DERMACLAIM
Test & Trust

## Project Reference

**DC.186.36.102**

## Sponsor and Test Product

**WANKA TANKA LTD**

**BRACELET TANKA T-RELAX**

## Title of Study

# HUMAN USE TEST IN 21 VOLUNTEERS AFTER TOPICAL TREATMENT FOR 8 WEEKS

**Dermaclaim Lab S.L.** ® || VAT: B16909699 || www.dermaclaim.com

Parc Científic Universitat València. C/ Catedràtic Agustín Escardino, 9. 46980 Paterna, Valencia (España)

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## 1. EXECUTIVE SUMMARY

**OBJECTIVE**: To evaluate the volunteers' perception about "Bracelet T-Relax" in 21 volunteers with frequent stress, insomnia, restless, and/or nerviness, after topical treatment for 8 weeks.

**PROCEDURE**: 22 volunteers, aged from 30 to 62 years (mean 44.5 ± 10.2) were initially recruited for a human use test with Bracelet T-Relax after topical treatment for 8 weeks (wearing 1 bracelet per month in one of the wrists). The volunteers were required to be between 30 and 65 years, with frequent stress, insomnia, restless, and/or nerviness, without using any medical treatment 15 days before and/or during the study, and a willingness to comply with instructions. All the subjects participating in the study gave their informed consent signed before the start of the treatment. The study was in compliance with the tenets of the Declaration of Helsinki. The selected volunteers were ordered according to the date of recruitment and worn the bracelet in one of the wrists for 8 weeks, according to client's needs. 21 out of the 22 volunteers completed the treatment. Before the start of the treatment, subjects attended clinical facilities to receive the samples and sign the corresponding informed consents. After 28 and 56 days of treatment, subjects attended clinical facilities and participant's subjective perception of the product efficacy was assessed with an individual questionnaire. The ordinal scale used was (1 = Poor | 2 = Fair | 3 = Good | 4 = Very good | 5 = Excellent). Satisfaction was considered for scores 3 - 5, and a remarkable percentage of acceptance was considered when average result is ≥ 80 %.

**RESULTS**: Data indicated an overall acceptance of 78.3 and 77.7, after 28 and 56 days of treatment, respectively. Specifically, significant positive evaluations (overall acceptance ≥ 80 %) were obtained for 6 out of 16 items after 4 weeks of treatment and 4 out of 16 items after 8 weeks. Regarding cutaneous compatibility and acceptability, none of the 22 volunteers initially recruited showed any acceptability problem neither manifested any adverse symptom or Serious Undesirable Effects (SUE) throughout the period of treatment or the following 5 days.

**CONCLUSION**: The **topical application with "Bracelet T-Relax" for 8 weeks in 21 volunteers shows good cutaneous compatibility and may claim "Dermatologically Tested", "Clinically Tested", and "Tolerance Tested"**. With regard to the volunteers' perception, data indicated an **overall acceptance of 78.3 and 77.7, after 28 and 56 days of treatment**, respectively.

| QUESTIONNAIRE AFTER 28 DAYS | | | | | | |
|---|---|---|---|---|---|---|
| **SENSORY EXPERIENCE** | **1** | **2** | **3** | **4** | **5** | **% Satisfaction** |
| 1. How much the application of the Bracelet is simple | 0 | 0 | 1 | 7 | 13 | **100** |
| 2. How much the appearance of the Bracelet is pleasant | 1 | 0 | 5 | 11 | 4 | **95** |
| 3. How much the feeling (texture) of the Bracelet is pleasant | 0 | 0 | 3 | 13 | 5 | **100** |
| 4. How much the odor of the Bracelet is pleasant | 3 | 1 | 7 | 9 | 1 | **81** |
| 5. How much the design of the Bracelet is attractive | 1 | 1 | 7 | 7 | 4 | **86** |
| **TREATMENT EFFECTIVENESS** | **1** | **2** | **3** | **4** | **5** | **% Satisfaction** |
| 6. How much the Bracelet improves your mood | 2 | 4 | 7 | 4 | 3 | 67 |
| 7. How much the Bracelet helps you to decrease your anxiety | 1 | 4 | 4 | 9 | 2 | 71 |
| 8. How much the Bracelet improves your daily tasks | 1 | 4 | 8 | 7 | 0 | 71 |
| 9. How much the Bracelet increase your energy | 1 | 4 | 7 | 4 | 4 | 71 |
| 10. How much the Bracelet improve your sleep quality | 1 | 3 | 4 | 11 | 1 | 76 |
| 11. How much the Bracelet increase your enjoyment | 2 | 1 | 7 | 9 | 1 | **81** |
| 12. How much the Bracelet help you overcome stress | 2 | 3 | 4 | 11 | 0 | 71 |
| 13. How much the Bracelet reduces your emotional discomfort? | 2 | 4 | 7 | 6 | 1 | 67 |
| 14. How much time needed for you to feel relief/improvements? Please rate in days | | | | | | **9,9 days** |
| **CONSUMER BEHAVIOUR** | **1** | **2** | **3** | **4** | **5** | **% Satisfaction** |
| 15. I am satisfied with the treatment | 2 | 2 | 4 | 7 | 5 | 76 |
| 16. I would use the Bracelet again | 3 | 3 | 0 | 6 | 8 | 67 |
| 17. I would recommend the treatment | 2 | 3 | 2 | 8 | 5 | 71 |
| 18. Have you ever used a similar product such as a food supplements (Y/N) | 14 | **Yes (%)** | | | **86** | **No (%)** |
| 19. I think the price of the Bracelet for 1 month should be (€) | **15,3 €** | | | | | |
| **OVERALL ACCEPTANCE** | **78,3** | | | | | |

***Table 1. Self-assessment questionnaire results after 28 days.*** *Volunteer's perception obtained for the different parameters regarding sensory experience, treatment effectiveness, and consumer behaviour, after 28 days of topical treatment with Bracelet T-Relax in 21 volunteers. The ordinal scale used was (1 = Poor | 2 = Fair | 3 = Good | 4 = Very good | 5 = Excellent). Satisfaction was considered for scores 3, 4, and 5, and a remarkable percentage of acceptance was considered when average result is ≥ 80 % (in bold).*

| QUESTIONNAIRE AFTER 56 DAYS | | | | | | |
|---|---|---|---|---|---|---|
| **SENSORY EXPERIENCE** | **1** | **2** | **3** | **4** | **5** | **% Satisfaction** |
| 1. How much the application of the Bracelet is simple | 0 | 0 | 2 | 6 | 13 | **100** |
| 2. How much the appearance of the Bracelet is pleasant | 0 | 2 | 4 | 11 | 4 | **90** |
| 3. How much the feeling (texture) of the Bracelet is pleasant | 0 | 2 | 2 | 8 | 9 | **90** |
| 4. How much the odor of the Bracelet is pleasant | 3 | 4 | 4 | 10 | 0 | 67 |
| 5. How much the design of the Bracelet is attractive | 0 | 4 | 8 | 5 | 4 | **81** |
| **TREATMENT EFFECTIVENESS** | **1** | **2** | **3** | **4** | **5** | **% Satisfaction** |
| 6. How much the Bracelet improves your mood | 2 | 4 | 5 | 6 | 4 | 71 |
| 7. How much the Bracelet helps you to decrease your anxiety | 2 | 3 | 6 | 7 | 3 | 76 |
| 8. How much the Bracelet improves your daily tasks | 4 | 1 | 12 | 2 | 2 | 76 |
| 9. How much the Bracelet increase your energy | 5 | 1 | 5 | 6 | 4 | 71 |
| 10. How much the Bracelet improve your sleep quality | 2 | 5 | 5 | 7 | 2 | 67 |
| 11. How much the Bracelet increase your enjoyment | 3 | 2 | 9 | 6 | 1 | 76 |
| 12. How much the Bracelet help you overcome stress | 3 | 3 | 8 | 5 | 2 | 71 |
| 13. How much the Bracelet reduces your emotional discomfort? | 2 | 3 | 11 | 4 | 1 | 76 |
| 14. How much time needed for you to feel relief/improvements? Please rate in days | | | | | | **10,2 days** |
| **CONSUMER BEHAVIOUR** | **1** | **2** | **3** | **4** | **5** | **% Satisfaction** |
| 15. I am satisfied with the treatment | 2 | 3 | 5 | 8 | 3 | 76 |
| 16. I would use the Bracelet again | 3 | 2 | 3 | 8 | 5 | 76 |
| 17. I would recommend the treatment | 3 | 2 | 3 | 8 | 5 | 76 |
| 18. Have you ever used a similar product such as a food supplements (Y/N) | 10 | **Yes (%)** | | | **90** | **No (%)** |
| 19. I think the price of the Bracelet for 1 month should be (€) | **14,2 €** | | | | | |
| **OVERALL ACCEPTANCE** | **77,7** | | | | | |

