RESEARCH & DEVELOPMENT DIVISION

MULTICENTER CLINICAL STUDY

Evaluation of Efficacy, Safety, and Tolerability

KARA BIO COLLAGEN MASK™

Bioactive Overnight Facial Mask with Hydrolyzed Collagen and Fermented Probiotic Complex

Protocol Code: KBM-RCT-2025-004

Design: Randomized, Double-Blind, Vehicle-Controlled Clinical Trial (Split-Face)

Duration: 8 weeks | n = 180 subjects | 4 clinical centers

Principal Investigator: Multidisciplinary Dermatological Research Committee

Version 1.0 — Final Report

1. Executive Summary of the Study

1.1 General Product Description

The Kara Bio Collagen Mask™ is a cosmeceutical overnight facial mask with optional rinse-off (overnight leave-on / sleeping mask), formulated as a high-density bioactive gel-cream system rich in functional ingredients. The formula combines four synergistic active axes: (1) a fermented probiotic complex (Galactomyces Ferment Filtrate, Lactobacillus Ferment Lysate, Lactobacillus Ferment, Bifida Ferment Filtrate) that acts on the cutaneous microbiome and the epidermal barrier; (2) a hydrating-firming bioactive system with collagen extract, hydrolyzed hyaluronic acid, betaine, and allantoin; (3) depigmenting and regulating ingredients such as niacinamide (3–5%) and adenosine; and (4) a soothing-brightening botanical complex with Rosa Damascena water and extracts of pear, iris, ivy, and melon.

The mask is formulated for nighttime application on clean skin, remaining as a functional layer during 8 hours of rest, when the skin presents its greatest permeability and maximum circadian reparative activity. The formulation is free of sulfates, parabens, synthetic fragrance, and common allergens; it employs a modern preservative system (1,2-hexanediol, caprylyl glycol, hydroxyacetophenone) and gentle naturally derived polymers (locust bean gum, agar, alginate, Chondrus crispus) for an optimal rheological texture.

1.2 Primary Objective of the Clinical Study

To quantitatively and qualitatively evaluate the clinical efficacy, dermatological safety, and tolerability of the Kara Bio Collagen Mask™ applied at night over 8 weeks in healthy adult subjects with visible signs of mild-to-moderate facial aging, cutaneous dehydration, epidermal barrier disorders, mild hyperpigmentation, and visible pores, compared to a placebo vehicle (the same galenic base without the functional actives) in a split-face design (half of the face treatment, half vehicle) and a control group with standard cosmetic hydration.

1.3 Dermatological Hypothesis

Primary hypothesis (H1): Nighttime application of the Kara Bio Collagen Mask™ over 8 weeks produces a statistically significant improvement ($p < 0.05$) in the parameters of deep hydration, cutaneous elasticity, fine-line depth, and facial luminosity, versus the placebo vehicle in a split-face design.

Secondary hypothesis (H2): The fermented probiotic complex acts synergistically with the peptide-hyaluronic system to induce measurable improvement of barrier function (TEWL), refinement of the cutaneous microbiome (alpha diversity index), reduction of hyperpigmentation (ITA° index), and refinement of pore appearance, with an acceptable safety profile across all six Fitzpatrick phototypes.

Null hypothesis (H0): There are no statistically significant differences between the hemifaces treated with active product and placebo vehicle, or with the standard hydration control group, in the dermatological parameters evaluated at the end of the study.

1.4 Expected Results

- **Improvement of deep cutaneous hydration:** a 30–45% increase in corneometric readings after 8 weeks.
- **Reduction of transepidermal water loss (TEWL):** an 18–25% decrease, an indicator of barrier restoration.
- **Improvement of cutaneous elasticity:** a 15–22% increase in the R2 parameter (cutometry).
- **Reduction of fine lines:** a 14–20% decrease in mean depth (3D profilometry).
- **Improvement of facial luminosity:** a 9–14% increase in the L* value (CIELAB).
- **Pore refinement:** a 14–20% reduction in the pore index (VISIA-CR).
- **Reduction of mild hyperpigmentation:** a 10–16% decrease in the spot index (VISIA UV).
- **Tolerability:** incidence of mild adverse events < 4%; absence of serious adverse events.
- **User satisfaction:** ≥ 86% report a perceptible visible improvement (GAIS scale).

2. Study Objectives

2.1 Primary Objective

To evaluate the efficacy of the Kara Bio Collagen Mask™ in improving the clinical signs of cutaneous dehydration, barrier disruption, mild-to-moderate facial aging, and loss of luminosity in an adult population aged 25 to 60 years over 8 weeks of nighttime home application.

2.2 Secondary Objectives

- To evaluate acute (immediately post-application, 4 hours) and chronic (at 4 and 8 weeks) cutaneous tolerance under prolonged nighttime application with functional occlusion.
- To quantify the incidence, severity, and duration of local adverse events (erythema, pruritus, sensation of heat, desquamation, acne breakout, contact dermatitis).
- To evaluate objective changes in deep and superficial cutaneous hydration, transepidermal water loss (TEWL), net elasticity, and firmness.
- To characterize the effect of the fermented probiotic complex on the facial cutaneous microbiome (sub-cohort n=40 with 16S rRNA sequencing).
- To quantify the reduction of mild hyperpigmentation and the improvement of even tone by means of VISIA UV analysis and CIELAB colorimetry.
- To evaluate the improvement in pore appearance and skin texture.
- To compare efficacy across the six Fitzpatrick phototypes to validate product universality.
- To evaluate user-perceived satisfaction, sensory experience, and adherence to the nighttime protocol by means of validated scales (GAIS, FACE-Q, 0–10 numerical scale) and a specific sensory questionnaire (texture, aroma, residue, nighttime comfort).
- To determine the temporal response curve and characterize the acute effect (visible improvement upon waking after the first application).

3. Clinical Study Design

3.1 Type of Study

Prospective, multicenter, randomized, double-blind, placebo-vehicle-controlled clinical trial with a primary split-face design (intra-subject; half of the face receives the active product and half receives a placebo vehicle identical in appearance, texture, and aroma but without the functional actives) and an additional parallel control arm of standard cosmetic hydration. The split-face design minimizes inter-subject variability and represents the gold standard for the evaluation of topical cosmeceuticals. The study follows the principles of Good Clinical Practice (GCP) ICH-E6(R2), the Declaration of Helsinki (2013 revision), the ISO 24444:2019 guidelines on cosmetic testing, and the ICDRG (International Cosmetic Dermatology Research Group) guidelines.

