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CLINICAL INSTRUMENTAL EVALUATION OF THE HYDRATING, ANTI-WRINKLES, ANTI-DARK CIRCLES AND ANTI-EYE BAGS EFFICACY OF A COSMETIC PRODUCT FOR THE FACE

TORSTONE SA

TRAITEMENT ULTRA CORRECTIF

LAB-00002.24

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

GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

Sede legale: Via Guido Rossa, 1 20024 Garbagnate M.se (MI) Italy, I P.I./C.F. 11093320155
Capitale Sociale € 161.834 i.v., C.C.I.A.A. MI 1437929 - Registro Società N. 342215
Centro di Saggio operante in BPL - Sistema di gestione qualità certificato ISO 9001
Iscritto al Registro Regione Lombardia ai fini dell'autocontrollo alimentare (N 030015309008)
Laboratorio di Prova Accreditato ACCREDIA LAB N 1318L (UNI CEI EN ISO/IEC 17025:2018)
L'elenco delle prove accreditate è consultabile su www.accredia.it

KEY PERSONNEL

Customer

TORSTONE SA
International Center Cointrin
Route de Pré-Bois, 20
Bât. C, 2è étage
CP1913
CH-1215 GENÈVE 15

Principal experimenter

Dr. **Gloria ROVEDA**
Degree in Medicine and Surgery, Specialist in Dermatology and Venereology
Consultant to Complife Italia s.r.l.

Study director

Dr. **Ileana DE PONTI**
Chemist and pharmaceutical technologist
Complife Italia s.r.l.

Data analysis & Report

Dr. **Federica RUGGERI**
Biologist
Complife Italia s.r.l.

Complife Italia S.r.l.

Complife Italia S.r.l.
Via Angelini, 21
27028 San Martino Siccomario (PV)
Italy
tel. +39-0382 25504 fax. +39-0382 536006
Mail: info@complifegroup.com

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
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INDEX

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complifegroup.com
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STUDY DESIGN

1.1. Title

Clinical instrumental evaluation of the hydrating, anti-wrinkles, anti-dark circles and anti-eye bags efficacy of a cosmetic product for the face.

1.2. Aim of the study

The study is designed to evaluate the efficacy of a cosmetic product for the face; in particular the anti-wrinkles, anti-dark circles and anti-eye bags efficacy as well as the hydrating properties are evaluated. In order to reach this goal a clinical/instrumental study is carried out on 30 female subjects aged between 35 and 60 (±2) years old, showing eye bags (15 volunteers), dark circles (15) and visible crow's feet wrinkles (20 volunteers). Evaluations are performed at baseline (T0) and after 14, 28 and 42 days of product use by means of non-invasive bioengineering techniques and with the self-assessment of the volunteers.

1.3. Tested Product

1.3.1. Information provided by the Customer

- ☒ Product name: **TRAITEMENT ULTRA CORRECTIF LAB-00002.24**
- ☒ The tested cosmetic product conforms to REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance) and to their annexes.
- ☒ Way of use: apply the product twice a day, morning and evening, on the eye contour, gently picking with your fingers from the inside towards the outside.
- ☒ Qualitative INCI formula:
  AQUA (WATER), CAPRYLIC/CAPRIC TRIGLYCERIDE, PENTYLENE GLYCOL, BUTYLENE, GLYCOL, CETEARYL ALCOHOL, ETHYL LINOLEATE, SQUALANE, GLYCERYL STEARATE, CITRATE, HYDROGENATED, PHOSPHATIDYLCHOLINE, BUTYROSPERMUM PARKII (SHEA), BUTTER, C12-15 ALKYL BENZOATE, GLYCERIN, NIACINAMIDE, PROPANEDIOL, UNDECANE, TOCOPHERYL ACETATE, TRIDECANE, CAPRYLYL GLYCOL, PHENYLPROPANOL, FRAXINUS, EXCELSIOR BARK EXTRACT, XANTHAN GUM, BORON NITRIDE, TAMARINDUS INDICA SEED, GUM, DISODIUM ADENOSINE TRIPHOSPHATE, GELLAN GUM, GLYCOLIC ACID, HYDROLYZED OATS, SODIUM HYDROXIDE, LECITHIN, SILANETRIOL, CERAMIDE NP, VITIS, VINIFERA (GRAPE) VINE EXTRACT, TOCOPHEROL, HELIANTHUS ANNUUS (SUNFLOWER), SEED OIL

1.4. Ethical requirements

The study is carried out following the ethical requirements listed below.

I. All participants in the study must be healthy volunteers, aged over 18 years old.
II. All participants in the study must be selected under the supervision of an experimenter, using inclusion/non-inclusion criteria.
III. Volunteers must choose to participate of their own accord.
IV. All participants in the study must be volunteers who are informed of the aim and the nature of the study.
V. All participants in the study must be informed of the possible risks involved in the study.
VI. All participants in the study must sign a written consent form before the study begins.
VII. Before volunteers are exposed to the tested product, all safety information regarding the product and its individual ingredients must be assessed.
VIII. All the study procedures are carried out in compliance with the ethical principles for medical research (Ethical Principles for Medical Research Involving Human Subjects, Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and its amendment)
IX. All the precautions have to be taken to avoid that adverse reactions will appear.

COMPLIFE Italia S.r.l.
info@complifegroup.com
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complifegroup.com
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X. In case of non-expected/adverse skin reaction occurrence the medical investigating specialist will evaluate the severity of the reaction (reporting it in the data collecting sheet of the volunteer) and as a consequence will start the appropriate therapy.

1.5. Subjects

1.5.1. Subjects selection

The subjects participating in the study are selected under the supervision of a board-certified dermatologist from a panel of healthy subjects in accordance with the following inclusion and non-inclusion criteria.

1.5.1.1. Inclusion criteria

- ☑ Healthy female subjects
- ☑ Age: between 35 and 60 (±2) years old
- ☑ Caucasian ethnicity
- ☑ Subjects with visible crow's feet wrinkles
- ☑ Subjects with eye bags (15 vol)
- ☑ Subjects with dark circles (15 vol)
- ☑ Willingness to not use products likely to interfere with the products to be tested
- ☑ Willingness to not use, during all the study period, face creams other than the study products
- ☑ Subjects who did not expose to the sun/solar lamps, who use self-tanning products in the last month prior to the study
- ☑ Willingness to not vary the normal daily routine
- ☑ Subject is under effective contraception (oral/not oral); not expected to be changed during the study period
- ☑ Subjects informed on the test purposes and that have signed an informed consent form.

1.5.1.2. Not inclusion criteria

- ✘ Subjects who do not fit the inclusion criteria
- ✘ Pregnant or nursing women
- ✘ Subjects that have shown allergies to cosmetic products, toiletries, sunscreens and/or topical drugs
- ✘ Subjects with skin disorders on the test area
- ✘ Subjects under pharmacological treatment (both locally or systemically) that may interfere with the test execution
- ✘ Positive anamnesis for atopy (if this condition interferes with the test execution)

1.5.1.3. Withdrawal of subjects

A subject enrolled in the study can be withdrawn and considered as a drop-out when: (i) adverse reactions, judged severe and attributable to the tested product, occur, (ii) the subject is no longer eligible to participate in the study, (iii) the subject develops a pathological condition, not related to the study, but appearing during the study period, (iv) it is required the prescription of a concomitant treatment, (v) the study requirements are not satisfied (significant deviation from the protocol), (vi) significant non-compliance with respect to product use or to the study protocol.

1.6. Study development

The study is carried out as follow:

- **T0:** enrolment of 30 subjects according to inclusion/non-inclusion criteria. Clinical-instrumental assessment of the parameters under study before product use (T0). Moreover volunteers are asked to express their opinion on the tested product after the first application by answering to a questionnaire.
- **T0-T42:** daily use of the product according to provided instructions.
- **T14:** clinical-instrumental assessment of the parameters under study after 14 days of product use.
- **T28:** clinical-instrumental assessment of the parameters under study after 28 days of product use.

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

- **T42:** clinical-instrumental assessment of the parameters under study after 42 days of product use. Moreover, at the end of the study, volunteers are asked to express their opinion on tested product by answering to a questionnaire.

1.7. Materials and methods

In the sections here below are reported the materials and methods employed in the study. All the study procedures are carried out under temperature and humidity-controlled conditions.

1.7.1. Evaluation of skin moisturizing

Skin moisturizing is evaluated by means of Corneometer® measurement. This measurement is based on the completely different dielectric constant of water (81) and other substances (mostly < 7). The measuring capacitor shows changes of capacitance according to the moisture content of the skin. A metallic lamina separates the metallic tracks (gold) in the probe head from the skin in order to prevent current conduction in the measured area. An electric field between the tracks with alternating attraction develops. One track builds up a surplus of electrons (minus charge) the other a lack of electrons (plus charge). The scatterfield penetrates the very first layer of the skin during the measurement and the capacitance is determined.

1.7.2. Skin pH evaluation

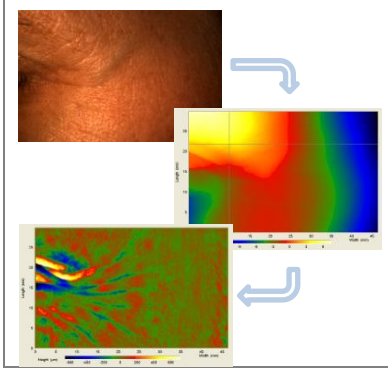
The used instrument is the SKIN pH-METER 905®, Courage + Khazaka GmbH. The measure is based on a combined electrode of high quality, in which both the glass electrode sensitive to H+ and the additional reference electrode are placed in the same site. It is connected to a handle probe containing the measurement electronics. Before the measurements, the SKIN pH-meter® 905 (Courage + Khazaka electronic GmbH) is calibrated using two buffer solutions with known pH (pH 4.01 and 1.7) as reference.
Measurement range: 0 to 12; accuracy: ± 0.1 pH.