***Table 2. Self-assessment questionnaire results after 56 days.*** *Volunteer's perception obtained for the different parameters regarding sensory experience, treatment effectiveness, and consumer behaviour, after 56 days of topical treatment with Bracelet T-Relax in 21 volunteers. The ordinal scale used was (1 = Poor | 2 = Fair | 3 = Good | 4 = Very good | 5 = Excellent). Satisfaction was considered for scores 3, 4, and 5, and a remarkable percentage of acceptance was considered when average result is ≥ 80 % (in bold).*

## 2. IDENTIFICATION OF STUDY

**PROJECT REFERENCE**: DC.186.36.102

**SPONSOR**: Wanka Tanka Ltd

**TEST PRODUCTS**: Bracelet T-Relax

**TITLE**: Human use test in 21 volunteers after topical application for 8 weeks.

**CLINICAL PROJECT MANAGER**: Lucía Fernández Gómez, MSc

**STUDY DIRECTOR**: Alejandro Pérez Fernández, PhD

**DERMATOLOGICAL SURVEILLANCE**: Eduardo Bernía Petit, MD **License No**.: 464624840

## 3. PROVIDER AND EXPERIMENTAL CENTRE

**COMPANY**: Dermaclaim Lab S.L.

**VAT NUMBER**: B16909699

**ADDRESS**: Parc Cientific Universitat de Valencia (PCUV). Calle Agustín Escardino Benlloch, 9. 46980, Paterna (Valencia), España

**EMAIL**: dermaclaim@dermaclaim.com **PHONE**: +34 644 41 61 12

**TESTING FACILITIES**: Calle Doctor Vicente Zaragozà, 38 Bajo. 46020, Valencia (Valencia), España

**EMAIL**: clinica@dermaclaim.com **PHONE**: +34 644 03 50 20

## 4. SPONSOR

**COMPANY**: Wanka Tanka Ltd

**ID TAX**: 516061769

**ADDRESS**: Rehov Hasadna 8. 1173836 Beit Shean, Israel

**PROJECT RESPONSIBLE**: Nimrod Vardi, CEO

**EMAIL**: amnonvardi@gmail.com

## 5. TEST PRODUCT

**PRODUCT NAME**: BRACELET TANKA T-RELAX

**REFERENCE & BATCH**: Not provided

**INCI**: Not provided

**DERMACLAIM REFERENCE**: DC.0284

**GALENIC**: Not applicable

**NUMBER AND TYPE OF SAMPLES**: 54 samples

**CONTENT**: 1 Bracelet (one month)

**STORAGE CONDITIONS**: Room temperature (23 ± 1 ºC)

***Figure 1.*** *Image showing Bracelet T-Relax in its original container, used for the clinical study.*

Upon arrival at Dermaclaim Lab S.L. facilities, the test material was assigned a unique laboratory code number and registered into a daily log identifying sponsor, product name, batch number, number of units and quantity received, date of reception, status of the reception, storage conditions and reference of the project in which the sample is being analyzed.

Samples are kept for a period of 24 months, beyond submission of final report, unless otherwise specified by the sponsor.

## 6. DATES OF STUDY

**STUDY START DATE:** 07/12/2022

**DATE OF SAMPLES' RECEPTION:** 10/01/2023

**PROCEDURE'S START DATE**: 26/01/2023

**PROCEDURE'S END DATE**: 23/02/2023

**FINAL REPORT DATE**: 28/03/2023

**REPORT REVIEWED DATE**: 29/03/2023

**REPORT DELIVERY DATE**: 29/03/2023

## 7. ETHICAL RELEVANCE

This study was performed under clinical surveillance at the testing facilities. Experimental controls are the same participants whose parameters are evaluated upon product application, prior to initiate the treatment. This study has been conducted according to the general conditions of Dermaclaim Lab S.L., established for research studies involving human volunteers.

Before the beginning of the study, Dermaclaim internally assessed and approved its suitability for the product type and the methodology to be used. The study aimed at a better knowledge of the efficacy of the test product and the foreseeable risk incurred by the volunteers who took part in the study were minor, thus, there was a suitability between the aim of the study and its possible risks.

The experimental conditions adopted (type of treatment, quantity of product, frequency, duration, etc.) reproduced the normal conditions of use of the test product, and the test performed on a "small scale" reflected the application by the future consumers.

The study protocol is in accordance with the Scientific Committee on Consumer Safety (SCCS) guidance. It meets all international standards for research studies involving human subjects, Structure and Content of Clinical Study Reports from ICH Harmonised Tripartite Guideline; International Recommendations ICH Topic E6, European Parliament and Council Guideline 2001/20/CE, the Good Clinical Practices (ICH-GCP), and the World Medical Association. It has been conducted pursuant to the Declaration of Helsinki (1964), with the amendments of Tokyo (1975), Venice (1983), Hong Kong (1989), South Africa (1996), Edinburgh (2000), Seoul (2008), and Fortaleza (2013).

## 8. INTRODUCTION

Insomnia is a common sleep disorder that can be related to stress [*Anxiety and Depression Association of America, 2023*]. Insomnia is defined as persistent difficulty with sleep onset, maintenance, consolidation, or overall quality. It occurs despite adequate time allotted for sleep on a given night and a comfortable place to sleep. A sleep deficit can make you feel mentally slower and more emotional, for instance, which can exacerbate your experience of stress. And if your insomnia is stress-related, being overly tired does nothing to help solve the problems creating the stress.

People with insomnia experience excessive daytime sleepiness, fatigue, irritability, and other impairments when they are awake. The prevalence of insomnia varies from study to study. Some research shows that one-third to two-thirds of adults experience bouts of insomnia, with 10% to 15% reporting daytime impairments caused by fragmented sleep [*Bonnet and Arand, 2023*].

Elevated stress levels have also been shown to influence the structural organization of sleep, including the duration of each sleep stage [*Harvard Medical School, 2007*]. People experiencing chronic stress may experience a decrease in the amount of time spent in deep sleep, and disruptions during REM sleep.

Dealing with lasting insomnia can cause stress, which can lead to more stress-related insomnia. It's a vicious stress-insomnia cycle.

# 9. PANEL OF VOLUNTEERS

## 9.1 Number

The number of volunteers initially recruited for the study was 22. Volunteer 17 was removed from the study by the researcher due to a break in the treatment after losing the bracelet before D28. The remaining 21 volunteers attended to all the measurements and complete the treatment, and corresponding data was included in the analysis.

According to the date of recruitment, the subjects were ordinally assigned a permanent identification number within the study, from 1 to 22.

## 9.2 Inclusion criteria

The specific inclusion criteria, defined in the protocol, were as follows:

- ✓ Gender: Female/Male.
- ✓ Age: Between 30 and 65 years.
- ✓ Presenting frequent stress, insomnia, restless, and/or nerviness.
- ✓ Last participation in a clinical study, ending at least one month before the start of this experiment.
- ✓ Wash-out period of 15 days before the start of the treatment with no medical treatment related to depression.
- ✓ Individuals with overall good health status and free of relevant health problems, including neurological, dermatological, or systemic disorders that could interfere with the results, under the Clinical Project Manager and the Study Director criteria. To be assessed by the principal researcher.
- ✓ Individuals who understand the instructions of use and are willing to cooperate with the study, as stated.
- ✓ Reading, understanding, and signature of the Protection of Personal Data and Communication consent.
- ✓ Reading, understanding, and signature of the Informed Consent for the study DC.186.36.102.

### 9.3 Exclusion criteria

- Subjects with a history of any form of skin cancer, melanoma, lupus, psoriasis, connective tissue disease, diabetes, or any disease that would increase risk associated with study participation.
- Allergy or reactivity to any of the components of the test product, or a product within the same or similar category than the tested one.
- Individuals currently undergoing medical treatment that may mask or interfere with the test results, under the Clinical Project Manager and the Study Director criteria.
- Relevant treatments (surgery procedures, etc.), on the experimental area finishing less than 6 months before the start of the study.
- Females who are pregnant or lactating or have been pregnant or given birth within the six-month period immediately preceding the start of the study.
- Forecast of change of routine or relevant way of life, during the period of study.

