered into the study, as well as by those who are already in it. This is documented in the same way as previously described.

7.4. Confidentiality and Data Protection

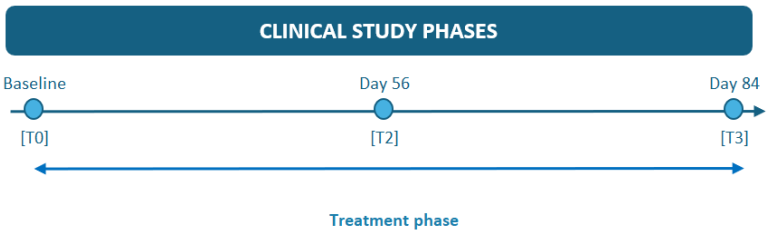
All information, data, and results of the study are strictly confidential, and all individuals with access to such data are informed of this obligation.
In accordance with the applicable law on data protection (EU Regulation 679/2016), the personal data, which may be special, including date of birth, sex, race, etc.., the information resulting from clinical studies and on health status are processed in confidence, only for research purposes in relation with this study. If the results arising from the clinical study should be published or disseminated in scientific journals or conferences, this is done in a manner that preserves confidentiality. For this purpose, relevant subject data may be forwarded to the Sponsor or its partners abroad. In each case, subject data will be pseudonymised and identified only by a code number and initials. The Principal Investigator will be responsible for maintaining the list of codes that links each subject's number with their identity.
In all cases, nominative information shall not be transmitted to the Sponsor. If a subject's name appears on a document required by the Sponsor (e.g., photographs), the name will be permanently blacked out by the site personnel, leaving only the initials visible and annotating the subject number for identification.
The data will remain strictly confidential and will not be made public. However, at any time during or after the study, health authorities may be granted direct access to the records to verify the accuracy of the collected information. In such cases, subject identity may be disclosed. All individuals granted access to these records are bound by professional secrecy.

8. STUDY SCHEDULE AND PROCEDURES

The study will last 84 ± 2 days. Clinical visits are planned at T0 (Initial visit), T2 (follow-up visit, after 56 ± 2 days of product use) and at T3 (final visit, after 84 ± 2 days of product use).

8.1 Timeline diagram

A schematic flow diagram is provided below:



8.2. Summary of study visits and procedures

The following table summarizes the planned visits and procedures:

Procedures	T0	T2	T3
Signature of informed consent and privacy statement of screened subjects	X	-	-
Verification of subject eligibility	X	X	X

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

Centro di Saggio operante in BPL | Sistema di gestione qualità certificato **ISO 9001** e **ISO 13485** | Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N. 030015309008)

Collection of subjects' demographic data and variables relevant to eligibility assessment	X	-	-
Randomization to treatment	X	-	-
Distribution of products	X	-	-
Execution of phototrichogram	X*	X*	X*
Digital photographs acquisition	X	X	X
Completion of the self-assessment questionnaire by subjects	-	-	X
Check of the adverse events	-	X	X
Monitoring of Tolerability	-	◄———	———►

*A follow-up visit is scheduled 48 hours after the visit for the assessment of phototrichogram parameters (for details see paragraph 9.1.)

8.3. Baseline visit (T0)

Subjects to be enrolled will be screened in the volunteer's database by appropriate personnel (authorized by the investigator, pursuant to and for the effects of the legislation on protection of personal data) and invited to participate in the study.

At the first visit, the Principal Investigator or designated personnel will assess whether each participant meets all inclusion and exclusion criteria and collect the subject's demographic data together with the variables relevant to eligibility assessment. Subjects will be informed of the study procedure and will be asked to sign an informed consent form and an authorization for the personal data treatment.
Procedures related to the phototrichogram will be performed.
Standardized digital photographs will be taken to evaluate changes in hair conditions in particular in hair density, at subsequent timepoints.
According to the previously defined randomization list, 22 subjects will receive the active product, and 22 subjects will receive the placebo product (enough for at least 84 days of treatment). Subjects will be advised to bring back the advanced products at end of the study.
Subjects will be instructed to use the product in accordance with the usage instructions of the assigned product for 84 consecutive days.
The Principal Investigator or designated personnel will set the date of the follow-up visit.