1.7.3. Evaluation of the skin profilometry

Wrinkle depth - Eye bags volume

Skin surface is quantitatively assessed by Primos 3D (GFMesstechnik GmbH). Primos 3D is a non-contact in vivo skin measurement device based on structured light projection. In conjunction with a comprehensive 3-D measurement and evaluation software, the sensor allows to evaluate skin surface properties (i.e. wrinkle depth, volume, roughness etc.). *In this study the calculated parameters are the wrinkle depth on the periocular area and the eye bags volume. For further information see box 1.*

BOX 1 Skin profilometry by means of Primos 3D analysis.



The technique. Primos 3D is a 3D scanner that create a point cloud (set of vertices in a three-dimensional coordinate system) of geometric samples on the surface of the object to be measured. These points are then used to extrapolate the shape of the object (a process called reconstruction). Like cameras, 3D-scanner have a cone-like field of view, and like cameras, they can only collect information about surfaces that are not obscured. While a camera collects color information about surfaces within its field of view, 3D scanners collect distance information about surfaces within its field of view. The "picture" produced by a 3D scanner describes the distance of a surface at each point in the picture (see the image in the insert).

Calculation of wrinkle depth. It is calculated the height of wrinkles in the sampling length. This calculation is done on the sectional picture (wrinkle depth vs. section).

COMPLIFE Italia S.r.l.
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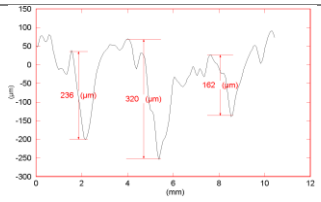
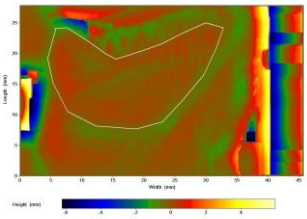
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

	
	**Calculation of eye bags volume** It is calculated the volume of the under eye swelling (eyebags).

1.7.4. Evaluation of the color of dark circles

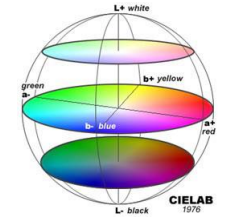
The measurement of under-eyes dark circles colour and of skin radiance/brightness is carried out by means of a spectrophotometer/colorimeter CM-700d (Konica Minolta). The instrument is able to evaluate the colour according to a standard method defined by the International Lighting Commission (CIE).

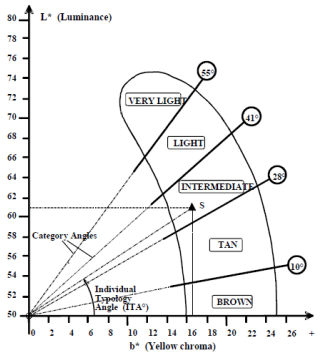
CIELab is a standardized colour space in which the colour is defined -under standard illumination conditions (illuminant) and observer angle- by three colorimetric parameters called a*, b* and L*. a* and b* values define hue and colour saturation and L* value is related to colour brightness.

In this study the colorimetric parameters a* and ITA° are taken into consideration for the evaluation of dark circles colour variation. In particular a* value is related to the green (-a*)/red (+a*) component of skin colour and ITA° to skin colour/pigmentation. In particular, a decrease of a* value indicates a reduction of the red component of the skin colour/dark circles and an increase of ITA° value indicates a reduction of skin colour intensity.

For further information see box 2.

BOX 2 – CIELab colour space and calculation of ITA angle





The technique. The spectrophotometer which principle of function is the reflectance spectrophotometry, emits an intense white light that re-emitted from the object (at an angle of 10°) is collected by 36 photodiodes each with different spectral sensitivity (from 400 nm to 700 nm). The sensitivity of the photodiodes is regulated according to a "standard observer" simulating the sensitivity of the human eye. This information is then elaborated by a microprocessor and displayed graphically.

ITA° calculation. ITA° is calculated as follows:

$$ITA° = \text{ArcTan}\frac{(L^*-50)}{b^*} \times \frac{180}{3.14159}$$

Based on ITA° it is possible to define the following skin colour categories:

ITA°>55°	Very light
55°>ITA°>41°	Light
41°>ITA°>28°	Intermediate
28°>ITA°>10°	Tanned
ITA°<10°	Brown

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complifeitalia@legalmail.it
complifegroup.com
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SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

1.7.5. Self- assessment

At the end of the study (T42) volunteers are asked to express their opinion about product efficacy by answering to a questionnaire.

1.7.6. Digital pictures

Digital pictures acquired with Visioface (Courage+Khazaka, electronic GmbH) will be included in the report in Annex 1. Pictures will be taken at each experimental monitored check.

1.8. Results and statistics

1.8.1. Results

1) Results are reported in tables in their respective units.

2) Mean values are calculated as:

$$m = \frac{\sum_{1}^{n} p}{n}$$

where: p is the value of the parameter under analysis; n is the number of subjects participating in the study

3) Percentages are calculated as follows:

$$\%var.vs.T0 = \left(\sum_{1}^{n} \frac{p_t - p_0}{p_0}\right) x100$$

or

$$\%of\ subjects = \left(\frac{\sum_{1}^{n} answers}{n}\right) x100$$

where: p_t is the value of the parameter under analysis after product application; p_0 is the value of the parameter under analysis before product application; n is the number of subjects participating in the study

4) The mean standard error of data is calculated as:

$$SE = \frac{\sqrt{\frac{\sum_{1}^{n}(p_i^2) - \frac{\sum_{1}^{n} p_i^2}{n}}{(n-1)}}}{\sqrt{n}}$$

where: p is the value of the parameter under; n is the number of subjects participating in the study

All the calculations are done using a Microsoft® Excel 2013 (vers. 15.0.4815.1001; Microsoft, USA) worksheet running on Microsoft® Windows 10 Professional (Microsoft, USA).

Final self-assessment data are reported in a Microsoft® Excel sheet. The results are calculated as percentage (%) of subjects who assigned a particular judgment (among those proposed). For each question, the number of subjects related to each judgment is counted → (number of subjects) and this number is then divided by the total number of subjects→ % of answers.

1.8.2. Statistical analysis

Data of subjects who had completed the study, as protocol directed, were statistically analyzed.
Instrumental data are submitted to Student for paired data carried out using a Microsoft® Excel 2013 (vers. 15.0.4815.1001; Microsoft, USA) worksheet running on Microsoft® Windows 10 Professional (Microsoft, USA). Variations are considered statistically significant when p value is ≤ 0,05.

1.8.3 Interpretation of results

The study here above reported was designed to demonstrate the test product claim(s) in the current framework proposed by Commission Regulation (EU) No 655/2013. Endpoints are measured using techniques currently

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info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
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accepted in the cosmetic field while biases are minimized by procedure(s) standardization according to ISO 9001 Quality Management System. Data are analyzed and interpreted by skilled technician according to both descriptive and inferential statistical analysis procedures. Due to the lack of reference values in the cosmetic field, statistical significance (for instrumental analysis) and percentage of subjects showing an effect (for clinical/sensorial endpoints) are the primary criterion to evaluate the correspondence between the proposed claim(s) and the study output(s). In particular Intragroup (vs. T0) or intergroup (eg. active vs. placebo, treated vs non treated) statistical analysis criterion to reject the null hypothesis (no product effect) is set at $p<0.05$. For clinical evaluations, the positive effect of the product on the measured parameter is confirmed if more than 50% of the subjects register an improvement.

Finally, for the self-assessment questionnaires, the performance and the pleasantness of the product must be perceived by at least 60% of the subjects. Whenever reference values or threshold values exists those values are used to validate product claim(s).

1.9. Start/end date of study

The table here below reports date of beginning and end of the study.

Start date	End date
10/02/2020	07/09/2020

1.10. Report change record

The table here below reports the change log of all approved changes made to the document that make up the course after initial approval.

Rev. no	Date	Description
00	11/09/2020	First release

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
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PANEL DEMOGRAPHY

The following table reports the information of the enrolled subjects.

n.	Vol ID	AGE	SKIN TYPE	CONTACT LENSES WEARER	EYE CIRCLES	EYE BAGS	WRINKLES
01	P1599P	59	MIXED		X		X
02	B1081G	61	DRY		X		X
03	P4545D	47	MIXED	X	X		X
04	A0849R	62	NORMAL		X		
05	V1228M	60	NORMAL	X	X		
06	G4267I	62	NORMAL		X		X
07	M1519D	56	MIXED		X		X
08	C3710P	58	MIXED		X		X
09	C2901S	55	MIXED		X		X
10	M1950M	53	MIXED	X	X		
11	A3893A	59	MIXED		X		
12	P4241M	54	NORMAL/SENSITIVE		X		X
13	S2046S	51	MIXED/SENSITIVE		X		X
14	P2505M	47	MIXED		X		X
15	R3160L	42	MIXED/SENSITIVE	X	X		X
16	R1784M	60	NORMAL			X	X
17	P1778A	57	DRY/SENSITIVE			X	
18	T4004E	52	DRY/SENSITIVE			X	X
19	M3265G	58	MIXED/SENSITIVE			X	
20	M3661M	60	MIXED			X	X
21	B4300E	50	MIXED			X	X
22	M3754L	49	DRY			X	X
23	B4254N	55	NORMAL			X	X
24	V4293N	38	NORMAL			X	X
25	M4645S	38	MIXED/SENSITIVE	X		X	
26	G4255P	60	NORMAL	X		X	X
27	F3736S	62	MIXED/SENSITIVE			X	X
28	M4022P	53	MIXED			X	
29	P2541S	49	DRY			X	
30	M3679L	48	MIXED/SENSITIVE	X		X	
	Mean	54					
	Min	38					
	Max	62					