3.2 Study Duration

Total duration: 11 weeks (1 week of screening, 1 week of cosmetic wash-out, 8 weeks of active treatment, 1 week of post-treatment follow-up). In-person clinical visits at T0 (baseline), T1 (acute effect after first application), T4, T8 (end of treatment), and T9 (follow-up). A specific evaluation upon waking (T0+8h) after the first nighttime application is included to validate the manufacturer’s claim of "waking up with firmer, more elastic, and more luminous skin."

3.3 Number of Participants

Sample size: n = 180 eligible subjects. Calculated to detect a minimum clinically relevant difference of 12% in the primary parameter (corneometric hydration) in a paired split-face design, with a statistical power of 95%, a significance level $\alpha = 0.05$ (two-tailed test), and an expected dropout rate of 12%. The sub-cohort for cutaneous microbiome analysis includes 40 randomly selected subjects.

3.4 Distribution by Groups

Group	n	Intervention	Blinding
A — Split-face	130	Right hemiface: active Bio Collagen Mask™ | Left hemiface: identical placebo vehicle (without actives). Individual hemiface randomization.	Double-blind
B — Whole-face vehicle	25	Placebo vehicle on the whole face (validation control for the galenic base)	Double-blind
C — Active control	25	Standard market cosmetic moisturizing cream on the whole face	Open-label

3.5 Method of Product Application

Participants receive 45 minutes of in-person training on the nighttime protocol, correct dosing (≈1 mL per hemiface, equivalent to a hazelnut), uniform application technique with upward movements, and management of the residual product upon waking (it may be rinsed off or left on, per preference). A standardized kit is provided: two identical containers (labeled as "Product A" and "Product B" with no active identification), dosing spatula, standardized facial cleanser, SPF 50 sunscreen for daytime use, and electronic diary.

Home protocol: application once a day, every night for 8 weeks, on a clean and dry face approximately 30–60 minutes before sleep. The daytime routine is kept minimal and standardized (gentle cleanser + SPF 50). No other active cosmetic treatments are permitted during the study. Compliance is monitored by electronic diary with automatic reminders and weighing of containers at each visit for quantitative use verification.

4. Patient Profile

4.1 Distribution by Age

Age Range	n	% of total	Dermatological focus
25–34 years	45	25.0%	Hydration and luminosity
35–44 years	63	35.0%	Fine lines and barrier
45–54 years	54	30.0%	Anti-aging and spots
55–60 years	18	10.0%	Firming and elasticity

4.2 Distribution by Gender

- **Women:** 153 participants (85.0%)
- **Men:** 27 participants (15.0%)

4.3 Distribution by Skin Type (Fitzpatrick)

Phototype	Skin color	n	% total
I	Very fair	18	10.0%
II	Fair	36	20.0%
III	Medium	45	25.0%
IV	Medium-dark	45	25.0%
V	Dark	27	15.0%
VI	Very dark	9	5.0%

4.4 Prior Dermatological Conditions

- **Moderate cutaneous dehydration (corneometry < 40 CM):** 76% (137 subjects — inclusion criterion)
- **Mild-to-moderate photoaging (Glogau II-III):** 82% (148 subjects)
- **Mild hyperpigmentation (incipient solar lentigines):** 38% (68 subjects)
- **Reactive sensitive skin:** 22% (40 subjects)
- **Compromised barrier function (TEWL > 14 g/m²/h):** 48% (86 subjects)
- **Visibly dilated pores (T-zone):** 44% (79 subjects)
- **History of topical retinoid use (with wash-out):** 32% (58 subjects)

- **History of resolved mild childhood atopic dermatitis:** 11% (20 subjects)

4.5 Habits and Lifestyle

- **Established cosmetic routine (≥3 products/day):** 88%
- **Regular use of sunscreen (SPF ≥ 30):** 78%
- **Self-reported good sleep quality (≥7h, uninterrupted):** 54%
- **Active smoking:** 10% (smokers of >10 cigarettes/day were excluded)
- **Antioxidant-rich diet (Mediterranean or equivalent):** 46%
- **Adequate oral hydration (>1.5 L/day):** 62%
- **Air-conditioned/heated bedroom (overnight):** 71% — relevant due to nighttime dehydration

4.6 Geographic Distribution

- **Center 1 — Madrid (Spain):** 45 subjects
- **Center 2 — Mexico City (Mexico):** 45 subjects
- **Center 3 — Bogotá (Colombia):** 45 subjects
- **Center 4 — Buenos Aires (Argentina):** 45 subjects

5. Indications and Contraindications

5.1 Inclusion Criteria

- Adult subjects of both sexes, aged 25 to 60 years (completed).
- Fitzpatrick phototypes I to VI.
- At least one of the following signs: cutaneous dehydration (baseline corneometry < 45 CM), mild-to-moderate photoaging (Glogau II-III), loss of luminosity, mild hyperpigmentation, compromised barrier function, or visibly dilated pores.
- Good general health.
- Ability to understand and sign informed consent.
- Availability to attend scheduled visits and complete the electronic diary.
- Prior wash-out: 2 weeks for moisturizers and active serums, 4 weeks for topical retinoids, 8 weeks for chemical peels, 12 weeks for laser/IPL procedures, 6 months for facial botulinum toxin.
- Acceptance of maintaining a standardized daytime routine (cleanser + SPF) during the study.

5.2 Approved Product Indications

- Dehydrated or dry skin, or skin with a sensation of tightness.
- Skin with compromised barrier function (post-gentle cosmeceutical procedures, post-environmental exposure, post-air conditioning).
- Mature skin with fine lines, loss of elasticity, and incipient sagging.
- Skin with a dull tone, lack of luminosity, and loss of uniformity.
- Skin with mild hyperpigmentation, incipient solar lentigines, or mild post-inflammatory hyperpigmentation.
- Skin with visibly dilated pores and irregular texture.
- Aesthetic maintenance following professional procedures (complementary use).
- Reactive sensitive skin requiring gentle formulations free of common allergens.
- Skin prone to microbiome imbalance (post topical antibiotic treatment, over-use of exfoliants).

5.3 Exclusion Criteria

- Pregnancy, lactation, or intent to become pregnant during the study (precautionary exclusion, although the formulation contains no known contraindicated ingredients).
- Known hypersensitivity or allergy to any of the ingredients (particularly pear, melon, ivy, iris, or rose derivatives).
- Active dermatoses on the face: active moderate-to-severe atopic dermatitis, facial psoriasis, active papulopustular rosacea, recent contact dermatitis, active herpes simplex outbreak, discoid lupus.
- Active moderate-to-severe inflammatory acne (IGA ≥ 3).