8.4. Follow-up visit (T2: after 56 ± 2 days)

After 56 days (± 2 days) of product use subjects will be visited by the Principal Investigator or designated personnel.
The Principal Investigator or designated personnel will assess whether each participant still meets all inclusion and exclusion criteria.
Procedures related to the phototrichogram will be performed.
Standardized digital photographs will be taken to evaluate changes in hair conditions in particular in hair density.
Recruited subjects will complete the self-assessment questionnaire.
The Principal Investigator or designated personnel will set the date of the final visit.

8.5. Final visit (T3: after 84 ± 2 days)

After 84 days (± 2 days) of product use subjects will be visited by the Principal Investigator or designated personnel.
The Principal Investigator or designated personnel will assess whether each participant still meets all inclusion and exclusion criteria.
Procedures related to the phototrichogram will be performed.
Standardized digital photographs will be taken to evaluate changes in hair conditions in particular in hair density.
Recruited subjects will complete the self-assessment questionnaire.

NOTES:

The tolerability of the product will be monitored through the reporting of adverse events throughout the entire duration of the study (see paragraph 11).

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

Centro di Saggio operante in BPL | Sistema di gestione qualità certificato **ISO 9001** e **ISO 13485** | Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N. 030015309008)

9. ENDPOINTS

9.1 Analysis performed by Phototricogram

The procedure consists of the following steps:

1. Clipping: A scalp area located approximately two finger widths away from the parting line on the parietal-occipital region is clipped using a trimmer. A template (Ø 1.8 cm) is used to standardize the area.
2. Hair removal: The clipped hair are removed with adhesive tape.
3. Imaging: A dermatoscopic photograph of the clipped area is taken 48 hours after hair clipping. The following hair cycle related parameters are measured using the TrichoScan® software:

- Anagen hair density (number/cm^2)
- Telogen hair density (number/cm^2)
- Anagen hair (%)
- Telogen hair (%)
- Anagen/telogen ratio
- Hair density (number/cm^2)

9.2. Self-assessment questionnaire

Subjects are asked to reply to a self-assessment questionnaire (11 questions) to assess the efficacy perceived and the pleasantness of the product. Responses are provided spontaneously, without external influence.
The possible answers will include multiple-choice, the five possible answers will be: completely agree / agree / neither agree nor disagree / disagree / completely disagree. (See Annex 3).

10. SUPPORT MATERIAL

10.1. Digital photographs

Digital pictures will be taken from both the front and the back. Images will be taken under standard reproducible lighting conditions. The 3 best pictures for active treatment will be sent to the Customer.

11. SAFETY ASSESSMENT

The tolerability of the product will be closely followed by the study Principal Investigator during the study. Subjects will have access to the investigator via a contact phone number provided with the study information sheet in case of intolerance reactions. If a subject reports an event, the Principal Investigator will establish whether it is product-related. If so, report it as an adverse reaction. Any unexpected side effects related to the product will be reported to the sponsor. At the investigator's discretion, the subject may be withdrawn from the study, in which case the side effect will be monitored until it is resolved.

11.1. Causality assessment

There are five levels of causality that can be used to determine whether the event is related to the product.

- Very likely

Clinical signs suggest a link with the product. The reaction follows a clear temporal sequence in relation to the time of product use and rechallenge is positive.

- Likely

Clinical signs suggest a link with the product; the reaction follows a definite reasonable temporal sequence from the time of the product use and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product use and rechallenge is positive. Or, clinical signs only partially suggest or do not suggest a link with the product, the reaction follows a definite reasonable temporal sequence from the time of the product use and rechallenge is positive.

- Not clearly attributable

Clinical signs suggest a link with the product; the reaction follows a definite reasonable temporal sequence from the time of the product use and rechallenge is negative. Or clinical signs suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product use and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a definite reasonable temporal sequence from the time of the product use and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs only partially suggest or do not

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product use and rechallenge is positive.

- Unlikely

Clinical signs suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product use and rechallenge is negative. Or clinical signs only partially suggest or do not suggest a link with the product; the time sequence between use of the product and occurrence of the symptoms is compatible; and rechallenge is negative. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product use and there hasn't been a rechallenge or results of rechallenge are ambiguous. Or clinical signs only partially suggest or do not suggest a link with the product; the reaction follows a partially reasonable or unknown temporal sequence from the time of the product use and rechallenge is negative.

- Excluded

Causality can only be excluded if another aetiology has been medically validated or if the time sequence between exposure and the occurrence of signs is incompatible. In case of adverse events, subjects can also contact the Principal Investigator or designated personnel if necessary. If required, they would be assessed by the specialist who would perform the clinical assessment and decide the appropriate measures to take (i.e. medical treatment, withdrawal …).