### 9.4 Recruitment tools and panel management

Panel recruitment is accomplished through advertisements in social media (Facebook, Instagram, or LinkedIn), direct communication (WhatsApp or SMS), any other electronic media, or any combination thereof.

Panel management is conducted by using Clinic Cloud v20220215.1 premium application (DOCTORALIA INTERNET SL, B62834981).

### 9.5 Constraints of the study

The constraints imposed on the volunteers were as follows:

- Full respect of the test products conditions of use.
- No application of other products on the experimental areas during the period of study.

## 9.6 Panel features

| | |
|---|---|
| Number of subjects initially recruited \| completing the study<br>Drop-outs (N, % of total) | 22 \| 21<br>1 (4 %) |
| Age range (Mean) | 30 - 62 (44.5 ± 10.2) |
| Gender | Female: 21 \| Male: 1 |
| Ethnicity (race) | Caucasian: 19 \| Latin: 3 |
| Skin type (according to sebum levels) | Dry: 7 \| Normal: 12 \| Oily: 3 |
| Skin phototype<br>(according to Fitzpatrick) | I (pale): 1 \| II (white): 13<br>III (light brown): 5<br>IV (moderate brown): 3 |

Skin phototype is classified according to *Fitzpatrick, 1988*; whereas skin type is classified according to *Kim et al., 2006*:

| Type | U-zone (cheek, chin) | T-Zone (forehead, nose) |
|---|---|---|
| Dry | < 70 µg/cm$^2$ | < 100 µg/cm$^2$ |
| Normal | 70 – 170 µg/cm$^2$ | 100 – 210 µg/cm$^2$ |
| Oily | > 170 µg/cm$^2$ | > 210 µg/cm$^2$ |

***Table 3.*** *Classification of the objective facial skin type by reference values of sebum casual levels measured with Sebumeter SM 815 (µg/cm$^2$).*

## 9.7 Informed consents

Informed consent forms describing reasons for the study, possible adverse effects, associated risks and potential benefits, and their limits of liability were obtained from volunteers prior to initiating the study. The participants read, signed, and dated the informed consent document to indicate their authorization to proceed and acknowledge their understanding of the contents (Attachment 5).

Additionally, all the volunteers included in this study had previously read, understood, and signed the Protection of Personal Data and Communication consent.

# 10. METHODOLOGY

## 10.1 Experimental conditions of use of the test product

The experimental conditions, defined in the protocol, were the following:

- Experimental areas: Wrist / Arm.
- Guidelines of use for the test product: To wear 1 bracelet in the same wrist / arm for 8 weeks (bracelet at D28 is substituted for 1 new bracelet).
- Application at research center: Plastic bag containing the bracelet was open in the clinical facilities and placed into volunteers' wrist, in order to start the treatment.
- Application at home: 1 bracelet per month, in the same wrist / arm.

## 10.2 Verification of the panel

On the first day of attendance to the experimental center, the Clinical Project Manager verified the inclusion and exclusion criteria previously defined for this study. In case of non-compliance with any of the criteria, the volunteer was excluded prior to the start of the study.

## 10.3 Environmental conditions

Not applicable.

## 10.4 Measurement site and frequency of measurements

Not applicable.

## 10.5 Instrumental assessment of the efficacy

Not applicable.

## 10.6 Calibration of the instrumental equipment

Not applicable.

## 10.7 Subjective evaluation of the efficacy

The efficacy of the treatment was subjectively assessed by participants via an individual questionnaire, filled in after 28 and 56 days of treatment, which covered items concerning sensory experience, treatment effectiveness, and consumer behavior, previously defined with the Sponsor. Volunteers' opinion was considered since it could reflect that of the potential consumer.

All the volunteers included in the study were considered to assess the cosmetic efficacy via questionnaire. For each item, the volunteers had to express their satisfaction according to an ordinal scale. The ordinal scale used was (1 = Poor | 2 = Fair | 3 = Good | 4 = Very good | 5 = Excellent). Satisfaction was considered for scores 3-4 and a remarkable percentage of acceptance was considered when average result is ≥ 80 % (in bold).

## 10.8 Checking of the acceptability

A visual examination of the experimental area was performed by the responsible technician before and after the application of the test product.

The volunteers were requested to highlight any reaction observed and sensation of discomfort felt after the use of the test product, to the responsible technician conducting the study.

In case of reactivity or discomfort, the main sensations were described as heating, stinging, pruritus (itching), pulling, burning, or watering. The intensity of the sensations of discomfort was assessed according to an ordinal scale (slight, moderate, severe). The main visible signs that might be noted could be erythema, oedema, vesicle, bulla, papule, sab, dryness, coloration, or macula.

According to the specific information reported by the volunteer and the definitions provided by The European Cosmetic and Perfumery Association (Colipa), the reaction is classified as undesirable event, undesirable effect (UE), or serious undesirable effect (SUE) (Table 4, Attachment 15.3).

| Undesirable event | Undesirable effect (UE) | Serious undesirable effect (SUE) |
|---|---|---|
| 0 | 0 | 0 |

***Table 4. Undesirable events table****. Table showing undesirable events, undesirable effects (UE), and serious undesirable effects (SUE), taken place during the period of treatment.*

Participants showed no Serious Undesirable Effects (SUE) and declared neither discomfort nor Undesirable Effects (UE) throughout the period of treatment or the following 5 days.

## 10.9 Statistical analysis

For each item, the volunteers had to express their satisfaction according to an ordinal scale. Satisfaction was considered for scores 3 - 5 and the threshold to consider a remarkable satisfaction percentage was set at 80 % by Dermaclaim scientific staff.

## 10.10 Consumption control

Product samples assigned to volunteers were weighed before the start of the treatment and at each of the timepoints (D28 and D56) and the applied amount was calculated by subtraction (D28/D56 – D0) (Table 5, Attachment 3).

| N Vol | QUANTITY OF SAMPLES USED (g) | | |
|---|---|---|---|
| | D28 | D56 | Per day |
| MEAN | -0,025 | -0,020 | -0,001 |
| SD | 0,079 | 0,082 | 0,003 |

***Table 5. Consumption control results**. Mean average and standard deviation with regard to the quantity of sample used during the study after 4 and 8 weeks of treatment (in grams).*

## 10.11 Follow-up of volunteers during the period of treatment

In order to keep all the volunteers involved in the study, reduce the possibilities of abandonment, and assure the correct application of the corresponding treatment, Dermaclaim is in direct contact with the volunteers through the following:

- Reminder email for each appointment.
- Reminder WhatsApp before each specific appointment.
- Individual contact with each volunteer every 2 weeks.

## 10.12 Protocol deviations

The consumption control yielded negative values for some of the samples, when subtracting the weight of the plastic bag to the initial weight at D0. Similar effect was

obtained for some samples after the second month of treatment. This effect might be due to the slight variability of the weighing scale between measurements at different timepoints, due to an absence of extract release within some specific bracelets, or due to possible interferences with external fluids or particles the bracelets could have acquired (e.g. sweating, water, urban dust…).

## 11. RESULTS

The number of volunteers that assigned each possible score to the indicated item and the percentage of satisfied volunteers (also indicated as percentage of acceptance), is described in Table 6-7.

| QUESTIONNAIRE AFTER 28 DAYS | | | | | | |
|---|---|---|---|---|---|---|
| **SENSORY EXPERIENCE** | **1** | **2** | **3** | **4** | **5** | **% Satisfaction** |
| 1. How much the application of the Bracelet is simple | 0 | 0 | 1 | 7 | 13 | **100** |
| 2. How much the appearance of the Bracelet is pleasant | 1 | 0 | 5 | 11 | 4 | **95** |
| 3. How much the feeling (texture) of the Bracelet is pleasant | 0 | 0 | 3 | 13 | 5 | **100** |
| 4. How much the odor of the Bracelet is pleasant | 3 | 1 | 7 | 9 | 1 | **81** |
| 5. How much the design of the Bracelet is attractive | 1 | 1 | 7 | 7 | 4 | **86** |
| **TREATMENT EFFECTIVENESS** | **1** | **2** | **3** | **4** | **5** | **% Satisfaction** |
| 6. How much the Bracelet improves your mood | 2 | 4 | 7 | 4 | 3 | 67 |
| 7. How much the Bracelet helps you to decrease your anxiety | 1 | 4 | 4 | 9 | 2 | 71 |
| 8. How much the Bracelet improves your daily tasks | 1 | 4 | 8 | 7 | 0 | 71 |
| 9. How much the Bracelet increase your energy | 1 | 4 | 7 | 4 | 4 | 71 |
| 10. How much the Bracelet improve your sleep quality | 1 | 3 | 4 | 11 | 1 | 76 |
| 11. How much the Bracelet increase your enjoyment | 2 | 1 | 7 | 9 | 1 | **81** |
| 12. How much the Bracelet help you overcome stress | 2 | 3 | 4 | 11 | 0 | 71 |
| 13. How much the Bracelet reduces your emotional discomfort? | 2 | 4 | 7 | 6 | 1 | 67 |
| 14. How much time needed for you to feel relief/improvements? Please rate in days | | | | | | **9,9 days** |
| **CONSUMER BEHAVIOUR** | **1** | **2** | **3** | **4** | **5** | **% Satisfaction** |
| 15. I am satisfied with the treatment | 2 | 2 | 4 | 7 | 5 | 76 |
| 16. I would use the Bracelet again | 3 | 3 | 0 | 6 | 8 | 67 |
| 17. I would recommend the treatment | 2 | 3 | 2 | 8 | 5 | 71 |
| 18. Have you ever used a similar product such as a food supplements (Y/N) | 14 | **Yes (%)** | | | **86** | **No (%)** |
| 19. I think the price of the Bracelet for 1 month should be (€) | **15,3 €** | | | | | |
| **OVERALL ACCEPTANCE** | **78,3** | | | | | |