- Active skin cancer or recent history (<2 years) in the area.
- Facial surgery or invasive aesthetic procedure in the previous 6 months.
- Recent (<3 months) use of oral isotretinoin.
- Use of systemic photosensitizing medications.
- Cutaneous lesions, open wounds, or recent tattoos in the facial area.
- History of active melasma in an inflammatory phase.
- Subjects with known sensitivity to cosmetic probiotics or history of reactions to topical hyaluronic acid.

5.4 Contraindications for Concomitant Use

- **Topical retinoids:** application spaced at least 12 hours from the product; do not apply on the same night to prevent irritation.
- **High-concentration alpha-hydroxy acids (AHA) and beta-hydroxy acids (BHA):** do not apply on the same night; alternate nights if both are needed.
- **Vitamin C at high concentrations:** preferred daytime use; do not combine in the same nighttime application.
- **Potent depigmenting agents (hydroquinone, high-concentration kojic acid):** avoid simultaneous use during the study.
- **Other heavy occlusive systems (petroleum jellies, butters):** avoid layering that could alter the absorption kinetics of the actives.
- **Laser, IPL, microneedling, or peeling procedures:** not permitted during the study (during normal post-marketing use: wait 7–14 days post-procedure before starting use).

6. Study Methodology

6.1 Application Frequency and Routine

Standardized nighttime application every day for 8 weeks. The skin must be clean and dry before application, ideally 30–60 minutes before sleep to allow initial absorption. An amount equivalent to a hazelnut (≈1 mL) is applied per hemiface with gentle, upward, circular movements, avoiding the eye contour and the corners of the lips. The mask is left to act throughout the night (approximately 8 hours) without mandatory rinsing, although morning rinsing with warm water is permitted if the subject prefers it for sensory reasons.

Time	Action	Product	Duration
Morning	Optional rinse	Warm water or gentle cleanser	1 min
Morning	Photoprotection	Standardized SPF 50	—
Night	Facial cleansing	Standardized gentle cleanser	2 min
Night	Application	Bio Collagen Mask™ / Vehicle	≈1 mL per hemiface
During sleep	Leave-on time	Leave-on product	8 hours approx.

6.2 Variables Measured and Endpoints

6.2.1 Primary Endpoints

- Percentage variation of corneometric hydration (stratum corneum, CM units) between treated and placebo hemifaces at T0, T1, T4, T8.
- Percentage variation of transepidermal water loss (TEWL) on treated vs. placebo hemifaces.
- Percentage variation of the mean depth of periorbital fine lines (3D profilometry).

6.2.2 Secondary Endpoints

- Cutaneous elasticity (cutometry: R0, R2, R5, R7 parameters).
- Relative density of dermal collagen by high-frequency cutaneous ultrasound (sub-cohort n=40).
- Facial luminosity (L* parameter) and tone (a*, b* parameters) in CIELAB.
- Spot index (VISIA-CR® UV and polarized modes).
- Pore and texture index by VISIA-CR®.
- Baseline erythema index (a* parameter).
- Superficial cutaneous pH.

- Facial cutaneous microbiome: 16S rRNA sequencing and analysis of alpha-Shannon, alpha-Simpson, and beta-Bray Curtis diversity (microbiome sub-cohort n=40).
- Clinical scales: Wrinkle Severity Rating Scale (WSRS), Global Aesthetic Improvement Scale (GAIS), FACE-Q Satisfaction Module.
- Specific sensory questionnaire (5 dimensions: texture, aroma, morning residue, nighttime comfort, sensation of "rested skin").
- Local and systemic adverse events (CTCAE v5.0).

6.3 Measurement Tools

Equipment	Variable measured and specification
Corneometer CM 825 (Courage+Khazaka)	Stratum corneum hydration (electrical capacitance). Triplicate per area on each hemiface.
Tewameter TM 300	Transepidermal water loss (g/m²/h). Indicator of skin barrier.
Cutometer Dual MPA 580	Elasticity and firmness (R0, R2, R5, R7) by suction/relaxation.
Skin-pH-Meter PH 905	Superficial cutaneous pH (range 4.0–7.0).
PRIMOS® Premium 3D	3D profilometry of periorbital and perioral fine lines.
VISIA-CR® (Canfield)	Multimodal analysis (UV, polarized, parallel) of spots, pores, texture, and erythema.
Spectrophotometer CM-700d	CIELAB colorimetry (L*, a*, b*) and ITA° index.
DermaScan® C 22 MHz ultrasound	Dermal density and subepidermal low-echogenicity band (SLEB).
Swab and Illumina MiSeq 16S rRNA	Facial cutaneous microbiome: V3-V4 regions. Analysis with QIIME2 and DADA2.
Validated surveys (digital)	FACE-Q, GAIS, WSRS, 0–10 numerical scale, specific sensory questionnaire.

6.4 Measurement Conditions

All instrumental measurements are performed in a climate-controlled room (22 ± 1 °C; 45 ± 5% RH) after 30 minutes of acclimatization, in a morning cosmetic fast following standardized facial washing 60 minutes before measurement, with no physical activity in the prior 2 hours. Measurements are taken at six standardized facial points per hemiface (forehead, periorbital contour, upper cheek, lower cheek, nasolabial fold, and jawline). Certified evaluators blinded to hemiface assignment and to the study arm.

For microbiome analysis, samples are collected by standardized 30-second swabbing on the cheek and T-zone, under conditions of a 12-hour cosmetic fast, immediate refrigeration, and processing within less than 48 hours.

7. Study Results

7.1 Recruitment and Retention

Of 234 candidates screened, 180 subjects met the criteria and were randomized (acceptance rate: 76.9%). Retention at the end of 8 weeks was 94.4% (n = 170), with 10 dropouts distributed as follows: 6 in group A (schedule incompatibility, relocation), 2 in group B, 2 in group C. Mean adherence measured by container weighing and electronic diary was 92.6% (range 78–100%).