11.2. Recording and evaluation of adverse reactions

For each sign, intensity, location, duration (hours, minutes), and frequency are recorded. Moreover, the investigator collects all discomfort or reactions reported by the subjects. Each time a sign (physical or functional) appears (new sign or worsened compared to the baseline evaluation i.e. evaluation on the first day of the study), a reaction is recorded. All the reactions observed by the specialist and reported by the subject are recorded. The following information are recorded: i) subject characteristics, ii) details about study product (product code or name, date of first use, way of use), iii) description of the reaction (functional and physical signs, intensity of the signs, location, date/time of onset, timeframe between product use and onset of the reaction, date/time of end or duration (hours, minutes), frequency, diagnosis/nature of the reaction), iv) significant medical history , v) concomitant events: cutaneous diseases, medical treatments, products application, food, external factors (weather conditions), other diseases, vi) outcome and actions taken (way of use modification, temporary interruption, definitively discontinuation, medical treatment, care), and viii) relationship to the product (causality assessment). This assessment is done in conjunction with clinical expertise, and knowledge of the product (type of product, conditions of use…).

11.3. Documentation of Adverse Event and Serious Adverse Event

All Adverse Events considered likely to be related to the study product, as well as all Serious Adverse Events, will be documented in the data collection sheet and included in the report of the study. If no Adverse Events occur, the report will explicitly state that no side effects were observed during the study.

11.4. Notification to the Sponsor

Any adverse events occurring during the study or after the study will be reported to the Sponsor's vigilance officer by e-mail to Giulia Priore – g.priore@skinfirstcosmetics.it with a copy to the project manager, using the appropriate notification forms. Serious adverse events will be reported within 24 hours of observation, and adverse events related to the product will be reported as soon as possible. If pictures of the reactions are available, these will be included in the notification.

11.5. Follow-up procedures

Any adverse events or serious adverse events related to the product will be followed up until they are resolved or stabilised. To inform the sponsor's vigilance officer of any new information, the investigator will use the appropriate forms, which will be filled in with the results collected from the examination carried out. Reports of hospitalisation will be enclosed with the notification form.

11.6. Definitions

Adverse Event (AE): An Adverse Event is any untoward medical occurrence in a clinical investigation subject administered a test product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a test product, whether related to the test product.

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

Centro di Saggio operante in BPL | Sistema di gestione qualità certificato **ISO 9001** e **ISO 13485** | Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N. 030015309008)

Serious Adverse Event (SAE): A Serious Adverse Event is any untoward medical occurrence that: i) results in death, ii) is life-threatening, iii) requires inpatient hospitalization or prolongation of existing hospitalization, iv) results in persistent or significant disability/incapacity, or v) is a congenital anomaly/birth defect.

12. DATA HANDLING AND RECORD KEEPING

12.1. Data collection

Data will be recorded in paper and/or electronic data collection sheets. The Principal Investigator, or appropriately qualified staff authorized by the Investigator, will be responsible for completing the data collection sheets. Paper forms will be completed in blue ballpoint pen, while electronic data capture will be performed using Microsoft® Office 365.
The Principal Investigator will review the data collection sheets and all adverse event reporting forms, attesting to the accuracy and completeness of the information. Any corrections made to the data collection sheets or source documents must be performed by the responsible staff member or an authorized delegate in a manner that does not obscure the original entry. For paper forms, all corrections must be dated and initialled by study site personnel. For electronic data capture, all modifications will be automatically tracked. Where the reason for a correction is not self-evident, an explanatory note must be provided.
Data entry and quality control will be performed by two different persons. The Principal Investigator remains ultimately responsible for all recorded data.
In line with Good Clinical Practice, the following definitions apply to clarify the nature and origin of recorded information:

- Source Data: all original records and certified copies of original records of clinical findings, observations, or other activities necessary for the reconstruction and evaluation of the trial. Source data are contained within source documents (i.e., original records or certified copies).
- Source Documents: original documents, data, and records, such as subject files, data collection sheets, notes, or evaluation checklists.

12.2. Quality assurance

All study-related files (including data collection sheets, the protocol, results, the final report, and other study documents) are subject to quality assurance procedures in compliance with regulatory requirements. Investigating sites authorize inspections by Regulatory Authorities and audits or controls by the Sponsor, granting access to raw data as needed.