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
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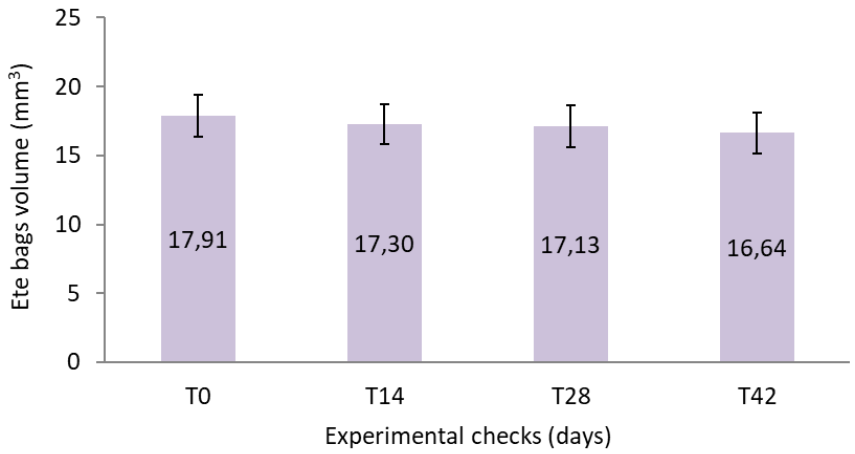
RESULTS
EYE BAGS VOLUME

TABLE 1 - The table below reports the raw data obtained for each subject participating in the study for the analyzed skin parameters. Data are expressed in mm^3.

n.	Vol ID	T0	T14	T28	T42	Variation % vs T0	T14	T28	T42
01	R1784M	20,15	21,07	21,54	19,93		4,5%	6,9%	-1,1%
02	P1778A	16,11	16,04	15,92	15,52		-0,4%	-1,2%	-3,7%
03	T4004E	21,20	21,65	18,41	18,63		2,1%	-13,2%	-12,1%
04	M3265G	15,69	15,59	14,63	14,14		-0,7%	-6,8%	-9,9%
05	M3661M	10,32	9,35	8,67	8,44		-9,4%	-16,0%	-18,2%
06	B4300E	10,37	10,18	9,96	9,62		-1,8%	-4,0%	-7,3%
07	M3754L	21,71	19,68	21,50	21,09		-9,4%	-0,9%	-2,9%
08	B4254N	32,72	30,50	31,70	31,45		-6,8%	-3,1%	-3,9%
09	V4293N	21,99	22,51	22,36	21,39		2,4%	1,7%	-2,7%
10	M4645S	11,36	11,30	10,78	10,19		-0,6%	-5,2%	-10,3%
11	G4255P	15,75	15,40	16,03	15,10		-2,2%	1,8%	-4,1%
12	F3736S	17,04	17,02	16,18	16,30		-0,1%	-5,0%	-4,3%
13	M4022P	12,41	11,34	11,89	12,03		-8,6%	-4,2%	-3,1%
14	P2541S	20,53	18,12	19,38	19,25		-11,7%	-5,6%	-6,2%
15	M3679L	21,28	19,67	17,97	16,54		-7,6%	-15,5%	-22,3%
	Mean	17,91	17,30	17,13	16,64		-3,3%	-4,7%	-7,5%
	SEM	1,5	1,4	1,5	1,5	Max	4,5%	6,9%	-1,1%
	TEST.t vs T0	--	0,040	0,022	0,001	Min	-11,7%	-16,0%	-22,3%

GRAPH 1 - The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean ± SEM. Above the error bar the intragroup statistical analysis is reported as follows: *** p<0.001; ** p<0.01; * p<0.05.



Comment: the tested product determines a statistically significant decrease of eye bags volume at each experimental monitored check, reaching at T42 an reduction by 7.5%.

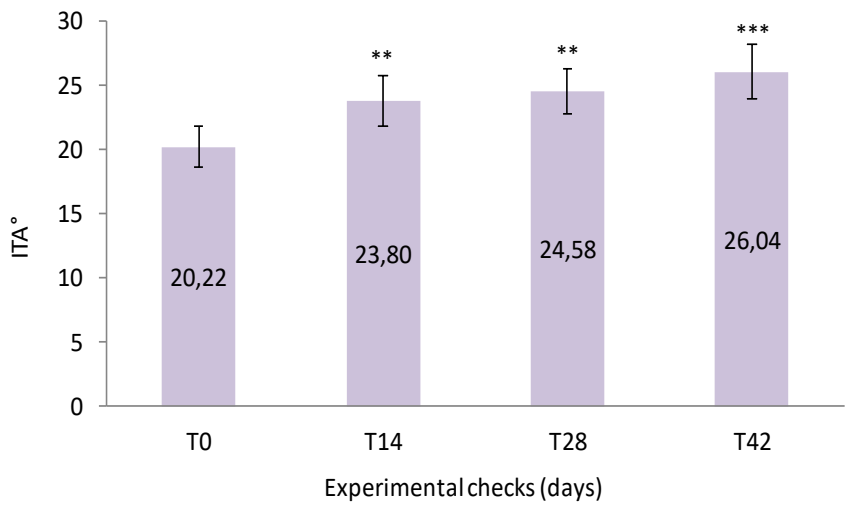
COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

DARK CIRCLES COLOUR ANALYSIS

TABLE 2 - The table below reports the raw data obtained for each subject participating in the study for the analyzed skin parameters. Data are expressed as arbitrary units.

n.	Vol ID	T0	T14	T28	T42	Variation % vs T0	T14	T28	T42
01	P1599P	19,92	20,69	19,71	18,44		3,8%	-1,0%	-7,5%
02	B1081G	16,04	17,91	20,50	21,19		11,7%	27,8%	32,1%
03	P4545D	19,10	20,16	22,07	22,30		5,6%	15,6%	16,8%
04	A0849R	19,88	21,10	22,60	28,33		6,2%	13,7%	42,5%
05	V1228M	28,83	28,64	23,39	29,16		-0,7%	-18,9%	1,1%
06	G4267I	22,03	29,71	32,30	28,66		34,8%	46,6%	30,1%
07	M1519D	14,82	22,71	22,42	24,89		53,2%	51,3%	67,9%
08	C3710P	36,91	41,34	39,58	48,05		12,0%	7,2%	30,2%
09	C2901S	24,57	35,98	34,33	34,88		46,4%	39,8%	42,0%
10	M1950M	13,55	19,32	19,38	20,32		42,6%	43,1%	50,0%
11	A3893A	11,46	12,77	14,89	14,62		11,5%	29,9%	27,6%
12	P4241M	17,86	22,43	22,23	22,99		25,5%	24,5%	28,7%
13	S2046S	20,66	19,11	24,20	23,74		-7,5%	17,2%	14,9%
14	P2505M	17,94	15,98	19,07	19,55		-10,9%	6,3%	9,0%
15	R3160L	19,71	29,21	31,95	33,43		48,2%	62,1%	69,6%
	Mean	20,22	23,80	24,58	26,04		18,8%	24,3%	30,3%
	SEM	1,6	2,0	1,8	2,1	Max	53,2%	62,1%	69,6%
	TEST.t vs T0	--	0,005	0,002	0,000	Min	-10,9%	-18,9%	-7,5%

GRAPH 2 - The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean ± SEM. Above the error bar the intragroup statistical analysis is reported as follows: *** p<0.001; ** p<0.01; * p<0.05.



Comment: the tested product determines a statistically significant increase of ITA° values vs. T0 at each experimental monitored check (+18.8% at T14, +24.3% at T28 and +30.3% at T42), showing a reduction of dark circles visibility.
ITA° categorized skin color: a low ITA° value indicates a brown pigmentation, while a high ITA° value indicates a very light pigmentation.

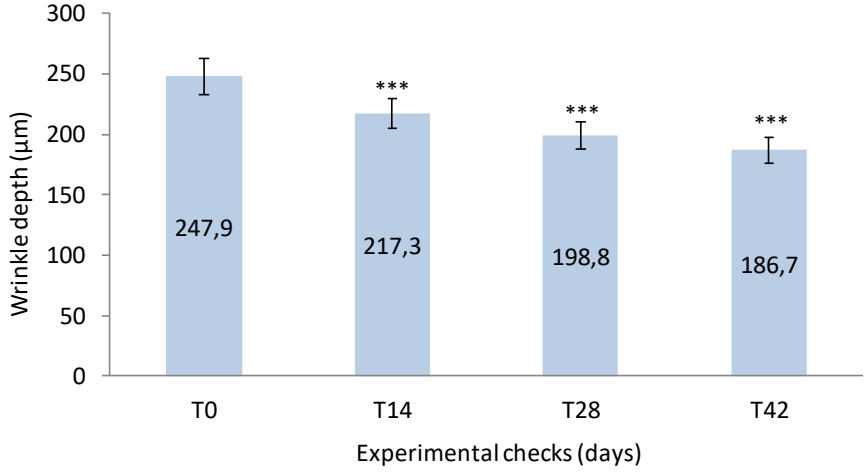
COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

SKIN PROFILOMETRY, Wrinkle depth

TABLE 3 - The table below reports the raw data obtained for each subject participating in the study for the analyzed skin parameters. Data are expressed in µm.