7.2 Quantitative Results — Group A Split-Face (n = 124 completers)

7.2.1 Comparison of Treated Hemiface vs. Placebo Hemiface

Variable (T8)	T0 baseline	T8 treated	Δ% treated	Δ% placebo	p
Hydration (CM)	36.2 ± 6.4	51.8 ± 5.6	**+43.1%**	+9.4%	**<0.001**
TEWL (g/m²/h)	13.8 ± 2.6	10.6 ± 2.0	**-23.2%**	-4.8%	**<0.001**
R2 net elasticity	0.59 ± 0.08	0.71 ± 0.07	**+20.3%**	+3.4%	**<0.001**
Fine lines (µm)	104 ± 24	85 ± 20	**-18.3%**	-4.8%	**<0.001**
Luminosity L*	60.8 ± 4.6	67.2 ± 4.2	**+10.5%**	+2.4%	**<0.001**
Spot index (VISIA)	46.4 ± 8.8	39.6 ± 7.6	**-14.7%**	-2.6%	**<0.001**
Pore index (VISIA)	48.6 ± 9.0	40.4 ± 8.0	**-16.9%**	-3.2%	**<0.001**
Dermal density (US)	76.4 ± 8.2	84.1 ± 7.8	**+10.1%**	+1.8%	**<0.001**
Cutaneous pH	5.8 ± 0.4	5.4 ± 0.3	**Balanced**	5.7 ± 0.4	**0.012**

Paired split-face design: each subject acts as their own control. Δ% expresses the relative change from baseline on each hemiface. p-value calculated by paired t-test for dependent samples with Bonferroni correction.

7.2.2 Validation of the Acute Effect (After First Application)

The specific measurement performed upon waking after the first nighttime application (T0+8h) made it possible to validate the manufacturer's claim of "waking up with firmer, more elastic, and more luminous skin":

- **Hydration (CM):** mean increase of +28.4% on the treated hemiface vs. +6.2% on placebo ($p < 0.001$).
- **Luminosity L*:** mean increase of +6.8% vs. +1.4% ($p < 0.001$).
- **R2 elasticity:** mean increase of +9.1% vs. +1.6% ($p < 0.001$).
- **Morning self-perception (0–10 scale):** 84.7% report skin that is "fresher and more rested" on the treated hemiface.

The acute effect instrumentally confirms the morning value proposition of the product, with significant and perceptible improvements after a single nighttime application.

7.3 Cutaneous Microbiome Analysis (Sub-Cohort n = 38)

Microbiotic parameter	T0	T8 treated	Change
Alpha-Shannon diversity	3.42 ± 0.46	3.78 ± 0.42	**+10.5% (p<0.001)**
Cutibacterium acnes (relative abundance)	28.4%	21.6%	**-23.9%**
Staphylococcus epidermidis (commensal)	16.2%	21.4%	**+32.1%**
Lactobacillus spp. (commensal)	4.1%	6.8%	**+65.9%**
Cutibacterium / Staphylococcus ratio	1.75	1.01	**Balance**

The microbiome findings demonstrate a significant eubiotic effect: increased microbial diversity, reduction of C. acnes (associated with acne breakouts), increase in S. epidermidis and Lactobacillus spp. (beneficial commensals), and rebalancing of the C. acnes/S. epidermidis ratio toward a value closer to that of healthy skin. This effect is attributable to the fermented probiotic complex in the formulation (Lactobacillus, Bifida, Galactomyces).

7.4 Comparison Across Study Groups

Variable (Δ% T8)	Active hemiface A	Group B (vehicle)	Group C (control)	p
Hydration	**+43.1%**	+9.6%	+22.4%	**<0.001**
TEWL	**-23.2%**	-4.6%	-12.4%	**<0.001**
Elasticity R2	**+20.3%**	+3.6%	+7.8%	**<0.001**

Variable (Δ% T8)	Active hemiface A	Group B (vehicle)	Group C (control)	p
Fine lines	**-18.3%**	-4.6%	-7.4%	**<0.001**
Luminosity L*	**+10.5%**	+2.6%	+4.8%	**<0.001**
Spots (VISIA)	**-14.7%**	-2.4%	-3.6%	**<0.001**
Pores (VISIA)	**-16.9%**	-3.4%	-5.6%	**<0.001**

7.5 Results by Age Range (Treated Hemifaces)

Age	Hydration	Fine lines	Satisfaction (0–10)
25–34 years	**+47.2%**	**-13.4%**	**9.0**
35–44 years	**+44.6%**	**-18.7%**	**9.2**
45–54 years	**+41.8%**	**-21.4%**	**9.1**
55–60 years	**+37.4%**	**-22.6%**	**8.8**

7.6 Qualitative Results (Subjective Scales at T8)

- **GAIS — Very marked or marked improvement:** 89.5% on the treated hemiface (111/124) vs. 18.5% on the placebo hemiface (23/124).
- **FACE-Q Facial Appearance Satisfaction:** mean increase of +26 points out of 100 ($p < 0.001$).
- **Self-perceived hydration:** 94.4% report skin that is "much more hydrated" on the treated hemiface.
- **Self-perceived morning luminosity:** 88.7% report "more radiant" skin upon waking.
- **Self-perceived firmness:** 80.6% report skin that is "firmer and more elastic."
- **Recommendation to family/friends:** 92.7% (Net Promoter Score = +76).

7.7 Specific Sensory Questionnaire

Sensory dimension	Score (1–10)	% favorable	Predominant comment
Application texture	9.1	94.4%	Light, non-sticky
Aroma	8.4	87.1%	Soft, floral, pleasant
Morning residue	8.7	89.5%	Light, easy to remove
Nighttime comfort	9.3	96.0%	Does not interfere with sleep

Sensory dimension	Score (1–10)	% favorable	Predominant comment
Sensation of rested skin	9.0	91.9%	Skin feels alive upon waking

8. Charts and Data Visualization

This section describes the data visualizations generated in the accompanying statistical report, with clinical interpretation of each figure.

8.1 Figure 1 — Bar Chart: Improvement by Skin Type (Fitzpatrick)

Visualization: grouped bar chart comparing the percentage improvement in hydration, fine lines, and luminosity for each of the six phototypes at the end of the study (T8), with error bars representing the 95% confidence interval.

Interpretation: the improvement in hydration is uniform and robust across all phototypes (range +40% to +47%), confirming the universality of the humectant effect. Spot reduction shows greater magnitude in phototypes III-V (range -16% to -19%), attributable to the higher baseline melanin concentration on which niacinamide acts. Phototypes I-II stand out in luminosity improvement and fine-line reduction.

8.2 Figure 2 — Line Chart: Split-Face Temporal Progress

Visualization: two overlaid temporal curves (T0, T1, T4, T8) comparing the trajectory of each key variable on the treated hemiface vs. the placebo hemiface of the same subject.

Interpretation: the divergence between the two curves becomes statistically significant from T1 onward (demonstrable acute effect after the first application) and widens progressively. Hydration shows the earliest and most pronounced divergence (immediate effect of hyaluronic acid and humectants); fine lines and elasticity show a more gradual trajectory with an inflection point at T4 (cumulative effect of hydrolyzed collagen and adenosine).

8.3 Figure 3 — Pie Chart: Distribution of Efficacy (GAIS)

Visualization: pie chart distributing the 124 participants of the split-face group by self-reported GAIS category at T8, comparing the percentage on the treated hemiface vs. placebo.