12.3. Archiving and Retention

An original copy of all study documentation (signed protocol, Sponsor's safety assessment letter, case report forms, raw data, administrative file including all correspondence, etc.) will be retained in the records of Complife SrL for 10 years. The archives will only be destroyed after receipt of written and signed authorization from the Sponsor. However, documents will be kept for a longer period if required by applicable regulatory requirements or by agreement with the Sponsor. The Investigator must take appropriate measures to prevent accidental or premature destruction of these documents. Archiving arrangements will be defined at site close-out. The Sponsor will inform Complife SrL in writing when the documents are no longer required to be kept.

13. STATISTIC

13.1. Study population for analysis

The analysis will be conducted on the Per Protocol population. The per-protocol (PP) population is defined as all subjects who will complete the study without any major protocol violations. Subjects will be excluded from the per-protocol population if: they miss the one or more evaluation visit; or they do not used the product properly during the study period (as reported by the subject itself).
Any drop-outs and the reason for each drop-out will be reported in the final report.

13.2. Descriptive analysis

Demographic data and baseline characteristics of the enrolled population will be summarized and reported in a Microsoft® Excel spreadsheet together with the randomization list and will be summarized using: i) mean value and/or median value; ii) standard error and/or interquartile range; iii) minimum value; iv) maximum value.
Variables will include age (years).

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

Centro di Saggio operante in BPL | Sistema di gestione qualità certificato **ISO 9001** e **ISO 13485** | Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N. 030015309008)

Endpoint variables will be recorded in a Microsoft® Excel spreadsheet, graphically represented, and analysed using: i) mean value; ii) standard error; iii) minimum value; iv) maximum value; v) individual variation or percentage variation versus baseline; vi) mean variation versus baseline.
The data on the self-evaluation questionnaire will be described with the frequency percentage of subjects that give a judgment among those proposed.

13.3. Inferential statistical analysis

To assess the efficacy of the product, inferential statistical analyses will be performed on the endpoints with the exception of the self-evaluation questionnaires.
For each endpoint, appropriate parametric or non-parametric technique will be applied to compare active and placebo product and to evaluate their effect over time.
No inferential analysis by subgroup will be provided.
The significance level (α) will be set at 0,05.
Statistical analysis will be performed using NCSS 10 data analysis (Copyright © 1983-2015, NCSS, LLC.) or RStudio (Copyright © 2009-2025 Posit Software, PBC).

14. ADMINISTRATIVE ASPECTS

14.1. Publication policy

The results of the study as well as any other data disclosed or generated in the context of the study are confidential. Any publication in relation to the study shall be subject to Sponsor's prior written approval and authorization of the Principal Investigator of the study.

14.2. Contractual and financial agreements

The Principal Investigator and the Sponsor sign a clinical study agreement prior to the start of the study, outlining overall sponsor and investigator responsibilities in relation to the study. Financial remuneration covers the cost per included subject, based on the calculated costs of performing the study assessments in accordance with the protocol, and the terms of payment are described in the contract.

14.3. Insurance

Product liability insurance may be provided by the Sponsor.

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

Centro di Saggio operante in BPL | Sistema di gestione qualità certificato **ISO 9001** e **ISO 13485** | Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N. 030015309008)

ANNEX 1- List of Potential Study Sites

Complife Italia SRL

- Piazzale Siena 11, 20146 – Milano (MI), Italy
- Via Fratelli Signorelli 159, 20024 – Garbagnate Milanese (MI), Italy
- Via Angelini 21, 27028 – S. Martino Siccomario (PV), Italy
- Corso San Maurizio, 25 – 13900 Biella (BI), Italy
- Via Mortara 171, 44121 – Ferrara (FE), Italy

Nutratech SRL
Via Francesco Todaro 20/22, 87036 - Rende (CS), Italy

Complife France SAS
LE QUADRILLE, 18 rue Jacqueline Auriol, 69008 – Lyon, France

Complife South Africa Pty LTD
Unit H 3, The Willows Office Park, c/o Simon Vermooten and farm Roads, The Willows – Pretoria, South Africa

Complife Iberia SLU
Calle del Capitán Arenas 3, Local 3, 08028 – Barcelona, Spain

Complife (Beijing) Testing Technology Co., Ltd
Beizhan North Street 17, Room 902, Xicheng District, 100089 – Beijing, China

Complife Romania SRL
Strada Orzari 92A, 021554 – București, Romania

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

ANNEX 2- Labelling

Complife SrL will affix on each product the following labels:

Figure 1. Active label

	Prodotto cosmetico	
Utilizzare in accordo con il modo d'uso Campione solo per test	**Prodotto 1** N° lotto: 260225/1 PAO: 6M **IT0001994/26** Modo d'uso: applicare quotidianamente su capelli asciutti o umidi. Dividere i capelli in quattro sezioni e distribuire una pipetta completa per ciascuna sezione direttamente sul cuoio capelluto. Massaggiare delicatamente fino a completo assorbimento. Non risciacquare.	Complife SrL SrL Via Monsignor Angelini, 21 - 27028, S. Martino Siccomario (PV), Italy
AVVERTENZE: --		

Figure 2. Placebo

	Prodotto cosmetico	
Utilizzare in accordo con il modo d'uso Campione solo per test	**Prodotto 2** N° lotto: 260225/2 PAO: 6M **IT0001994/26** Modo d'uso: applicare quotidianamente su capelli asciutti o umidi. Dividere i capelli in quattro sezioni e distribuire una pipetta completa per ciascuna sezione direttamente sul cuoio capelluto. Massaggiare delicatamente fino a completo assorbimento. Non risciacquare.	Complife SrL SrL Via Monsignor Angelini, 21 - 27028, S. Martino Siccomario (PV), Italy
AVVERTENZE: --		

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

ANNEX 3 - Self assessment questionnaire

N°	Items	Completely agree	Agree	Neither agree nor disagree	Disagree	Completely Disagree
01	I have noticed a reduction in the amount of hair I lose during washing	☐	☐	☐	☐	☐
02	Overall, I perceive a reduction in hair loss compared to the beginning of the treatment	☐	☐	☐	☐	☐
03	My hair appears stronger and less fragile	☐	☐	☐	☐	☐
04	I perceive greater resistance to hair loss	☐	☐	☐	☐	☐
05	I believe the product has promoted the growth of my hair	☐	☐	☐	☐	☐
06	My hair appears visually fuller	☐	☐	☐	☐	☐
07	My hair appears thicker and more substantial	☐	☐	☐	☐	☐
08	My hair appears more voluminous compared to the beginning of the treatment	☐	☐	☐	☐	☐
09	I have noticed the appearance of new hair (especially in thinning areas)	☐	☐	☐	☐	☐
10	I believe the product has helped counteract hair loss	☐	☐	☐	☐	☐
N°	Items	Yes	No	--	--	--
11	Was the product well tolerated on the scalp during use?	☐	☐	--	--	--

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215

Self assessment questionnaire – Italian translation

N°	Domanda	Completamente d'accordo	D'accordo	Nè in accordo nè in disaccordo	In disaccordo	Completamente in diasccordo
01	Ho notato una riduzione della quantità di capelli che perdo durante il lavaggio	☐	☐	☐	☐	☐
02	Nel complesso percepisco una diminuzione della caduta rispetto all'inizio del trattamento	☐	☐	☐	☐	☐
03	I miei capelli sembrano più resistenti e meno fragili	☐	☐	☐	☐	☐
04	Percepisco una maggiore resistenza alla caduta	☐	☐	☐	☐	☐
05	Ritengo che il prodotto abbia favorito la crescita dei miei capelli	☐	☐	☐	☐	☐
06	I miei capelli appaiono visivamente più folti	☐	☐	☐	☐	☐
07	I miei capelli appaiono più spessi e corposi	☐	☐	☐	☐	☐
08	I miei capelli appaiono più voluminosi rispetto all'inizio del trattamento	☐	☐	☐	☐	☐
09	Ho notato la comparsa di nuovi capelli (specialmente nelle aree diradate)	☐	☐	☐	☐	☐
10	Ritengo che il prodotto abbia aiutato a contrastare la caduta	☐	☐	☐	☐	☐
N°	Domanda	Sì	No	--	--	--
11	Il prodotto è stato ben tollerato sulla cute durante l'utilizzo?	☐	☐	--	--	--

COMPLIFE ITALIA S.r.l.
info@complifegroup.com | complifeitalia@legalmail.it | complifegroup.com

SEDI PRINCIPALI | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI) | + 39 02.990.25138
VIA MONSIGNOR ANGELINI 21, 27028 SAN MARTINO SICCOMARIO (PV) | + 39 0382.25504
SEDE LEGALE | VIA GUIDO ROSSA 1, 20024 GARBAGNATE MILANESE (MI)
P.I./C.F. 11093320155 | Capitale Sociale € 500.000 i.v. | C.C.I.A.A. MI 1437929 - Registro Società N. 342215