n.	Vol ID	T0	T14	T28	T42	Variation % vs T0	T14	T28	T42
01	P1599P	309,1	281,0	242,0	236,5		-9,1%	-21,7%	-23,5%
02	B1081G	375,1	324,3	290,4	274,8		-13,5%	-22,6%	-26,7%
03	P4545D	267,0	220,5	224,9	226,9		-17,4%	-15,8%	-15,0%
04	G4267I	320,2	274,4	229,7	212,0		-14,3%	-28,3%	-33,8%
05	M1519D	189,0	158,5	162,5	165,0		-16,1%	-14,0%	-12,7%
06	C3710P	394,9	304,4	278,5	248,2		-22,9%	-29,5%	-37,1%
07	C2901S	208,7	173,7	166,4	194,6		-16,8%	-20,3%	-6,8%
08	P4241M	241,3	238,5	233,6	196,7		-1,2%	-3,2%	-18,5%
09	S2046S	117,1	97,4	82,0	93,4		-16,8%	-30,0%	-20,2%
10	P2505M	174,1	159,0	146,8	124,5		-8,7%	-15,7%	-28,5%
11	R3160L	196,4	190,8	187,6	160,5		-2,9%	-4,5%	-18,3%
12	R1784M	113,0	91,0	119,0	108,0		-19,5%	5,3%	-4,4%
13	T4004E	311,0	295,4	222,2	230,3		-5,0%	-28,6%	-25,9%
14	M3661M	354,0	276,0	308,0	276,0		-22,0%	-13,0%	-22,0%
15	B4300E	194,0	168,0	158,0	142,0		-13,4%	-18,6%	-26,8%
16	M3754L	171,2	141,5	129,9	120,0		-17,3%	-24,1%	-29,9%
17	B4254N	233,0	199,0	149,0	126,0		-14,6%	-36,1%	-45,9%
18	V4293N	176,3	153,9	152,9	125,0		-12,7%	-13,3%	-29,1%
19	G4255P	284,0	253,0	181,0	187,0		-10,9%	-36,3%	-34,2%
20	F3736S	328,7	345,0	312,0	286,0		5,0%	-5,1%	-13,0%
	Mean	247,9	217,3	198,8	186,7		-12,5%	-18,8%	-23,6%
	SEM	15,3	12,3	11,4	11,1	Max	5,0%	5,3%	-4,4%
	TEST.t vs T0	--	0,000	0,000	0,000	Min	-22,9%	-36,3%	-45,9%

GRAPH 3 - The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean ± SEM. Above the error bar the intragroup statistical analysis is reported as follows: *** p<0.001; ** p<0.01; * p<0.05.



Comment: As it is possible to note, the tested product determines a statistically significant decrease of crow's feet wrinkles depth at each experimental monitored check, reaching at T42 a reduction of wrinkles depth by 23.6% vs T0.

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

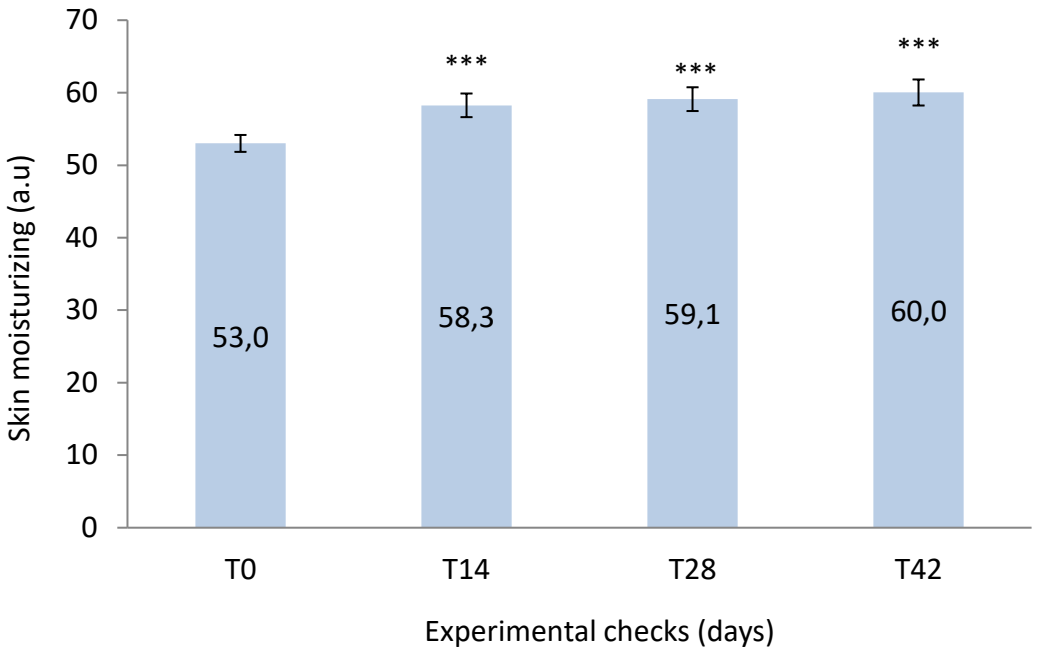
SKIN MOISTURIZATION

TABLE 4 - The table below reports the raw data obtained for each subject participating in the study for the analyzed skin parameters. Data are expressed in corneometric units (c.u.).

n.	Vol ID	T0	T14	T28	T42	Variation % vs T0	T14	T28	T42
01	P1599P	51,5	53,4	52,5	53,8		3,7%	1,9%	4,5%
02	B1081G	57,4	67,8	70,2	70,8		18,1%	22,3%	23,3%
03	P4545D	55,8	58,3	58,3	58,5		4,5%	4,5%	4,8%
04	A0849R	51,7	51,5	52,7	59,7		-0,4%	1,9%	15,5%
05	V1228M	63,7	62,9	62,2	67,5		-1,3%	-2,4%	6,0%
06	G4267I	55,7	68,9	67,6	69,5		23,7%	21,4%	24,8%
07	M1519D	62,8	64,0	64,3	64,7		1,9%	2,4%	3,0%
08	C3710P	56,6	59,3	52,9	55,1		4,8%	-6,5%	-2,7%
09	C2901S	47,6	48,9	54,4	61,1		2,7%	14,3%	28,4%
10	M1950M	59,2	62,4	71,4	77,1		5,4%	20,6%	30,2%
11	A3893A	57,6	69,4	76,4	79,2		20,5%	32,6%	37,5%
12	P4241M	50,2	68,8	60,6	55,6		37,1%	20,7%	10,8%
13	S2046S	49,5	60,2	56,4	54,8		21,6%	13,9%	10,7%
14	P2505M	51,3	57,6	52,6	51,9		12,3%	2,5%	1,2%
15	R3160L	52,1	62,2	51,2	50,6		19,4%	-1,7%	-2,9%
16	R1784M	60,3	64,9	73,5	75,7		7,6%	21,9%	25,5%
17	P1778A	49,7	62,8	64,2	65,1		26,4%	29,2%	31,0%
18	T4004E	62,5	61,8	59,6	64,7		-1,1%	-4,6%	3,5%
19	M3265G	46,9	70,7	62,9	76,2		50,7%	34,1%	62,5%
20	M3661M	63,1	68,3	65,6	64,7		8,2%	4,0%	2,5%
21	B4300E	43,2	41,1	66,1	61,7		-4,9%	52,9%	42,8%
22	M3754L	50,0	52,5	54,2	53,3		5,1%	8,4%	6,7%
23	B4254N	60,0	69,3	61,7	58,2		15,6%	2,8%	-3,0%
24	V4293N	47,0	46,5	49,8	50,8		-1,1%	6,0%	8,2%
25	M4645S	50,0	52,4	58,3	58,0		4,8%	16,6%	16,0%
26	G4255P	48,5	52,4	54,8	56,2		8,1%	13,0%	15,8%
27	F3736S	42,3	41,6	43,3	40,0		-1,7%	2,4%	-5,4%
28	M4022P	44,6	45,9	46,5	42,3		3,1%	4,4%	-5,1%
29	P2541S	42,9	44,6	48,8	48,8		3,9%	13,8%	13,8%
30	M3679L	56,5	57,3	60,2	55,1		1,5%	6,7%	-2,4%
	Mean	53,0	58,3	59,1	60,0		10,0%	12,0%	13,6%
	SEM	1,2	1,6	1,6	1,8	Max	50,7%	52,9%	62,5%
	TEST.t vs T0	--	0,000	0,000	0,000	Min	-4,9%	-6,5%	-5,4%

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

GRAPH 4 - The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean ± SEM. Above the error bar the intragroup statistical analysis is reported as follows: *** p<0.001; ** p<0.01; * p<0.05.



Comment: As it is possible to notice, the tested product determines a statistically significant increase of skin moisturization at each experimental monitored check; +10% at T14, +12% at T28 and +13.6% at T42.