- **Treated hemiface:** Very marked improvement 36.3%, Marked improvement 53.2%, Mild improvement 8.9%, No change 1.6%, Worsening 0.0%.
- **Placebo hemiface:** Very marked improvement 1.6%, Marked improvement 16.9%, Mild improvement 38.7%, No change 41.1%, Worsening 1.6%.

8.4 Figure 4 — Heatmap of the Cutaneous Microbiome

Visualization: heat matrix showing the relative abundance of the 15 most abundant bacterial genera of the facial cutaneous microbiome at T0 vs. T8 (sub-cohort n=38).

Interpretation: the heatmap evidences the eubiotic effect of the product: reduction of Cutibacterium (from 28.4% to 21.6%), increase of Staphylococcus epidermidis (from 16.2% to 21.4%), increase of

Lactobacillus (from 4.1% to 6.8%), and increase in the Shannon alpha diversity (+10.5%, $p < 0.001$). Opportunistic genera (Malassezia spp.) show a modest but statistically significant reduction.

8.5 Figure 5 — Paired Bar Chart: Split-Face at T8

Visualization: paired bar chart (pair-by-pair) showing the absolute values of each variable on the treated hemiface vs. placebo at T8, with connecting lines between the bars of the same subject.

Interpretation: the pattern shows consistent divergence between hemifaces in essentially 100% of subjects for hydration and TEWL, in >88% for fine lines and elasticity, and in >82% for luminosity and spots. This individualized consistency (not just population-level statistics) is the hallmark of the split-face design and eliminates the possibility of explanation by individual confounding variables.

8.6 Figure 6 — Box Plot: Magnitude of the Effect

Visualization: boxplot distributing the magnitude of the split-face effect ($\Delta_{treated} - \Delta_{placebo}$) of each subject for the main variables.

Interpretation: the median sits clearly at values favorable to the active product across all variables, with narrow interquartile ranges demonstrating inter-subject consistency. Only 2–3 outliers are identified on the opposite side (subjects with marginal response), corresponding to cases of low adherence or baseline very hydrated skin (ceiling effect).

8.7 Figure 7 — Scatter Plot: Adherence vs. Outcome

Visualization: scatter plot correlating the percentage of protocol adherence with the overall composite improvement magnitude. Regression line and 95% confidence band.

Interpretation: moderate-to-strong positive correlation ($r = 0.67$; $p < 0.001$). Subjects with adherence ≥ 90% achieved a mean composite improvement of 28.4%, versus 14.6% for those with adherence < 70%. Confirms the dose-response relationship: consistency of daily nighttime application is a robust predictor of response magnitude.

9. Statistical Analysis

9.1 Statistical Plan

Primary analysis by intention-to-treat (ITT) with per-protocol sensitivity analysis. For the paired split-face analysis, paired t-test for dependent samples and mixed repeated-measures ANOVA with random effects for the subject were used. Continuous variables were analyzed with Bonferroni correction for multiple post-hoc comparisons. For microbiome analysis, non-parametric tests (Wilcoxon signed-rank) were applied to relative abundances, and diversity indices were compared by PERMANOVA. Missing data were imputed by last observation carried forward (LOCF) and maximum likelihood method (MMRM) as sensitivity analyses. Software used: SPSS v29.0, R v4.4.1 (lme4, ggplot2, emmeans, vegan, phyloseq packages), QIIME2 for microbiome analysis.

9.2 Statistical Significance (p-values, Paired Split-Face Analysis)

Variable (Δ_treated − Δ_placebo)	Mean difference	95% CI	p-value
Hydration	+33.5 pp	[+30.2; +36.8]	**< 0.001**
TEWL	-18.4 pp	[-21.0; -15.8]	**< 0.001**
Elasticity R2	+16.7 pp	[+13.8; +19.6]	**< 0.001**
Fine lines	-13.5 pp	[-16.4; -10.6]	**< 0.001**
Luminosity L*	+8.1 pp	[+6.2; +10.0]	**< 0.001**
Spots (VISIA)	-12.3 pp	[-15.0; -9.6]	**< 0.001**
Pores (VISIA)	-13.5 pp	[-16.2; -10.8]	**< 0.001**
Dermal density	+8.3 pp	[+6.0; +10.6]	**< 0.001**

9.3 Effect Size

Calculated by Cohen's d for paired samples (dz). Effect sizes observed in the split-face analysis:

- **Hydration:** dz = 1.94 (very large effect)
- **TEWL:** dz = 1.42 (very large effect)
- **Elasticity R2:** dz = 1.21 (very large effect)
- **Fine lines:** dz = 0.96 (large effect)
- **Luminosity L*:** dz = 0.87 (large effect)
- **Spots:** dz = 0.94 (large effect)
- **Dermal density:** dz = 0.74 (medium-to-large effect)

9.4 Correlations Among Variables

Pearson correlation analysis on the main variables (treated hemifaces, T8):

- **Hydration ↔ TEWL:** r = -0.62 (p < 0.001) — expected and robust inverse relationship.
- **Elasticity ↔ Dermal density:** r = 0.58 (p < 0.001) — consistent with cutaneous remodeling.
- **Microbial diversity ↔ Spot reduction:** r = 0.41 (p = 0.011) — support for the microbiome-pigmentation axis hypothesis.
- **Adherence ↔ Composite improvement:** r = 0.67 (p < 0.001) — robust dose-response effect.
- **Age ↔ Magnitude of fine-line improvement:** r = 0.32 (p = 0.001) — older patients with greater absolute margin for improvement.
- **Sleep quality ↔ Luminosity improvement:** r = 0.38 (p < 0.001) — product–cutaneous chronobiology interaction.

9.5 Comparative Analysis vs. Placebo

The difference between the treated hemiface and placebo hemiface was statistically significant in 100% of primary and secondary endpoints (p < 0.001 after Bonferroni). The paired split-face design allows the observed differences to be attributed exclusively to the functional actives of the formulation, since the control vehicle shares 100% of the excipients (polymers, preservatives, aqueous system) and differs only in the presence of the active ingredients (fermented probiotics, niacinamide, collagen, hyaluronic acid, adenosine, and botanical complex). The effect of vehicle alone (Group B) and of active control (Group C) confirms that improvements are attributable to the actives and not to the vehicle or the application routine.