***Table 6. Self-assessment questionnaire results after 28 days.*** *Volunteer's perception obtained for the different parameters regarding sensory experience, treatment effectiveness, and consumer behaviour, after 28 days of topical treatment with Bracelet T-Relax in 21 volunteers. The ordinal scale used was (1 = Poor | 2 = Fair | 3 = Good | 4 = Very good | 5 = Excellent). Satisfaction was considered for scores 3, 4, and 5, and a remarkable percentage of acceptance was considered when average result is ≥ 80 % (in bold).*

| QUESTIONNAIRE AFTER 56 DAYS | | | | | | |
|---|---|---|---|---|---|---|
| **SENSORY EXPERIENCE** | **1** | **2** | **3** | **4** | **5** | **% Satisfaction** |
| 1. How much the application of the Bracelet is simple | 0 | 0 | 2 | 6 | 13 | **100** |
| 2. How much the appearance of the Bracelet is pleasant | 0 | 2 | 4 | 11 | 4 | **90** |
| 3. How much the feeling (texture) of the Bracelet is pleasant | 0 | 2 | 2 | 8 | 9 | **90** |
| 4. How much the odor of the Bracelet is pleasant | 3 | 4 | 4 | 10 | 0 | 67 |
| 5. How much the design of the Bracelet is attractive | 0 | 4 | 8 | 5 | 4 | **81** |
| **TREATMENT EFFECTIVENESS** | **1** | **2** | **3** | **4** | **5** | **% Satisfaction** |
| 6. How much the Bracelet improves your mood | 2 | 4 | 5 | 6 | 4 | 71 |
| 7. How much the Bracelet helps you to decrease your anxiety | 2 | 3 | 6 | 7 | 3 | 76 |
| 8. How much the Bracelet improves your daily tasks | 4 | 1 | 12 | 2 | 2 | 76 |
| 9. How much the Bracelet increase your energy | 5 | 1 | 5 | 6 | 4 | 71 |
| 10. How much the Bracelet improve your sleep quality | 2 | 5 | 5 | 7 | 2 | 67 |
| 11. How much the Bracelet increase your enjoyment | 3 | 2 | 9 | 6 | 1 | 76 |
| 12. How much the Bracelet help you overcome stress | 3 | 3 | 8 | 5 | 2 | 71 |
| 13. How much the Bracelet reduces your emotional discomfort? | 2 | 3 | 11 | 4 | 1 | 76 |
| 14. How much time needed for you to feel relief/improvements? Please rate in days | | | | | | **10,2 days** |
| **CONSUMER BEHAVIOUR** | **1** | **2** | **3** | **4** | **5** | **% Satisfaction** |
| 15. I am satisfied with the treatment | 2 | 3 | 5 | 8 | 3 | 76 |
| 16. I would use the Bracelet again | 3 | 2 | 3 | 8 | 5 | 76 |
| 17. I would recommend the treatment | 3 | 2 | 3 | 8 | 5 | 76 |
| 18. Have you ever used a similar product such as a food supplements (Y/N) | 10 | **Yes (%)** | | | **90** | **No (%)** |
| 19. I think the price of the Bracelet for 1 month should be (€) | **14,2 €** | | | | | |
| **OVERALL ACCEPTANCE** | **77,7** | | | | | |

***Table 7. Self-assessment questionnaire results after 56 days.*** *Volunteer's perception obtained for the different parameters regarding sensory experience, treatment effectiveness, and consumer behaviour, after 56 days of topical treatment with Bracelet T-Relax in 21 volunteers. The ordinal scale used was (1 = Poor | 2 = Fair | 3 = Good | 4 = Very good | 5 = Excellent). Satisfaction was considered for scores 3, 4, and 5, and a remarkable percentage of acceptance was considered when average result is ≥ 80 % (in bold).*

Data indicated an overall acceptance of 78.3 and 77.7, after 28 and 56 days of treatment, respectively.

Specifically, significant positive evaluations (overall acceptance ≥ 80 %) were obtained for 6 out of 16 items after 4 weeks:

- How much the application of the Bracelet is simple.
- How much the appearance of the Bracelet is pleasant.
- How much the feeling (texture) of the Bracelet is pleasant.
- How much the odor of the Bracelet is pleasant.
- How much the design of the Bracelet is attractive.
- How much the Bracelet increase your enjoyment.

Significant positive evaluations (overall acceptance ≥ 80 %) were obtained for 4 out of 16 items after 8 weeks:

- How much the application of the Bracelet is simple.
- How much the appearance of the Bracelet is pleasant.
- How much the feeling (texture) of the Bracelet is pleasant.
- How much the design of the Bracelet is attractive.

## 12. CONCLUSION AND SIGNATURES

The goal of this study was to evaluate the volunteers' perception about "Bracelet T-Relax" in 21 volunteers with frequent stress, insomnia, restless, and/or nerviness, after topical treatment for 8 weeks.

To achieve this goal, 22 volunteers, aged from 30 to 62 years (mean 44.5 ± 10.2) were initially recruited for a human use test with Bracelet T-Relax after topical treatment for 8 weeks (wearing 1 bracelet per month in one of the wrists). The volunteers were required to be between 30 and 65 years, with frequent stress, insomnia, restless, and nerviness, without using any medical treatment 15 days before and/or during the study, and a willingness to comply with instructions. All the subjects participating in the study gave their informed consent signed before the start of the treatment. The study was in compliance with the tenets of the Declaration of Helsinki. The selected volunteers were ordered according to the date of recruitment and worn the bracelet in one of the wrists for 8 weeks, according to client's needs. 21 out of the 22 volunteers completed the treatment. Before the start of the treatment, subjects attended clinical facilities to receive the samples and sign the corresponding informed consents. After 28 and 56 days of treatment, subjects attended clinical facilities and participant's subjective perception of the product efficacy was assessed with an individual questionnaire. The ordinal scale used was (1 = Poor | 2 = Fair | 3 = Good | 4 = Very good | 5 = Excellent). Satisfaction was considered for scores 3 - 5, and a remarkable percentage of acceptance was considered when average result is ≥ 80 %.

Results indicated an overall acceptance of 78.3 and 77.7, after 28 and 56 days of treatment, respectively. Specifically, significant positive evaluations (overall acceptance ≥ 80 %) were obtained for 6 out of 16 items after 4 weeks of treatment and 4 out of 16 items after 8 weeks. Regarding cutaneous compatibility and acceptability, none of the 22 volunteers initially recruited showed any acceptability problem neither manifested any adverse symptom or Serious Undesirable Effects (SUE) throughout the period of treatment or the following 5 days.

**In conclusion**, the **topical application with "Bracelet T-Relax" for 8 weeks in 21 volunteers shows good cutaneous compatibility and may claim "Dermatologically Tested", "Clinically Tested", and "Tolerance Tested"**. With regard to the volunteers' perception, data indicated an **overall acceptance of 78.3 and 77.7, after 28 and 56 days of treatment**, respectively.

**Clinical Project Manager**

**Lucía Fernández Gómez, MSc** **Date:** 28/03/2023

… declares the study was conducted in accordance with the spirit of the Good Clinical Practices (International Recommendations ICH topic E6), and the results reported in this final report accurately and completely reflect the raw data of the study.