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

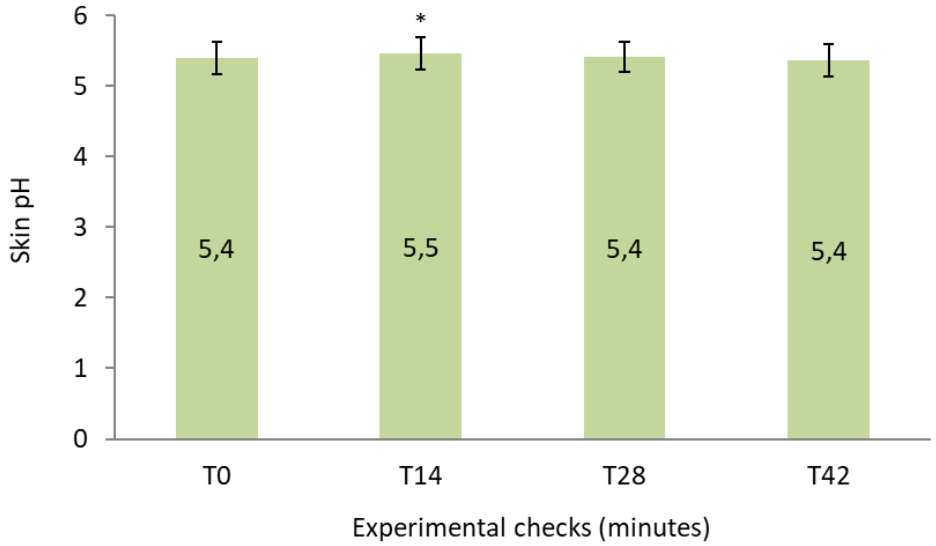
SKIN pH

TABLE 5 - The table below reports the raw data obtained for each subject participating in the study for the analyzed skin parameters. Data are expressed as pH values.

n.	Vol ID	T0	T14	T28	T42	Variation % vs T0	T14	T28	T42
01	P1599P	4,3	4,3	4,4	4,4		0,7%	3,0%	3,3%
02	B1081G	4,4	4,3	4,3	4,3		-1,1%	-2,7%	-2,1%
03	P4545D	4,4	4,5	4,3	4,3		4,4%	-0,9%	-0,5%
04	A0849R	4,3	4,3	4,2	4,4		0,0%	-1,2%	2,6%
05	V1228M	4,3	4,3	4,4	4,3		0,7%	2,8%	1,4%
06	G4267I	4,2	4,3	4,5	4,3		1,4%	5,2%	1,7%
07	M1519D	4,5	4,5	4,4	4,4		-0,2%	-2,7%	-3,1%
08	C3710P	4,4	4,4	4,4	4,3		0,0%	1,8%	-2,5%
09	C2901S	4,4	4,4	4,4	4,3		-0,9%	0,7%	-2,3%
10	M1950M	4,3	4,2	4,4	4,2		-3,2%	1,9%	-2,8%
11	A3893A	6,0	6,2	6,1	6,3		4,0%	1,7%	5,0%
12	P4241M	7,1	7,4	6,9	7,4		4,1%	-3,4%	3,6%
13	S2046S	7,2	7,4	7,0	7,2		2,5%	-2,6%	0,6%
14	P2505M	7,3	7,2	7,1	7,2		-1,4%	-1,7%	-0,7%
15	R3160L	7,0	7,0	6,8	6,8		0,6%	-1,9%	-1,9%
16	R1784M	7,2	7,2	6,9	7,0		0,0%	-3,6%	-2,8%
17	P1778A	6,9	7,0	7,4	7,1		1,2%	7,2%	2,9%
18	T4004E	7,1	7,3	7,0	7,2		3,1%	-1,4%	1,4%
19	M3265G	7,1	7,3	7,1	6,8		2,8%	0,0%	-3,9%
20	M3661M	7,6	7,4	7,0	7,3		-2,8%	-8,1%	-4,1%
21	B4300E	5,0	5,3	5,1	4,8		5,6%	2,2%	-4,8%
22	M3754L	4,8	5,0	4,9	4,8		3,5%	1,4%	-0,6%
23	B4254N	4,4	4,5	4,3	4,5		2,7%	-2,7%	3,2%
24	V4293N	4,3	4,4	4,5	4,3		0,7%	2,8%	-0,7%
25	M4645S	5,2	5,3	5,4	5,3		2,3%	4,2%	1,7%
26	G4255P	4,3	4,4	4,4	4,0		0,2%	1,2%	-6,9%
27	F3736S	4,7	4,9	5,0	4,6		3,4%	5,8%	-2,1%
28	M4022P	5,1	5,0	5,4	5,1		-1,6%	6,1%	0,0%
29	P2541S	5,3	5,3	5,0	5,0		-0,6%	-5,3%	-6,6%
30	M3679L	5,1	5,1	5,6	5,0		0,2%	9,9%	-1,4%
	Mean	5,4	5,5	5,4	5,4		1,1%	0,7%	-0,7%
	SEM	0,2	0,2	0,2	0,2	Max	5,6%	9,9%	5,0%
	TEST.t vs T0	--	0,013	0,685	0,217	Min	-3,2%	-8,1%	-6,9%

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

GRAPH 5 - The graph sets out the mean data obtained at each experimental time for the parameter under study. Data are expressed as a mean ± SEM. Above the error bar the intragroup statistical analysis is reported as follows: *** p<0.001; ** p<0.01; * p<0.05.



Comment: As it is possible to notice, pH mean value keeps almost unvaried during the study; the significant increase find out at T14 it's not considered clinically important. In general the tested product doesn't alter the basal skin conditions.

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

SELF-ASSESSMENT

TABLE 6 - The table shows the results obtained from the questionnaire filled in by each volunteer after the first product application are summarized. The results are expressed as percentage (%) of subjects who expressed the same opinion among those proposed.

No.	After first product application	Very pleasant	Pleasant	Neither pleasant nor unpleasant	Unpleasant	Very unpleasant	Positive answers
01	What do you think about the product aspect?	23,3%	73,3%	3,3%	0,0%	0,0%	96,7%
02	What do you think about the product texture?	20,0%	80,0%	0,0%	0,0%	0,0%	100,0%
03	What do you think about the product fragrance?	26,7%	40,0%	33,3%	0,0%	0,0%	66,7%
04	What do you think about product spreadibility?	23,3%	70,0%	6,7%	0,0%	0,0%	93,3%
No.		Very good	Good	Not good	Bad	--	Positive answers
05	What do you think about product penetration?	30,0%	63,3%	6,7%	0,0%	--	93,3%
No.		Silky	Soft	Sticky	Oily	--	Positive answers
06	What is the after feel on the skin?	33,3%	60,0%	3,3%	3,3%	--	93,3%
No.		Very good	Good	Not good	Bad	--	Positive answers
07	What is your overall appreciation of this product?	26,7%	73,3%	0,0%	0,0%	--	100,0%
No.	After the application	Intense	Moderate	Slightly	Not at all	--	Positive answers
08	Have you noticed an amelioration of skin nourishment?	10,0%	26,7%	63,3%	0,0%	--	36,7%
09	Have you noticed an amelioration of skin softness?	13,3%	43,3%	40,0%	3,3%	--	56,7%
Other comments							
More hydrated skin (1 subject); It absorbs quickly, good spreadability (1 subject); I feel my skin soft (1 subject).							

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

TABLE 7 - The table shows the results obtained from the questionnaire filled in by each volunteer after 42 days of product use are summarized. The results are expressed as percentage (%) of subjects who expressed the same opinion among those proposed.

No.	After 7 weeks of application, have you noticed that:	Agree	Moderately agree	Not completely agree	Not agree	Positive answers
1a	Your skin is more moisturized	73,3%	26,7%	0,0%	0,0%	100,0%
1b	Your skin is smoother	63,3%	33,3%	3,3%	0,0%	96,7%
1c	Fine lines and wrinkles are less visible	36,7%	50,0%	13,3%	0,0%	86,7%
1d	Puffiness appear reduced (15 subjects)	33,3%	60,0%	6,7%	0,0%	93,3%
1e	Dark circles appear reduced (15 subjects)	26,7%	60,0%	6,7%	6,7%	86,7%
1f	Eye contour looks refreshed and younger	36,7%	56,7%	6,7%	0,0%	93,3%
No.	After application, the following issues seem improved:	Strongly improved	Improved	Unchanged	Aggravated	Positive answers
2a	Dehydration	13,3%	76,7%	10,0%	0,0%	90,0%
2b	Puffiness (15 subjects)	0,0%	86,7%	13,3%	0,0%	86,7%
2c	Dark circles (15 subjects)	20,0%	60,0%	20,0%	0,0%	80,0%
2d	Fines lines and wrinkles	13,3%	73,3%	13,3%	0,0%	86,7%
No.		Yes	No	--	--	Positive answers
03	When you have used the product, have you felt uncomfortable sensations?	0,0%	100,0%	--	--	100,0%
No.		Yes	No			Positive answers
4a	If yes, have you stopped the application?	--	--	--	--	--
4b	If the treatment has been stopped, has it been stopped for a skin reaction?	--	--	--	--	--
4c	Have you stopped the treatment for other reasons? If yes, specify why.	0,0%	100,0%	--	--	100,0%
No.	Subsequent use of the product	Yes	No	--	--	Positive answers
05	Would you continue using this product?	96,7%	3,3%	--	--	96,7%
No.		Luxe	Masstige	Mass market		Positive answers
06	According to you, this product is sold in which market segm	13,3%	83,3%	3,3%	--	--
No.		Absolutely yes	Maybe	Probably not	Absolutely not	Positive answers
07	Would you buy this product independently from price?	30,0%	56,7%	13,3%	0,0%	86,7%

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

TABLE 8 - The table shows the results obtained from the questionnaire filled in by the volunteers enrolled for study IT0000385/20-A and IT0000385/20-B after the first product application. The results are expressed as percentage (%) of subjects who expressed the same opinion among those proposed.

No.	After first product application	Very pleasant	Pleasant	Neither pleasant nor unpleasant	Unpleasant	Very unpleasant	Positive answers
01	What do you think about the product aspect?	25,0%	65,0%	10,0%	0,0%	0,0%	90,0%
02	What do you think about the product texture?	26,7%	68,3%	5,0%	0,0%	0,0%	95,0%
03	What do you think about the product fragrance?	25,0%	38,3%	31,7%	5,0%	0,0%	63,3%
04	What do you think about product spreadibility?	30,0%	66,7%	3,3%	0,0%	0,0%	96,7%
No.		Very good	Good	Not good	Bad	--	Positive answers
05	What do you think about product penetration?	38,3%	58,3%	3,3%	0,0%	--	96,7%
No.		Silky	Soft	Sticky	Oily	--	Positive answers
06	What is the after feel on the skin?	35,0%	56,7%	6,7%	1,7%	--	91,7%
No.		Very good	Good	Not good	Bad	--	Positive answers
07	What is your overall appreciation of this product?	25,0%	75,0%	0,0%	0,0%	--	100,0%
No.	After the application	Intense	Moderate	Slightly	Not at all	--	Positive answers
08	Have you noticed an amelioration of skin nourishment?	8,3%	45,0%	43,3%	3,3%	--	53,3%
09	Have you noticed an amelioration of skin softness?	11,7%	53,3%	31,7%	3,3%	--	65,0%
Other comments							
More hydrated skin (1 subject); It absorbs quickly, good spreadability (1 subject); I feel my skin soft (1 subject).							