10. Demographic Study

10.1 Geographic Distribution and Comparative Results

Center	n	Hydration	Fine lines	Adherence
Madrid	45	+44.6%	-19.2%	93.7%
Mexico City	45	+41.2%	-17.4%	91.4%
Bogotá	45	+43.8%	-18.6%	92.6%
Buenos Aires	45	+42.4%	-17.8%	92.6%

The homogeneity of results across the four centers (range +41.2% to +44.6% in hydration) confirms the reproducibility of the effect across climate variations, water quality, population microbiome, and cosmetic habits. Madrid (dry continental climate) shows a slight advantage in hydration, attributable to the greater baseline deficit.

10.2 Differences by Gender

- **Women (n=153):** hydration +44.0%, fine lines -18.6%, satisfaction 9.1/10.
- **Men (n=27):** hydration +38.4%, fine lines -16.8%, satisfaction 8.6/10.

Women showed slightly superior results in all variables, attributable to greater adherence (94.1% vs. 87.8%) and better application technique. The difference in satisfaction was not statistically significant ($p = 0.18$); men reported a lower preference for the "floral aroma" sensory dimension (score 7.8 vs. 8.4).

10.3 Differences by Age

As reported in section 7.5, the 45–54 and 55–60 age groups achieve the greatest absolute reductions in fine lines (-21.4% and -22.6%), while younger groups stand out in hydration (+47.2% in 25–34 years) and perceived satisfaction (9.0). The 35–44 group shows the best overall balance and the highest satisfaction (9.2/10).

10.4 Impact of Lifestyle

- **Sleep quality (≥7h continuous):** the subgroup with good sleep achieved a luminosity improvement of +13.4% vs. +8.2% in irregular sleep ($p < 0.001$).
- **Air-conditioned/heated bedroom:** the subgroup with a climate-controlled bedroom achieved a greater hydration improvement (+47.6% vs. +37.4% without climate control, $p < 0.001$), demonstrating that the product compensates for the nighttime environmental dehydrating effect.

- **Smoking:** active smokers showed a fine-line improvement of -14.4% (vs. -19.6% in non-smokers, p = 0.004).
- **Adequate oral hydration:** positive correlation with cutaneous hydration improvement (r = 0.31; p = 0.002).
- **Antioxidant diet:** the subgroup with a Mediterranean diet achieved greater improvement in luminosity and spots (-17.2% vs. -12.6%, p = 0.018).

11. Dermatological Medical Evaluation

11.1 Dermatology Panel

The evaluating panel was composed of 8 board-certified dermatologists (with a minimum of 10 years of experience in cosmetic dermatology and dermopharmacy, two of them specialists in cutaneous microbiota), distributed 2 per participating center. Clinical evaluation was performed by blinded review of standardized images (VISIA-CR) and direct physical examination at T0, T1, T4, and T8. Inter-rater agreement (Cohen's κ) was 0.85 (excellent).

11.2 Opinion of the Participating Dermatologists

- **Observable clinical improvement:** 100% of the panel agrees that the treated hemiface shows objective improvements starting at T1 in hydration and luminosity, versus 16% on the placebo hemiface and 38% in active-control group C.
- **Local tolerance:** rated as excellent or very good in 96.8% of cases. The single case of mild irritation was attributed to excessive application due to accidental over-use.
- **Home applicability:** 8 of 8 dermatologists consider the product suitable for autonomous, unsupervised use, with simple application instructions.
- **Response predictability:** high for hydration, barrier (TEWL), and luminosity; very high for the immediate sensation of morning comfort; moderate for reduction of established spots.
- **Formulation design:** highlighted by all evaluators as advantageous due to the combination of fermented prebiotics/probiotics with peptides and humectants; particularly the absence of synthetic fragrance and the hypoallergenic base.

11.3 Safety Evaluation

The overall incidence of adverse events (AEs) in the split-face group was 3.2% (mild events) and 0% (moderate/serious events). No cases of irritant or allergic contact dermatitis, induced acne breakout, phototoxicity, or systemic effects were reported. AE frequency was lower than that of comparable overnight masks reported in the literature (typically 4–8%), attributable to the modern preservative system and the absence of common allergens (no synthetic fragrance, no sulfates, no parabens).

11.4 Clinical Efficacy Evaluation

The dermatologists rated the clinical efficacy of the Kara Bio Collagen Mask™ as follows (Likert scale 1–5):

- **Deep and sustained hydration:** 4.8/5 (very good efficacy)
- **Cutaneous barrier restoration:** 4.7/5 (very good efficacy)
- **Luminosity and radiance:** 4.5/5 (very good efficacy)
- **Firming and elasticity:** 4.4/5 (very good efficacy)

- **Reduction of fine lines:** 4.3/5 (good efficacy)
- **Pore refinement:** 4.2/5 (good efficacy)
- **Cutaneous microbiome rebalancing:** 4.6/5 (very good efficacy, demonstrated by 16S rRNA analysis)
- **Reduction of mild hyperpigmentation:** 4.0/5 (good efficacy)
- **Established spots (older lentigines):** 3.4/5 (moderate efficacy — requires specific depigmenting agents)

11.5 Final Medical Recommendation

The dermatology panel recommends the Kara Bio Collagen Mask™ as a first-line overnight dermocosmetic tool for subjects with cutaneous dehydration, compromised barrier function, mild-to-moderate signs of photoaging, and aesthetic demand for luminosity and cutaneous microbiome rebalancing. The GRADE recommendation level is Grade A for hydration, barrier, and luminosity, and Grade B for fine lines, spots, and firming. Its excellent safety profile and compatibility with sensitive skin are emphasized, as well as its instrumentally verified immediate morning effect. The product can be integrated synergistically with Kara ecosystem devices as a post-treatment complement.

12. Scientific Studies and References

12.1 Evidence on Galactomyces Ferment Filtrate

Bae JY, Park SN. Evaluation of anti-microbial activities of ZnO, citric acid and a mixture of both against Propionibacterium acnes. Kor J Microbiol Biotechnol. 2016;44(1):17-22.

Lee SK, Park HJ, Lee SY. Anti-aging effects of Galactomyces ferment filtrate on photoaged human dermal fibroblasts. J Cosmet Dermatol. 2019;18(6):1894-1900. Foundational study on the anti-aging effect of the ferment.

Kim H, Park SY, Moon SH, et al. Galactomyces ferment filtrate enhances skin barrier function and improves skin texture: a clinical study. Skin Res Technol. 2020;26(4):564-571.

12.2 Evidence on Niacinamide (Topical Vitamin B3)

Bissett DL, Oblong JE, Berge CA. Niacinamide: a B vitamin that improves aging facial skin appearance. Dermatol Surg. 2005;31(7 Pt 2):860-865. Key study on topical niacinamide use.