**Study Director**

**Alejandro Pérez Fernández, PhD** **Date:** 29/03/2023

… declares the study was carried out under my responsibility, the content of the study report is reliable and takes into account the "Guidelines for the evaluation of the efficacy of cosmetics products" (May, 2008) from Colipa. The test product may claim Clinically Tested.

**Dermatologist**

**Eduardo Bernía Petit, MD. College Number 464624840** **Date:** 29/03/2023

… declares the clinical protocol was designed and conducted under my surveillance, in accordance with the Scientific Committee on Consumer Safety (SCSS) guidance. The test product may claim Dermatologically Tested and Tolerance Tested.

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## 13. ARCHIVING AND DISCLOSURE

All original raw data, including data sheets, clinical protocols, technical procedures, laboratory notebooks, correspondence files, copies of final reports, and remaining samples, are maintained on the premises of Dermaclaim Lab S.L., in limited access marked storage files. Altogether, including the information provided by the sponsor, volunteers' data, information about materials, reagents or methodology, and all the information generated by Dermaclaim Lab S.L. (statistical analysis, graphical representations, etc.) is considered Confidential, and will not be shared with third parties.

To prevent loss of and protect intellectual property, the final report has been electronically signed using the official signature of Dermaclaim Lab S.L. (VAT: B16909699). Any attempt to remove the signature will irreversibly damage the label and leave an immediate trace, thus invalidating the document.

Only reports containing the Dermaclaim Lab S.L. electronic signature intact, will be recognized by Dermaclaim Lab S.L. as a certified original.

Dermaclaim Lab S.L. represents filly independent testing facilities committed to the highest standards of unbiased testing and reporting. Dermaclaim Lab S.L. is not in partnership, affiliation and/or association, in any way, with any other corporation, company, sole proprietorship, partnership, client, laboratory, and/or any other business entity. Dermaclaim Lab S.L. is not legally responsible or bound to any claim(s) provided by a third party claiming any kind of association with Dermaclaim Lab S.L.

The industrial and intellectual property rights that may arise from the contracted services, as well as the ownership of the results, belongs entirely to the Sponsor, unless expressly stated otherwise in the corresponding budget.

# 14. CERTIFICATIONS AND REGULATIONS

The study protocol is in accordance with the Scientific Committee on Consumer Safety (SCCS) guidance. It meets all international standards for research studies involving human subjects, Structure and Content of Clinical Study Reports from ICH Harmonised Tripartite Guideline; International Recommendations ICH Topic E6, European Parliament and Council Guideline 2001/20/CE, the Good Clinical Practices (ICH-GCP), and the World Medical Association. It has been conducted pursuant to the Declaration of Helsinki (1964), with the amendments of Tokyo (1975), Venice (1983), Hong Kong (1989), South Africa (1996), Edinburgh (2000), Seoul (2008), and Fortaleza (2013).

The whole process involving this assay was performed following UNE-EN-ISO 9001/2015 Quality Management System guidelines, certified on August 5th, 2022 (reference code, EC-10984/22).

The studies follow the "Guidelines for the Evaluation of the Efficacy of cosmetic Products", COLIPA, May 2008.

## 14.1 GENERAL PRINCIPLES FOR ALL TESTS (Rev. Efficacy Evaluation Guidelines – May 2008, COLIPA)

Studies must be relevant and comprised of methods which are reliable and reproducible. The studies should follow a well-designed and scientifically valid methodology according to good practices. The criteria used for evaluation of product performances should be defined with accuracy and chosen in compliance with the aim of the test.

Studies conducted on volunteers should naturally respect ethical rules and products tested should have previously undergone a safety investigation. Human studies should be conducted on the target population, when necessary, defined by strict inclusion / exclusion criteria.

Depending on the aim of the study, tests can be open, single- or double-blind.

A study protocol must be drawn up and validated by the parties involved. This is essential to enable the study manager / promoter to monitor the study and the experimenter to carry out the test in order to ensure its quality.

The test laboratories must have standardized operating procedures. The equipment must be the subject of documented maintenance adapted to its use. Whatever the type of study, it is important that the person conducting the study:

- has the appropriate qualifications.

- has the training and experience in the field of the proposed study; and

- is respected for ethical quality and professional integrity.

A study monitoring system must be set up in order to ensure that the protocol and the operating procedures are correctly followed.

Data processing and the interpretation of results must be fair and should not overstep the limits of the test's significance. Data recording, transformations, and representation in tabular or graphical form should be transparent or clearly explained if complex. It should not be designed to overstate the effect(s) measured. Appropriate statistical analysis of the data should be performed.

A critical point for the validity of consumer tests is the wording of the questionnaire. The questions and proposed answers should be clear enough to be unequivocally understood by participants. The answers scale should be well balanced (e.g., same number of positive and negative answers) and not capable of influencing the answer. Special attention should be paid to the wording of questions for which responses will be used to substantiate the claim: the claim should be directly substantiated by the results related to the relevant question without any questionable interpretation.

### 14.2 SUBSTANTIATION OF CLAIMS (EU Regulation 655/2013)

Cosmetic claims must comply with EU Regulation 655/2013 that provides the Common Criteria to ensure that the information conveyed to the end-users through claims is useful, understandable, and reliable so that consumers can make informed decisions.

Claims for cosmetic products, whether explicit or implicit, shall be supported by adequate and verifiable evidence regardless of the types of evidential support used to substantiate them, including where appropriate expert assessments. Evidence for claim substantiation shall consider the state-of-the-art practices.

Products may bear claims that relate to the nature of experimental studies. Consumer expectations regarding these claims may vary depending upon the presentation of the claim and its specific context. However, in all circumstances, consumers will expect that such claims are made only when the effects tested are favorable.

Use test claims such as tolerance tested, under medical surveillance, clinically tested, dermatologically tested, etc… should be substantiated, according to the following explanation:

| TOLERANCE TESTED | CLINICALLY TESTED | DERMATOLOGICALLY TESTED |
|---|---|---|
| The product underwent tests under the supervision of a scientifically qualified professional intended to study its tolerance on a target group and that the results of those tests show that the product was well tolerated by this group. | The product was tested on humans under the supervision of a medically qualified professional or another scientifically qualified professional according to a clinical protocol or in a clinical setting. | The product was tested on humans under the supervision of a dermatologist. Depending on the presentation of the claim, it may refer to a specific efficacy or tolerance of the product. Consumer self-perceptions studies are not appropriate to support such claims. |

### 14.3 CLASSIFICATION OF ADVERSE REACTIONS (Colipa, March 2016)

An **undesirable or adverse event** is defined as any human adverse health event which is voluntarily reported by consumers, healthcare professionals, Competent Authorities, and any other individuals to have occurred during or after normal or reasonably foreseeable use (exclude misuse and abuse) of a cosmetic product. It is not necessarily related to the product.

**Undesirable effect (UE)** means an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product. Undesirable Effects include but are not limited to irritant or allergic reactions that can affect the skin, eyes or mouth. Undesirable effects caused by product misuse and abuse are not included in this definition.

A **serious undesirable effect (SUE)** means an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalization, congenital anomalies or an immediate vital risk or death.

## 15. REFERENCES

Anxiety and Depression Association of America. (n.d.). Sleep Disorders.

Bonnet, M., & Arand, D. (2022, April 15). Risk factors, comorbidities, and consequences of insomnia in adults. In R. Benca (Ed.).

Division of Sleep Medicine at Harvard Medical School. (2007, December 18). Natural Patterns of Sleep.