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
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SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

TABLE 9 - The table shows the results obtained from the questionnaire filled in by the volunteers enrolled for study IT0000385/20-A and IT0000385/20-B at the end of the study. The results are expressed as percentage (%) of subjects who expressed the same opinion among those proposed.

No.	After 7 weeks of application, have you noticed that:	Agree	Moderately agree	Not completely agree	Not agree	Positive answers
1a	Your skin is more moisturized	75,0%	25,0%	0,0%	0,0%	100,0%
1b	Your skin is smoother	63,3%	31,7%	5,0%	0,0%	95,0%
1c	Fine lines and wrinkles are less visible	41,7%	46,7%	10,0%	1,7%	88,3%
1d	Puffiness appear reduced (15 subjects)	36,7%	46,7%	10,0%	6,7%	83,3%
1e	Dark circles appear reduced (15 subjects)	43,3%	40,0%	10,0%	6,7%	83,3%
1f	Eye contour looks refreshed and younger	41,7%	48,3%	10,0%	0,0%	90,0%
No.	After application, the following issues seem improved:	Strongly improved	Improved	Unchanged	Aggravated	Positive answers
2a	Dehydration	20,0%	73,3%	6,7%	0,0%	93,3%
2b	Puffiness (15 subjects)	0,0%	80,0%	20,0%	0,0%	80,0%
2c	Dark circles (15 subjects)	13,3%	66,7%	20,0%	0,0%	80,0%
2d	Fines lines and wrinkles	11,7%	75,0%	13,3%	0,0%	86,7%
No.		Yes	No	--	--	Positive answers
03	When you have used the product, have you felt uncomfortable sensations?	0,0%	100,0%	--	--	100,0%
No.		Yes	No			Positive answers
4a	If yes, have you stopped the application?	--	--	--	--	--
4b	If the treatment has been stopped, has it been stopped for a skin reaction?	--	--	--	--	--
4c	Have you stopped the treatment for other reasons? If yes, specify why.	0,0%	100,0%	--	--	100,0%
No.	Subsequent use of the product	Yes	No	--	--	Positive answers
05	Would you continue using this product?	96,7%	3,3%	--	--	96,7%
No.		Luxe	Masstige	Mass market		Positive answers
06	According to you, this product is sold in which market segm	11,7%	81,7%	6,7%	--	--
No.		Absolutely yes	Maybe	Probably not	Absolutely not	Positive answers
07	Would you buy this product independently from price?	23,3%	65,0%	11,7%	0,0%	88,3%

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

CONCLUSIONS

According to the obtained results we can conclude that the tested product:

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after 42 day-use under dermatological control, it determined the following variations of the instrumental analyzed skin parameters:

- a significant reduction of the eye-bags volume by 7.5%*;
- a significant improvement in skin lightness of the eye contour area, confirmed by increased values of ITA° (mean value +30.3%*);
- a statistically significant decrease of crow's feet wrinkles by 23.6%*;
- a statistically significant increase of skin moisturization by 13.6%*,

Moreover, the pH mean value remains almost unvaried, index that the tested product doesn't alter the basal skin conditions.

* statistically significant variation compared to baseline (T0).

The reported % are referred to the mean variations of the analyzed parameter versus T0

Finally, the product was well tolerated (no adverse event occurred during the study period) and it was positively judged for all the investigated aspects by most of the enrolled subjects.

Principal experimenter

Dr. Gloria Roveda

Digitally signed by Dr. Roveda Gloria
Date: 2020.09.14 06:32:31 +02'00'

Data analysis and report

Dr. Federica Ruggeri

Digitally signed by Federica Ruggeri
Date: 2020.09.11 15:59:16 +02'00'

Study director

Dr. Ileana De Ponti

Digitally signed by Ileana De Ponti
Date: 2020.09.16 17:34:20 +02'00'

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

Annex 1 – digital pictures

UNDER EYE BAGS – Volunteer 20

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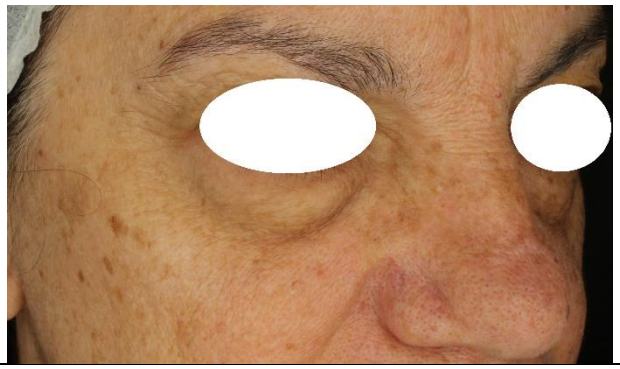	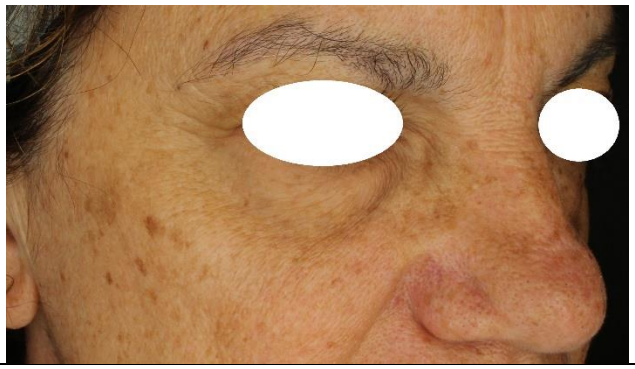
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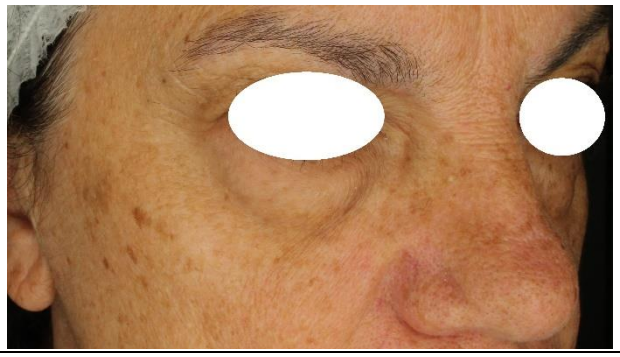	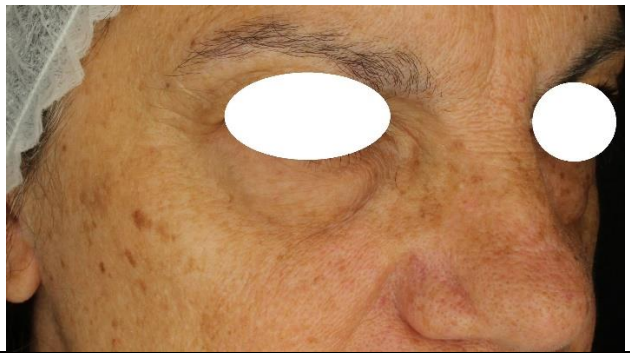