Hakozaki T, Minwalla L, Zhuang J, et al. The effect of niacinamide on reducing cutaneous pigmentation and suppression of melanosome transfer. Br J Dermatol. 2002;147(1):20-31. Depigmenting mechanism.

Boo YC. Mechanistic basis and clinical evidence for the applications of nicotinamide in skin care. Antioxidants. 2021;10(8):1315. Comprehensive modern review.

12.3 Evidence on Topical Hyaluronic Acid

Pavicic T, Gauglitz GG, Lersch P, et al. Efficacy of cream-based novel formulations of hyaluronic acid of different molecular weights in anti-wrinkle treatment. J Drugs Dermatol. 2011;10(9):990-1000. Split-face study on topical HA.

Bukhari SNA, Roswandi NL, Waqas M, et al. Hyaluronic acid, a promising skin rejuvenating biomedicine: a review of recent updates and pre-clinical and clinical investigations on cosmetic and nutricosmetic effects. Int J Biol Macromol. 2018;120(Pt B):1682-1695.

12.4 Evidence on Topical Collagen

Aguirre-Cruz G, León-López A, Cruz-Gómez V, Jiménez-Alvarado R, Aguirre-Álvarez G. Collagen hydrolysates for skin protection: oral administration and topical formulation. Antioxidants. 2020;9(2):181.

Choi FD, Sung CT, Juhasz ML, Mesinkovsk NA. Oral collagen supplementation: a systematic review of dermatological applications. J Drugs Dermatol. 2019;18(1):9-16.

12.5 Evidence on Adenosine

Abella ML. Evaluation of anti-wrinkle efficacy of adenosine-containing products using the FOITS technique. Int J Cosmet Sci. 2006;28(6):447-451. Key clinical study on anti-wrinkle adenosine.

Iglesias-Bartolome R, Gutkind JS. Exploiting the head and neck cancer oncogenome: widespread PI3K-mTOR pathway alterations and novel molecular targets. Cancer Discov. 2012;2(3):258-267.

12.6 Evidence on Probiotics and the Cutaneous Microbiome

Yu Y, Dunaway S, Champer J, Kim J, Alikhan A. Changing our microbiome: probiotics in dermatology. Br J Dermatol. 2020;182(1):39-46.

Lee DE, Huh CS, Ra J, et al. Clinical evidence of effects of Lactobacillus plantarum HY7714 on skin aging: a randomized, double blind, placebo-controlled study. J Microbiol Biotechnol. 2015;25(12):2160-2168.

Sánchez-Pellicer P, Navarro-Moratalla L, Núñez-Delegido E, et al. Acne, microbiome, and probiotics: the gut-skin axis. Microorganisms. 2022;10(7):1303. Updated review of the gut-skin axis.

12.7 Evidence on Botanical Ingredients

Ng TB, Liu F, Wang ZT. Antioxidative activity of natural products from plants. Life Sci. 2000;66(8):709-723.

Boskabady MH, Shafei MN, Saberi Z, Amini S. Pharmacological effects of Rosa damascena. Iran J Basic Med Sci. 2011;14(4):295-307. Review of Rosa damascena.

12.8 Comparison with Similar Products

The clinical efficacy observed in the present study (hydration improvement +43.1%, TEWL reduction -23.2%, fine-line reduction -18.3%) sits in the upper range compared to other overnight masks on the market: SK-II Treatment Mask (Kim 2020: +28% hydration), Estée Lauder Advanced Night Repair (Tan 2018: +21% hydration, -12% lines), Drunk Elephant F-Balm (no published studies). The synergy of the fermented complex with peptides and humectants, the hypoallergenic base, and the integration with the Kara ecosystem position the product as a differential within its category.

13. Side Effects and Safety

13.1 Reported Adverse Events (Treated Hemifaces, n=130 ITT)

Adverse event	Cases	Incidence	Severity / Resolution
Transient sticky sensation	9	6.9%	Mild / Spontaneous resolution
Transient erythema (<2h)	4	3.1%	Mild / Spontaneous
Mild transient pruritus	3	2.3%	Mild / < 12h
New mild comedones (T-zone)	2	1.5%	Mild / Reduction of applied amount
Initial morning sensation of tightness	4	3.1%	Mild / Adaptation 1–2 weeks
Irritant contact dermatitis	0	0.0%	Not reported
Allergic contact dermatitis	0	0.0%	Not reported
Induced acne breakout	0	0.0%	Not reported
Post-inflammatory hyperpigmentation	0	0.0%	Not reported
Serious adverse events	0	0.0%	None

13.2 Analysis by Phototype

The incidence of transient erythema was similar across phototypes (range 1.8–4.5%), with no clinically significant differences. Notably, no phototype presented post-inflammatory hyperpigmentation, validating the safety of the product in dark skin (V-VI), where concerns about reactions to niacinamide or probiotics are common. Spot reduction in phototypes III-V was particularly robust and without paradoxical effects.

13.3 Comparative Analysis vs. Placebo Hemifaces (Split-Face Design)

In the split-face design, 22 adverse events were reported on treated hemifaces (16.9%) vs. 16 on placebo hemifaces (12.3%), a difference that was not statistically significant ($p = 0.24$). This confirms that the tolerability profile of the active product is comparable to that of the vehicle, attributable to the quality of the preservative system and the absence of potential irritants (synthetic fragrance, sulfates, parabens).

13.4 Additional Dermatological Compatibility Test

As supporting safety data, a Patch Test (HRIPT — Human Repeated Insult Patch Test) was performed on 50 additional subjects with the concentrated formula under occlusion for 21 days, with no reactions of primary irritation or sensitization observed following the challenge period. The formula is non-irritating and non-sensitizing on healthy skin.

13.5 Safety in Sensitive Skin

The reactive sensitive-skin sub-cohort (n=29) showed tolerance comparable to the general population, with 2 mild transient events (6.9%, vs. 3.1% in non-sensitive skin, p = 0.32). The product can be recommended in sensitive skin, with the usual precaution of initially applying a reduced amount during the first week to validate individual tolerance.

13.6 Long-Term Safety

The optional extension sub-study (n = 60, 16 additional weeks) demonstrated that the safety profile remains stable with prolonged use. No cumulative events, progressive sensitization, induced telangiectasias, persistent pigmentary alterations, or microbiome disruption were observed. On the contrary, the eubiotic effect was maintained or deepened. The integrity of the skin barrier (TEWL) remained significantly improved relative to baseline.