# 16. ATTACHMENTS

## 16.1 Attachment 1. Volunteers' data

| VOLUNTEERS'S DATA | | | | | | | |
|---|---|---|---|---|---|---|---|
| Nº Volunteer | ID Volunteer | Gender | Age | Ethnicity | Skin Type | Skin Phototype | Wrist Side |
| 1 | 122 | Female | 31 | Caucasian | Combination | II (white) | R |
| 2 | 1944 | Female | 32 | Caucasian | Oily | II (white) | R |
| 3 | 1728 | Female | 34 | Caucasian | Dry | I (pale/white) | L |
| 4 | 824 | Female | 55 | Caucasian | Combination | II (white) | R |
| 5 | 343 | Female | 31 | Caucasian | Oily | II (white) | R |
| 6 | 732 | Female | 37 | Latin | Combination | III (light brown) | R |
| 7 | 1727 | Male | 30 | Caucasian | Oily | III (light brown) | L |
| 8 | 1547 | Female | 53 | Caucasian | Dry | II (white) | R |
| 9 | 350 | Female | 46 | Caucasian | Combination | III (light brown) | R |
| 10 | 1620 | Female | 51 | Caucasian | Dry | II (white) | L |
| 11 | 342 | Female | 48 | Caucasian | Dry | II (white) | L |
| 12 | 988 | Female | 62 | Caucasian | Dry | II (white) | R |
| 13 | 1807 | Female | 50 | Caucasian | Dry | II (white) | R |
| 14 | 1710 | Female | 48 | Caucasian | Combination | IV (moderate brown) | L |
| 15 | 986 | Female | 38 | Latin | Combination | IV (moderate brown) | L |
| 16 | 1877 | Female | 56 | Caucasian | Combination | III (light brown) | L |
| 17 | 1956 | Female | 51 | Caucasian | Combination | II (white) | R |
| 18 | 1936 | Female | 51 | Caucasian | Combination | II (white) | L |
| 19 | 718 | Female | 36 | Caucasian | Combination | II (white) | L |
| 20 | 1568 | Female | 40 | Caucasian | Combination | II (white) | L |
| 21_extra | 588 | Female | 38 | Latin | Combination | IV (moderate brown) | R |
| 22_extra | 1948 | Female | 62 | Caucasian | Dry | III (light brown) | L |

***Table 8**. Panel data. Data (Number of volunteers within the study, Dermaclaim's ID for each volunteer, age, gender, skin ethnicity, skin type, sensitive skin, skin phototype, and wrist wearing the bracelets during the treatment) of the volunteers included in the study.*

## 16.2 Attachment 2. Daily visit registration

| DAILY REGISTRATION | | | |
|---|---|---|---|
| **Nº Volunteer** | **Day 0** | **D28** | **D56** |
| **1** | 26/01/2023 8:00 | 23/02/2023 13:00 | 23/03/2023 8:00 |
| **2** | 26/01/2023 9:10 | 23/02/2023 9:00 | 23/03/2023 9:00 |
| **3** | 26/01/2023 15:15 | 23/02/2023 15:15 | 23/03/2023 15:15 |
| **4** | 26/01/2023 9:15 | 23/02/2023 9:00 | 23/03/2023 9:30 |
| **5** | 26/01/2023 13:45 | 23/02/2023 13:45 | 23/03/2023 13:45 |
| **6** | 26/01/2023 15:30 | 23/02/2023 15:40 | 23/03/2023 15:40 |
| **7** | 26/01/2022 8:00 | 23/02/2023 8:00 | 23/03/2023 8:00 |
| **8** | 26/01/2023 8:00 | 23/02/2023 8:15 | 23/03/2023 8:30 |
| **9** | 25/01/2023 11:15 | 22/02/2023 12:45 | 22/03/2023 12:45 |
| **10** | 26/01/2023 10:00 | 23/02/2023 10:00 | 23/03/2023 8:30 |
| **11** | 26/01/2023 13:40 | 23/02/2023 13:45 | 23/03/2023 13:45 |
| **12** | 26/01/2023 15:00 | 23/02/2023 15:00 | 22/03/2023 15:00 |
| **13** | 26/01/2023 15:30 | 23/02/2023 15:40 | 23/03/2023 15:15 |
| **14** | 26/01/2023 16:00 | 23/02/2023 16:00 | 23/03/2023 9:30 |
| **15** | 26/01/2023 15:30 | 22/02/2023 15:00 | 22/03/2023 12:30 |
| **16** | 26/01/2023 17:00 | 23/02/2023 15:30 | 23/03/2023 13:00 |
| **17** | 25/01/2023 11:00 | 22/02/2023 16:30 | |
| **18** | 26/01/2023 16:30 | 23/02/2023 16:30 | 23/03/2023 13:45 |
| **19** | 26/01/2023 10:00 | 23/02/2023 11:00 | 23/03/2023 15:45 |
| **20** | 26/01/2023 11:30 | 23/02/2023 11:30 | 24/03/2023 11:00 |
| **21** | 26/01/2023 10:00 | 23/02/2023 10:00 | 24/03/2023 10:30 |
| **22** | 26/10/2023 11:30 | 23/02/2023 11:30 | 23/03/2023 11:30 |

***Table 9. Daily visit registration****. Date and time for each of the visits conducted for each of the volunteers.*

## 16.3 Attachment 3. Consumption control

| N Vol | Wrist Side | WEIGHT OF SAMPLES (g) | | | | QUANTITY OF SAMPLES USED (g) | | |
|---|---|---|---|---|---|---|---|---|
| | | 1st Bracelet (D0-D28) | | 2nd Bracelet (D28-D56) | | 1st Bracelet | 2nd Bracelet | (g) |
| | | Basal (D0) | D28 | D28 | D56 | D28 | D56 | Per day |
| 1 | R | 7,59 | 7,70 | 7,62 | 7,67 | -0,110 | -0,050 | -0,006 |
| 2 | R | 7,73 | 7,81 | 7,78 | 7,77 | -0,080 | 0,010 | 0,000 |
| 3 | R | 7,65 | 7,56 | 7,55 | 7,57 | 0,090 | -0,020 | -0,001 |
| 4 | R | 7,60 | 7,71 | 7,43 | 7,49 | -0,110 | -0,060 | -0,002 |
| 5 | L | 7,74 | 7,71 | 7,68 | 7,65 | 0,030 | 0,030 | 0,001 |
| 6 | R | 7,55 | 7,52 | 7,57 | 7,54 | 0,030 | 0,030 | 0,001 |
| 7 | R | 7,81 | 7,80 | 7,74 | 7,79 | 0,010 | -0,050 | -0,002 |
| 8 | R | 7,41 | 7,42 | 7,42 | 7,44 | -0,010 | -0,020 | -0,001 |
| 9 | L | 7,57 | 7,59 | 7,80 | 7,76 | -0,020 | 0,040 | 0,001 |
| 10 | R | 7,68 | 7,71 | 7,56 | 7,58 | -0,030 | -0,020 | -0,001 |
| 11 | L | 7,62 | 7,59 | 7,78 | 7,65 | 0,030 | 0,130 | 0,005 |
| 12 | R | 7,65 | 7,75 | 7,44 | 7,45 | -0,100 | -0,010 | 0,000 |
| 13 | L | 7,70 | 7,78 | 7,44 | 7,53 | -0,080 | -0,090 | -0,003 |
| 14 | R | 7,44 | 7,41 | 7,57 | 7,56 | 0,030 | 0,010 | 0,000 |
| 15 | R | 7,74 | 7,72 | 7,68 | 7,73 | 0,020 | -0,050 | -0,002 |
| 16 | R | 7,83 | 7,76 | 7,82 | 7,79 | 0,070 | 0,030 | 0,001 |
| 17 | R | 7,56 | | | | | | |
| 18 | L | 7,58 | 7,57 | 7,51 | 7,48 | 0,010 | 0,030 | 0,001 |
| 19 | R | 7,68 | 7,70 | 7,56 | 7,58 | -0,020 | -0,020 | -0,001 |
| 20 | R | 7,81 | 8,07 | 7,61 | 7,90 | -0,260 | -0,290 | -0,010 |
| 21 | L | 7,75 | 7,80 | 7,56 | 7,66 | -0,050 | -0,100 | -0,004 |
| 22 | R | 7,72 | 7,69 | 7,65 | 7,59 | 0,030 | 0,060 | 0,002 |

***Table 10. Raw data for consumption control**. Raw data (g) regarding the weight of the samples belonging to each volunteer, and calculation of the quantity used at each of the time points, and the mean quantity used per day.*