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
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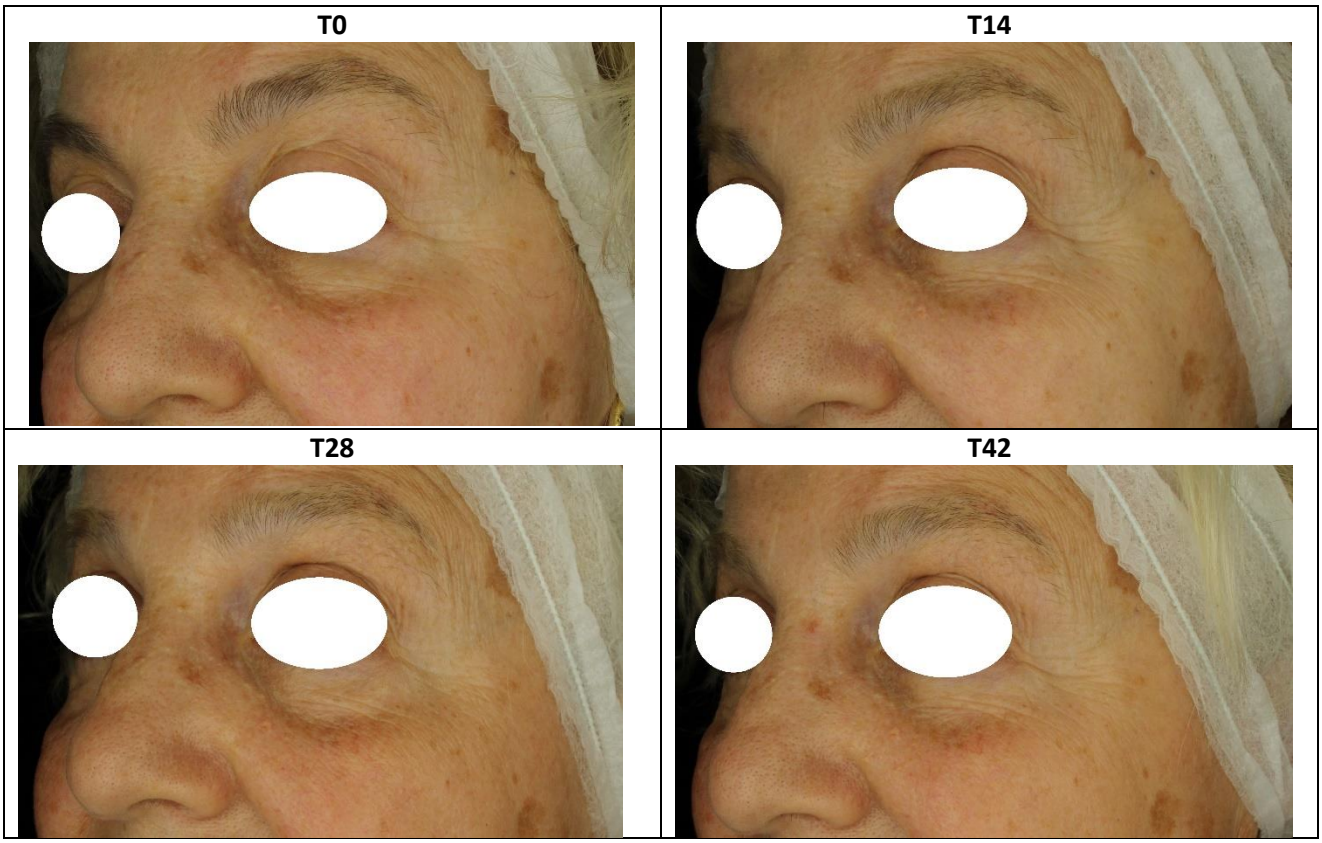
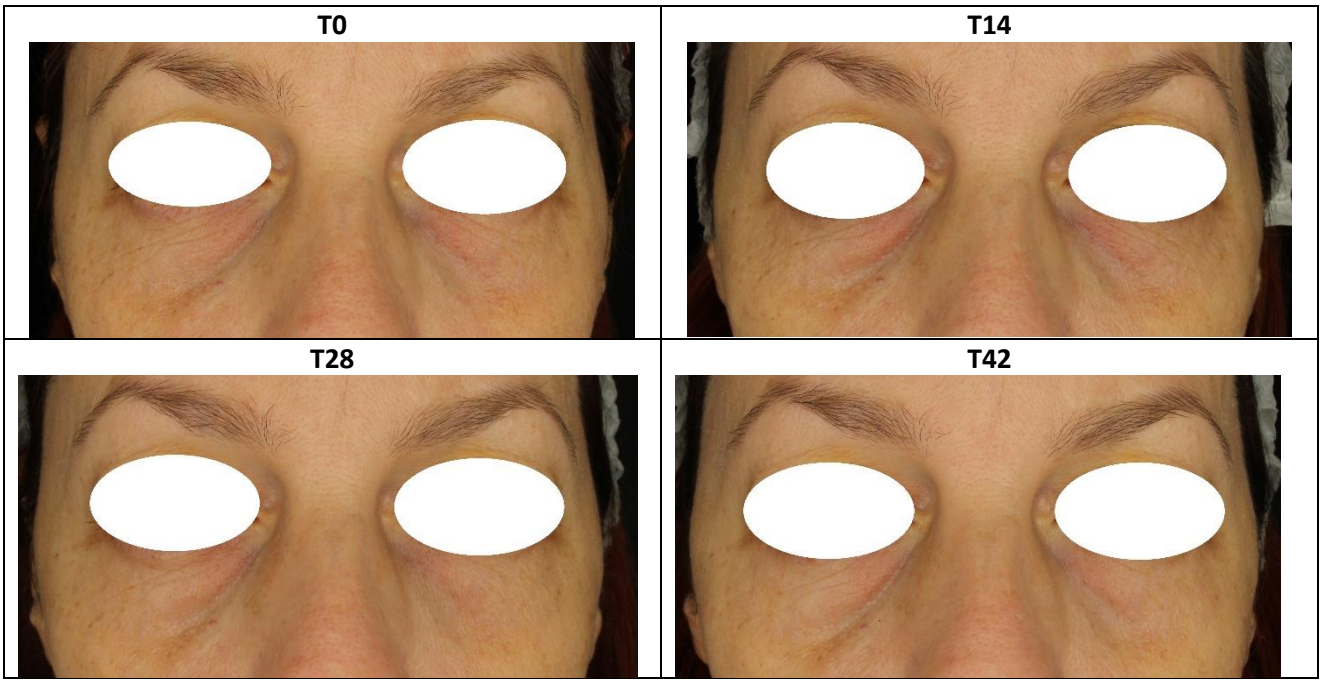
UNDER EYE BAGS – Volunteer 30