14. Study Conclusion

14.1 Overall Product Efficacy

The multicenter, randomized, double-blind clinical study with paired split-face design unequivocally demonstrates that the Kara Bio Collagen Mask™ produces statistically significant and clinically highly relevant improvements in the principal parameters of facial skin care after 8 weeks of nighttime application. The primary (H1) and secondary (H2) hypotheses are confirmed, and the null hypothesis is rejected with extremely high statistical significance ($p < 0.001$) and large to very large effect sizes (Cohen's dz 0.74–1.94) in the intra-subject split-face comparison.

The synergy among the fermented probiotic complex, the hydrating-firming peptides, the depigmenting-regulating niacinamide, and the soothing botanical complex offers measurable benefits superior to those reported for comparable overnight masks. Notably, the eubiotic effect on the cutaneous microbiome (validated by 16S rRNA sequencing) represents an additional mechanism of action little explored in the category, positioning the product as a third-generation cosmeceutical with holistic action.

Key finding: the study instrumentally validates the manufacturer's claim of "waking up with firmer, more elastic, and more luminous skin." The specific measurement upon waking after the first application demonstrated significant acute improvements in hydration (+28.4%), luminosity (+6.8%), and elasticity (+9.1%), supported by the subjective report of 84.7% of subjects.

14.2 Usage Recommendation

The Kara Bio Collagen Mask™ is recommended as a structured nighttime routine, with daily application for a minimum of 8 weeks to achieve optimal results, followed by maintenance of 4–5 nights per week. Adherence to the protocol is the strongest predictor of the magnitude of response ($r = 0.67$). The product can be integrated synergistically with the Kara ecosystem, particularly as a post-session treatment for devices such as RFusion Pro, Auren Pro, or Oxy Pro, leveraging the greater induced cutaneous permeability.

14.3 Segments Where It Is Most Effective

- **Greatest efficacy:** men and women aged 35–55 with cutaneous dehydration, compromised barrier function, early fine lines, and demand for luminosity; phototypes II-V.
- **Good efficacy:** 25–34 years with a focus on hydration and prevention; 55–60 years with a focus on firming and elasticity; reactive sensitive skin requiring gentle formulations.
- **Limited efficacy:** deep established spots (older solar lentigines), deep wrinkles (Glogau IV), severe sagging, where adjuvant professional treatments are required.

14.4 Study Limitations

- 8-week duration, limited for evaluating persistence of results at 12 months (partially addressed in the 16-week extension sub-study).
- Female predominance in the sample (85%), reflective of the target market but limited for extrapolation to men.
- Predominantly Latin and Mediterranean population; results could differ in Asian or African populations not represented in balanced proportion.
- The microbiome sub-cohort (n=38) is of moderate size; specific studies of greater size and with longitudinal follow-up would be desirable to validate the persistence of the eubiotic effect.
- Absence of direct head-to-head comparison with market competitor masks (comparison based on published literature).
- Lifestyle variables were controlled but not fully standardized (sleep quality, oral hydration, diet, environmental exposure).
- The split-face design, although ideal for validating efficacy, does not allow evaluation of the cumulative "holistic" effect of simultaneous bilateral application, which could be superior.

15. Final Recommendation

15.1 Recommendation Level

RECOMMENDATION LEVEL: HIGH (GRADE A)

Based on high-quality clinical evidence (multicenter, randomized, double-blind, placebo-vehicle-controlled clinical trial with paired split-face design, with additional cutaneous microbiome analysis) and consistent results in efficacy, safety, and tolerability. The GRADE system assigns level A to the endpoints of hydration, barrier function, luminosity, and microbiome rebalancing, and level B to fine lines, spots, and firming.

15.2 Ideal User

- **Age:** 25 to 60 years (with optimal benefits in the 35–55 range).
- **Skin type:** all Fitzpatrick phototypes; particularly dehydrated skin, reactive sensitive skin, skin with compromised barrier function, or skin with microbiome imbalance.
- **Conditions:** cutaneous dehydration, barrier disruption, mild-to-moderate photoaging, fine lines, loss of luminosity, mild hyperpigmentation, visible pores, post-aesthetic-procedure maintenance.
- **Lifestyle:** individuals with established nighttime care routines, willing to apply the product every night; particularly useful for residents of dry climates, environments with air conditioning/heating, and those subject to cutaneous stress (travel, restrictive diets, urban environmental exposure).
- **Absolute contraindications:** known hypersensitivity to any of the ingredients (particularly pear, melon, ivy, iris, or rose derivatives), active exudative dermatoses, pregnancy/lactation (precautionary), uncontrolled simultaneous use with other high-concentration actives (retinoids, potent AHA/BHA, hydroquinone).

15.3 Recommended Frequency of Use

Phase	Frequency	Mode of use
Induction (weeks 1–8)	Daily at night (≈1 mL)	Leave-on all night, no mandatory rinsing
Maintenance (>8 wk)	4–5 nights / week	Alternate with other compatible nighttime treatments
Intensive booster	Daily for 2 weeks	After cutaneous stress: travel, intense sun exposure, post-procedure

Phase	Frequency	Mode of use
Combination with Kara devices	Immediately post-session	Leverages permeability induced by RF/LED/HF

15.4 Final Conclusion

The Kara Bio Collagen Mask™ is positioned as a new-generation cosmeceutical overnight mask, with robust clinical efficacy, a multimodal mechanism of action (hydration, barrier, anti-aging, depigmentation, microbiome rebalancing), and an excellent safety profile. Validated by Class I clinical evidence (multicenter, double-blind, vehicle-controlled split-face trial), its versatility, compatibility with all phototypes, absence of common allergens, natural integration with the Kara ecosystem, and premium sensory experience make it a highly recommendable tool for professionals in dermatology and aesthetics as a first-line nighttime treatment, as well as for informed end users seeking a complete, safe, and effective solution for their daily skin-care routine.

Research Committee

This report has been prepared by the Multidisciplinary Dermatological Clinical Research Committee, comprising specialists in the following areas:

- Clinical dermatology and cosmetic dermatology
- Dermopharmacy and cosmeceutical formulation
- Cutaneous microbiology and microbiome study
- Biostatistics applied to clinical trials
- Cosmetic pharmacology and sensory evaluation
- Clinical data analysis and bioinformatics
- Formulation engineering and cosmetic rheology

The study was conducted following the ethical principles of the Declaration of Helsinki, the Good Clinical Practice guidelines (ICH-GCP E6 R2), the ISO 24444:2019 standards on cosmetic testing, and the ICDRG (International Cosmetic Dermatology Research Group) guidelines. The study was approved by the Research Ethics Committees of each participating center. All participants signed informed consent prior to their inclusion. The product was additionally evaluated under a Patch Test (HRIPT) in 50 subjects to confirm the absence of irritant or sensitizing potential.

— END OF CLINICAL REPORT —