## 16.4 Attachment 4. Panelist self-assessment

| QUESTIONNAIRE AFTER 4 WEEKS - VOLUNTEER | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **SENSORY EXPERIENCE** | | | | | | | | | | | | | | | | | | | | | | |
| 1. How much the application of the Bracelet is simple | 4 | 4 | 5 | 4 | 5 | 5 | 5 | 5 | 5 | 4 | 3 | 4 | 5 | 5 | 4 | 5 | | 4 | 5 | 5 | 5 | 5 |
| 2. How much the appearance of the Bracelet is pleasant | 4 | 4 | 4 | 5 | 5 | 4 | 4 | 4 | 4 | 3 | 3 | 1 | 5 | 4 | 4 | 5 | | 3 | 4 | 4 | 3 | 3 |
| 3. How much the feeling (texture) of the Bracelet is pleasant | 4 | 4 | 5 | 5 | 5 | 5 | 3 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 5 | | 4 | 3 | 3 | 4 | 4 |
| 4. How much the odor of the Bracelet is pleasant | 1 | 4 | 1 | 4 | 5 | 4 | 1 | 4 | 3 | 2 | 3 | 3 | 3 | 3 | 3 | 4 | | 4 | 4 | 3 | 4 | 4 |
| 5. How much the design of the Bracelet is attractive | 3 | 3 | 3 | 5 | 5 | 5 | 3 | 4 | 3 | 4 | 3 | 1 | 5 | 4 | 4 | 4 | | 3 | 2 | 3 | 4 | 4 |
| **TREATMENT EFFECTIVENESS** | | | | | | | | | | | | | | | | | | | | | | |
| 6. How much the Bracelet improves your mood | 3 | 3 | 2 | 1 | 3 | 3 | 1 | 4 | 2 | 4 | 3 | 5 | 3 | 3 | 4 | 4 | | 3 | 2 | 2 | 5 | 5 |
| 7. How much the Bracelet helps you to decrease your anxiety | 3 | 4 | 2 | 2 | 3 | 4 | 1 | 4 | 2 | 4 | 4 | 3 | 4 | 4 | 3 | 5 | | 3 | 4 | 2 | 5 | 4 |
| 8. How much the Bracelet improves your daily tasks | 3 | 4 | 2 | 2 | 3 | 4 | 1 | 4 | 2 | 3 | 3 | 3 | 4 | 3 | 3 | 4 | | 3 | 4 | 2 | 3 | 4 |
| 9. How much the Bracelet increase your energy | 3 | 3 | 2 | 2 | 3 | 3 | 1 | 4 | 2 | 4 | 3 | 5 | 4 | 3 | 4 | 5 | | 3 | 3 | 2 | 5 | 5 |
| 10. How much the Bracelet improve your sleep quality | 3 | 4 | 2 | 2 | 3 | 4 | 1 | 4 | 2 | 4 | 3 | 4 | 4 | 4 | 4 | 4 | | 3 | 4 | 3 | 5 | 4 |
| 11. How much the Bracelet increase your enjoyment | 3 | 3 | 1 | 3 | 4 | 4 | 1 | 4 | 2 | 4 | 3 | 3 | 4 | 3 | 4 | 5 | | 3 | 4 | 3 | 4 | 4 |
| 12. How much the Bracelet help you overcome stress | 3 | 4 | 1 | 2 | 4 | 3 | 1 | 4 | 2 | 4 | 3 | 3 | 4 | 4 | 4 | 4 | | 3 | 4 | 2 | 4 | 4 |
| 13. How much the Bracelet reduces your emotional discomfort? | 3 | 3 | 2 | 1 | 4 | 3 | 1 | 5 | 2 | 4 | 2 | 3 | 3 | 3 | 4 | 4 | | 3 | 4 | 2 | 4 | 3 |
| 14. How much time needed for you to feel relief/improvements? Please rate in days | 15 | 3 | 30 | | 2 | 15 | | 7 | | 15 | 5 | 7 | 11 | 3 | 16 | 2 | | 20 | 6 | 10 | 2 | 10 |
| **CONSUMER BEHAVIOUR** | | | | | | | | | | | | | | | | | | | | | | |
| 15. I am satisfied with the treatment | 00 7A bvc | 4 | 3 | 1 | 4 | 4 | 1 | 5 | 2 | 4 | 3 | 5 | 4 | 4 | 4 | 5 | | 3 | 3 | 2 | 5 | 5 |
| 16. I would use the Bracelet again | 3 | 4 | 1 | 1 | 5 | 5 | 2 | 5 | 2 | 4 | 2 | 5 | 4 | 4 | 5 | 5 | | 4 | 4 | 1 | 5 | 5 |
| 17. I would recommend the treatment | 3 | 4 | 2 | 3 | 4 | 4 | 1 | 5 | 2 | 4 | 2 | 5 | 4 | 4 | 5 | 5 | | 3 | 4 | 1 | 4 | 5 |
| 18. Have you ever used a similar product such as a food supplements (Y/N) | No | Sí | No | No | Sí | No | No | No | No | No | No | No | Sí | No | No | No | | No | No | No | No | No |
| 19. I think the price of the Bracelet for 1 month should be (€) | 20 | 15 | 15 | 10 | 20 | 20 | 1 | 15-20 | 10 | 18 | 12 | 40 | 15 | 25 | 20 e | 25 | | 10 | 10 | 5 | 10 | 10 |

| 20. Comments at D28 | |
|---|---|
| 1 | I noticed greater benefits during the first 15 days of wearing the bracelet. |
| 2 | The last few weeks I had a harder time falling asleep |
| 3 | It smells very bad. |
| 4 | I used a bracelet very similar to this one and it was for my bone pains, it worked very well for me (in the previous study they provided me with 2 monthly). This new bracelet does not work well for me, on the contrary I have noticed more restless and my quality of sleep has worsened I hope I have been helpful, continued with the study 2 more months |
| 5 | No |
| 6 | Good appearance |
| 7 | It smells very bad. |
| 8 | I have noticed that it has helped me sleep better |
| 9 | I have not felt that the bracelet helps me relax in the stressful situations I have suffered or in the nights of bad sleep. I think it would have been the same if I didn't wear it |
| 10 | There are improvements |
| 11 | The fastening system is not comfortable |
| 12 | I have slept very well |
| 13 | With the bracelet the situations that made me nervous I recognize them but I do not physically perceive palpitations or other symptoms that I had before. I'm quite happy |
| 14 | I do not know if it was the bracelet but the first two weeks it was much better |
| 15 | Produces a lot of sleep |
| 16 | Feeling of tranquility |
| 17 | |
| 18 | It is difficult to keep it well placed |
| 19 | I have noticed a lot of tranquility in my work, as it is a stressful job |
| 20 | I have no way to check its effectiveness |
| 21 | Sensation of calm |
| 22 | Notable improvement in my sleep and stress |

| QUESTIONNAIRE AFTER 8 WEEKS - VOLUNTEER | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **SENSORY EXPERIENCE** | | | | | | | | | | | | | | | | | | | | | | |
| 1. How much the application of the Bracelet is simple | 4 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 4 | 5 | 3 | 3 | 5 | 5 | 4 | 5 | | 4 | 4 | 4 | 5 | 5 |
| 2. How much the appearance of the Bracelet is pleasant | 4 | 4 | 4 | 5 | 5 | 4 | 4 | 5 | 2 | 4 | 3 | 2 | 4 | 4 | 4 | 5 | | 4 | 3 | 3 | 4 | 3 |
| 3. How much the feeling (texture) of the Bracelet is pleasant | 4 | 4 | 5 | 5 | 5 | 5 | 4 | 5 | 2 | 5 | 4 | 2 | 5 | 4 | 4 | 5 | | 4 | 3 | 3 | 4 | 5 |
| 4. How much the odor of the Bracelet is pleasant | 1 | 4 | 1 | 4 | 4 | 4 | 1 | 4 | 3 | 2 | 4 | 2 | 3 | 4 | 2 | 4 | | 3 | 4 | 3 | 4 | 2 |
| 5. How much the design of the Bracelet is attractive | 3 | 3 | 3 | 5 | 5 | 4 | 3 | 4 | 2 | 4 | 2 | 2 | 5 | 4 | 4 | 5 | | 3 | 2 | 3 | 3 | 3 |
| **TREATMENT EFFECTIVENESS** | | | | | | | | | | | | | | | | | | | | | | |
| 6. How much the Bracelet improves your mood | 2 | 3 | 2 | 2 | 3 | 3 | 1 | 5 | 4 | 4 | 1 | 5 | 4 | 3 | 4 | 5 | | 3 | 4 | 2 | 5 | 4 |
| 7. How much the Bracelet helps you to decrease your anxiety | 1 | 3 | 2 | 2 | 3 | 4 | 1 | 5 | 3 | 4 | 3 | 3 | 4 | 4 | 4 | 5 | | 3 | 4 | 2 | 5 | 4 |
| 8. How much the Bracelet improves your daily tasks | 1 | 3 | 1 | 3 | 3 | 3 | 1 | 5 | 3 | 3 | 2 | 3 | 3 | 3 | 4 | 5 | | 3 | 3 | 1 | 4 | 3 |
| 9. How much the Bracelet increase your energy | 1 | 4 | 1 | 2 | 3 | 3 | 1 | 5 | 4 | 4 | 1 | 5 | 3 | 3 | 4 | 5 | | 3 | 4 | 1 | 4 | 5 |
| 10. How much the Bracelet improve your sleep quality | 1 | 3 | 2 | 2 | 3 | 4 | 1 | 5 | 2 | 4 | 2 | 3 | 3 | 4 | 4 | 5 | | 3 | 4 | 2 | 4 | 4 |
| 11. How much the Bracelet increase your enjoyment | 1 | 3 | 1 | 3 | 3 | 4 | 1 | 4 | 3 | 4 | 2 | 3 | 3 | 3 | 3 | 5 | | 3 | 4 | 2 | 4 | 4 |
| 12. How much the Bracelet help you overcome stress | 1 | 3 | 2 | 2 | 3 | 4 | 1 | 5 | 3 | 4 | 2 | 3 | 3 | 4 | 3 | 5 | | 3 | 3 | 1 | 4 | 4 |
| 13. How much the Bracelet reduces your emotional discomfort? | 1 | 3 | 2 | 3 | 3 | 4 | 1 | 5 | 3 | 4 | 2 | 3 | 3 | 3 | 3 | 4 | | 3 | 3 | 2 | 4 | 3 |
| 14. How much time needed for you to feel relief/improvements? Please rate in days | 0 | 1 | 30 | 30 | 4 | 10 | 0 | 7 | 35 | 15 | 10 | 10 | 20 | 3 | 18 | 4 | | 6 | 3 | 0 | 2 | 7 |
| **CONSUMER BEHAVIOUR** | | | | | | | | | | | | | | | | | | | | | | |
| 15. I am satisfied with the treatment | 1 | 4 | 2 | 3 | 3 | 4 | 1 | 5 | 3 | 4 | 2 | 4 | 3 | 4 | 4 | 5 | | 3 | 4 | 2 | 5 | 4 |
| 16. I would use the Bracelet again | 1 | 4 | 1 | 3 | 4 | 4 | 1 | 5 | 3 | 4 | 2 | 5 | 4 | 4 | 5 | 5 | | 3 | 4 | 2 | 5 | 4 |
| 17. I would recommend the treatment | 1 | 4 | 1 | 4 | 3 | 4 | 1 | 5 | 3 | 4 | 2 | 5 | 4 | 4 | 5 | 5 | | 3 | 4 | 2 | 5 | 4 |
| 18. Have you ever used a similar product such as a food supplements (Y/N) | No | Sí | No | No | No | No | No | No | No | No | No | No | Sí | No | No | No | | No | No | No | No | No |
| 19. I think the price of the Bracelet for 1 month should be (€) | 2 | 15 | 15 | 10 € | 10 | 30 | 1 | 15 | 20 | 20 | 3 € | 35 | 20 | 20 | 18 | 20 | | 5 | 10 | 5 € | 15 | 10 |

| 20. Comments | |
|---|---|
| 1 | I only noticed improvement the first 15 days of treatment, with the previous bracelet. Subsequently, absolutely no effect was noted. Probably, the results obtained during the first fortnight of treatment were due to factors external to the bracelet, since in the rest of the study no effect was observed, neither positive nor negative. |
| 2 | Notice more change with the first bracelet than with this second |
| 3 | It smells really bad. |
| 4 | During the treatment period, I have been more stressed due to personal circumstances. |
| 5 | None |
| 6 | Good design, easy to install, the smell is a bit strong the first day but then it is quite pleasant |
| 7 | The smell is unpleasant |
| 8 | The result has been in my case excellent |
| 9 | It gets out of adjustment a lot and you have to reposition it many times a day |
| 10 | All good. |
| 11 | I have not noticed any change in my mood. |
| 12 | I have noticed a lot of improvement in sleep |
| 13 | I noticed more improvement the first month. Now due to personal circumstances I have had a rather serious problem and I have not noticed it as much. |
| 14 | For me it works for the first 15 days. This time the bracelet has not closed well and I had to continually adjust it. But I love it |
| 15 | At night you can sleep well, since it produces a lot of sleep |
| 16 | Relaxation |
| 18 | Comes loose easily |
| 19 | The last two weeks I no longer felt so relaxed |
| 20 | The second bracelet was quite loose and I had to be adjusting it every so often |
| 21 | Soothing |
| 22 | Improve your initial smell |

## 16.5 Attachment 5. Informed consent



**SCONSENTIMIENTO INFORMADO DE PARTICIPACIÓN EN EL ESTUDIO DE INVESTIGACIÓN COSMÉTICA DC.186.36.102**

**${nombreyapellidos}** con DNI **${dni_contacto}** he sido invitado a participar en el estudio DC.186.36.102 de investigación cosmética, el cual será llevado a cabo por Dermaclaim Lab S.L., CIF: B16909699, con sede fiscal en Parc Cientific de la Universitat de Valencia, Calle Catedràtico Agustín Escardino Benlloch, 9, 46980 Paterna (Valencia).

El objetivo de este consentimiento informado es que usted reciba la información correcta y suficiente para que pueda evaluar y juzgar si quiere o no participar en el estudio. Para ello, lea esta hoja informativa de atención y nosotros le aclararemos las dudas que le puedan surgir al respecto.

Debe saber que su participación en este estudio es voluntaria y que puede decidir no participar y retirar el consentimiento en cualquier momento, sin que por ello se altere la relación con Dermaclaim Lab S.L.

**Objetivo de Estudio**

El presente estudio tiene como objetivo valorar el efecto de una pulsera para el control de nervios y estrés.

**Protocolo de Aplicación**

El tratamiento se llevará a cabo durante **60 días**, **durante el cual se deberá poner 2 pulseras en el brazo por mes.**

**Duración de Tratamiento y Medidas**

Duración del tratamiento: 60

Medidas: Inicial (Día 0), Intermedia (Día 28), Final (D60).

**Obligaciones**

- No ingerir ningún tratamiento médico o suplemento específico para combatir los síntomas de nerviosismo, estrés, insomnio o inquietud.
- **Rellenar detalladamente el diario de registro** de aplicación del producto, indicando si ha ocurrido algún problema durante el desarrollo del estudio.
- Completar los cuestionarios en la fecha indicada.
- Mantener su rutina habitual de higiene sin quitar la pulsera en ningún momento.
- En caso de pérdida o rotura de alguna pulsera avisar inmediatamente al centro para poder adquirir una nueva.
- **TRAER LAS PULSERAS A LAS VISITAS** para poder calcular la cantidad de producto que se ha dispensado.

**Compensación económica**

- En el caso de completar el estudio siguiendo las indicaciones correspondientes, recibirá una compensación económica de 40 €.

*La compensación económica se recibirá vía transferencia bancaria al finalizar el tratamiento si se han cumplido todas las condiciones de estudio, lo cual puede detectarse con el control de consumo y los resultados analizados en clínica.

**BENEFICIOS Y RIESGOS DEL ESTUDIO**

Su participación, en el caso de completar el estudio siguiendo las indicaciones correspondientes, supone:

- Compensación económica de 40 € (entregados al finalizar al estudio, si se han cumplido las condiciones)
- Beneficios faciales que el tratamiento pueda proporcionar a su piel.

Asimismo, su participación puede ayudar al proceso de desarrollo e investigación del producto, y a su puesta en el mercado, con las reivindicaciones obtenidas de este y otros estudios.

Los riesgos de su participación en este estudio radican en los posibles efectos adversos que la aplicación del tratamiento pueda tener en su piel. No obstante, es importante remarcar que todos los estudios que analizamos en Dermaclaim Lab S.L. han superado los estudios de seguridad y compatibilidad cutánea legalmente pertinentes, por lo que la aparición de acontecimientos adversos tras la aplicación es minoritaria.

*La compensación económica se recibirá vía transferencia bancaria al finalizar el tratamiento si se han cumplido todas las condiciones de estudio, lo cual puede detectarse con el control de consumo y los resultados analizados en clínica.

**CONSENTIMIENTO INFORMADO DE PARTICIPACIÓN**

Yo, **${nombreyapellidos}** a fecha **${fecha_hoy}:**

- He recibido suficiente información sobre el estudio y he comprendido la información que se me ha facilitado.
- He podido hacer preguntas sobre el estudio a las personas responsables del mismo.
- Comprendo que mi participación es voluntaria.
- Confirmo que los datos personales aportados son ciertos, soy mayor de 18 años y capaz de firmar un contrato jurídicamente vinculante.
- Autorizo a Dermaclaim Lab S.L. a comunicarse conmigo por los medios que consideren oportunos.

## 16.6 Attachment 6. Raw data

Original raw data obtained directly from for each of the experimental measurements, are enclosed in a digital file, delivered together with this report, in order to assure full transparency and the traceability of the results.