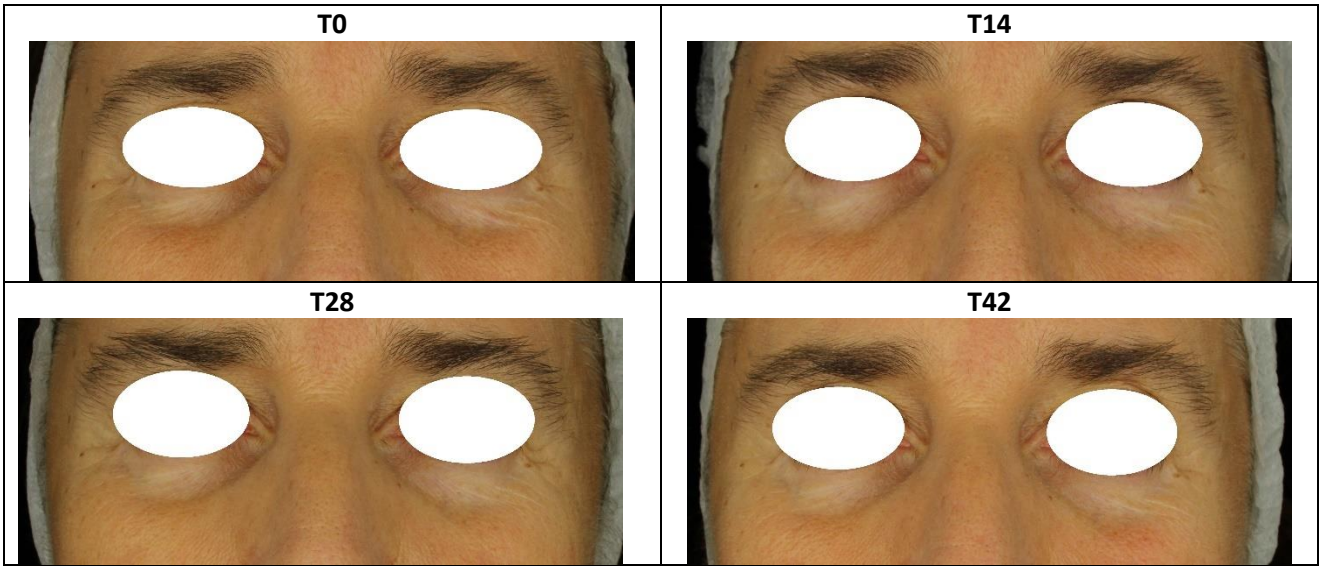


COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

DARK CIRCLES – Volunteer 15



DARK CIRCLES – Volunteer 9



COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

WRINKLE DEPTH – DIGITAL PICTURES– Volunteer 6

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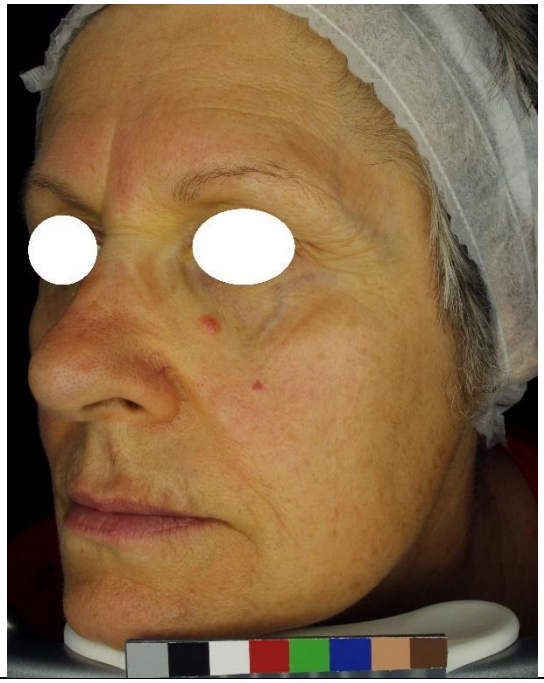	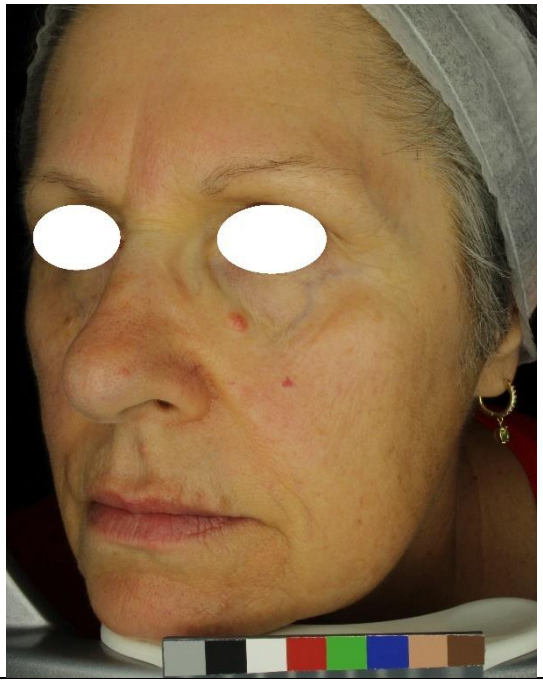
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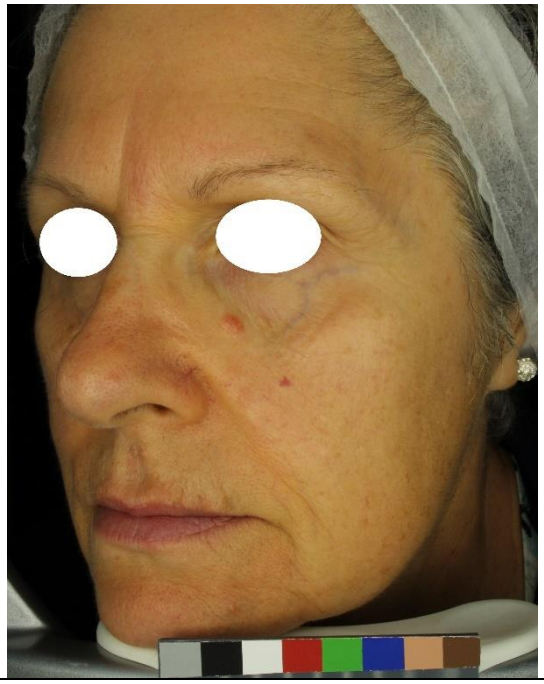
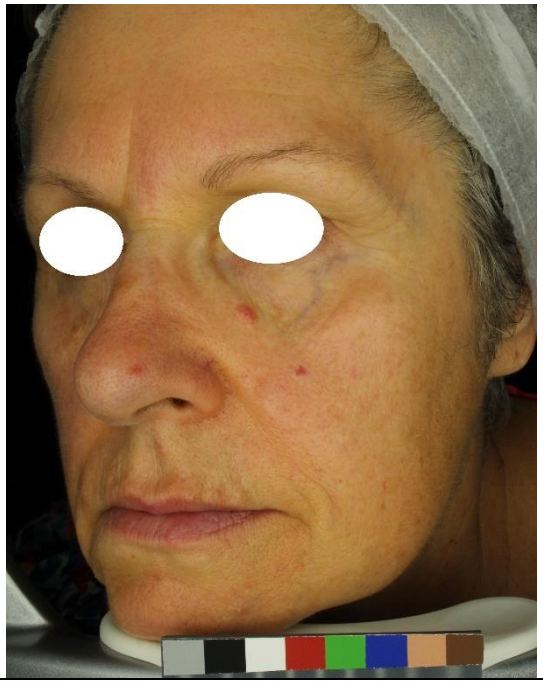
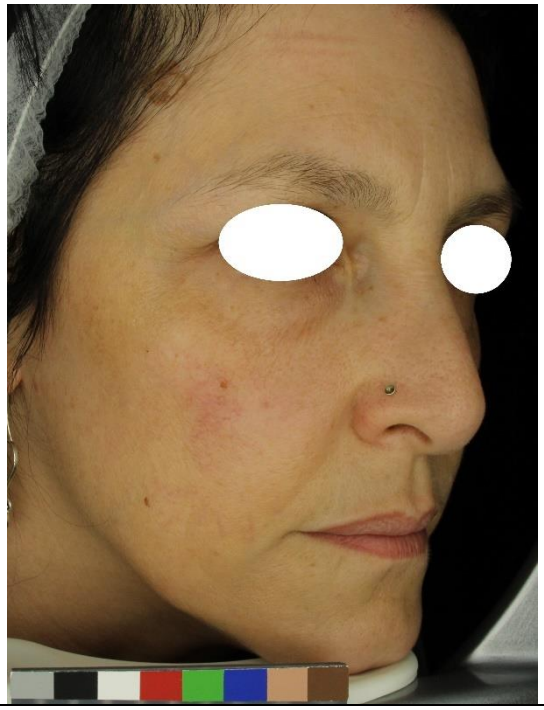
	

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

WRINKLE DEPTH – DIGITAL PICTURES – Volunteer 23

T0



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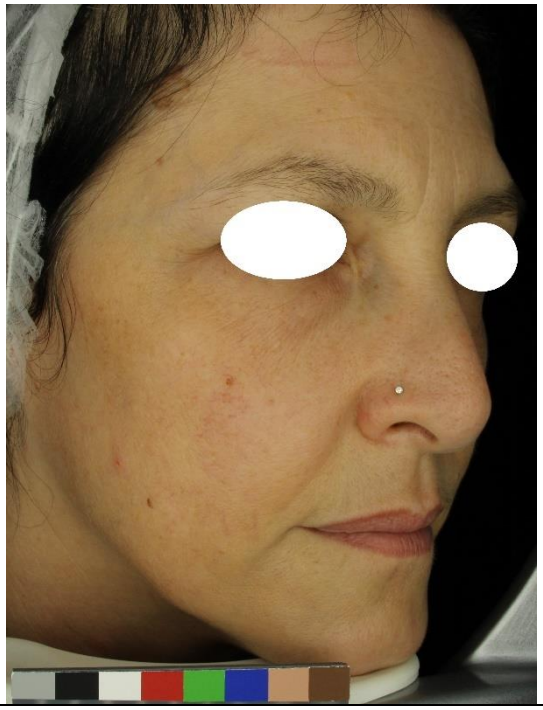

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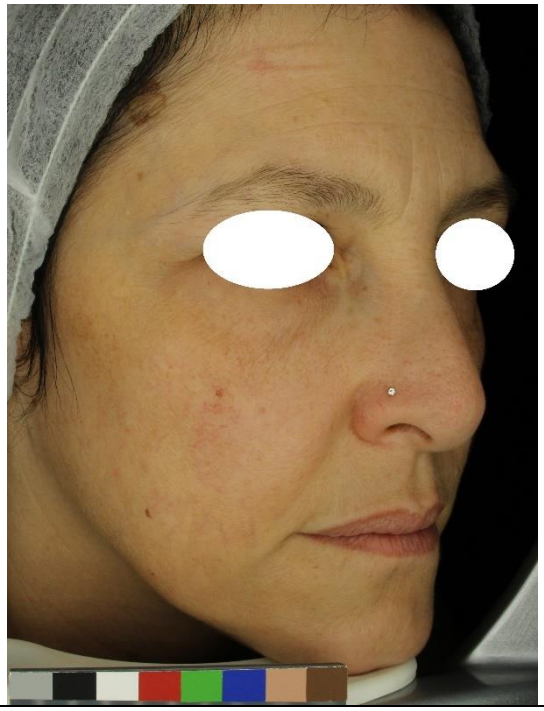

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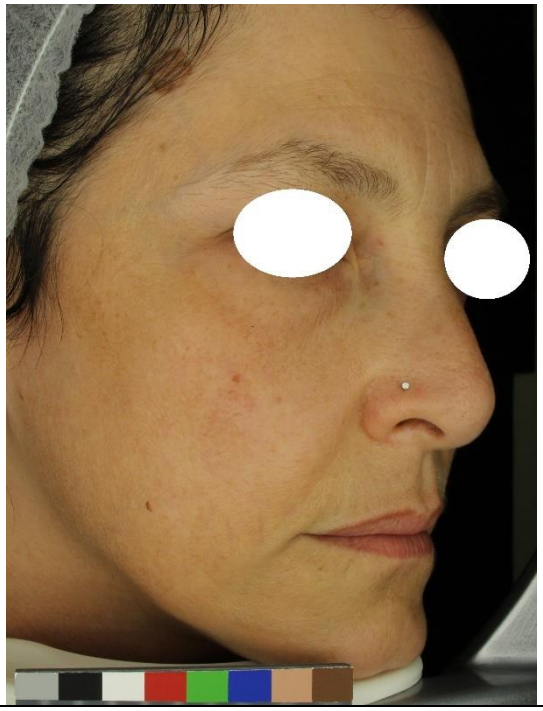
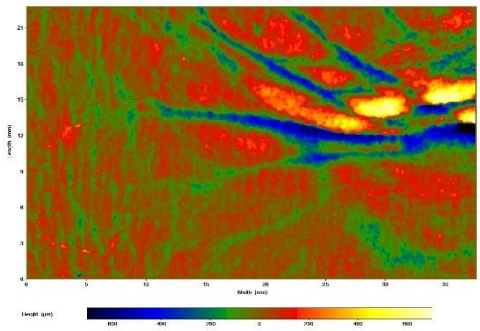
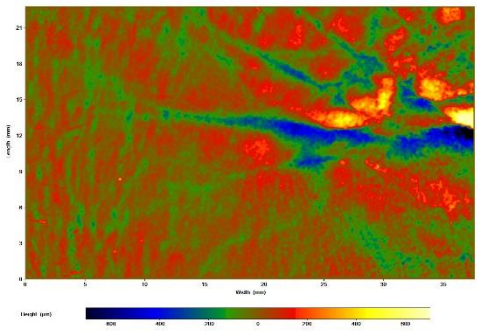


COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

WRINKLE DEPTH – PRIMOS PICTURES – Volunteer 8

T0	T14
	
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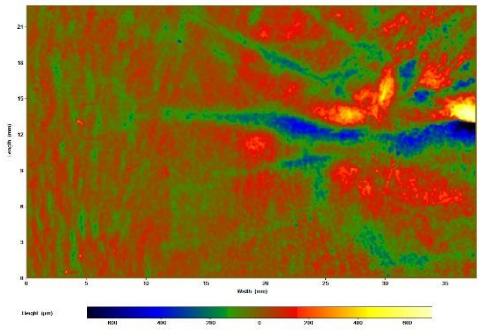
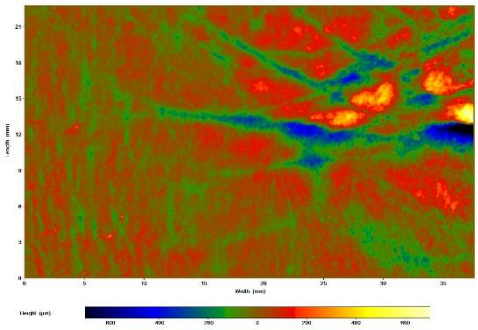
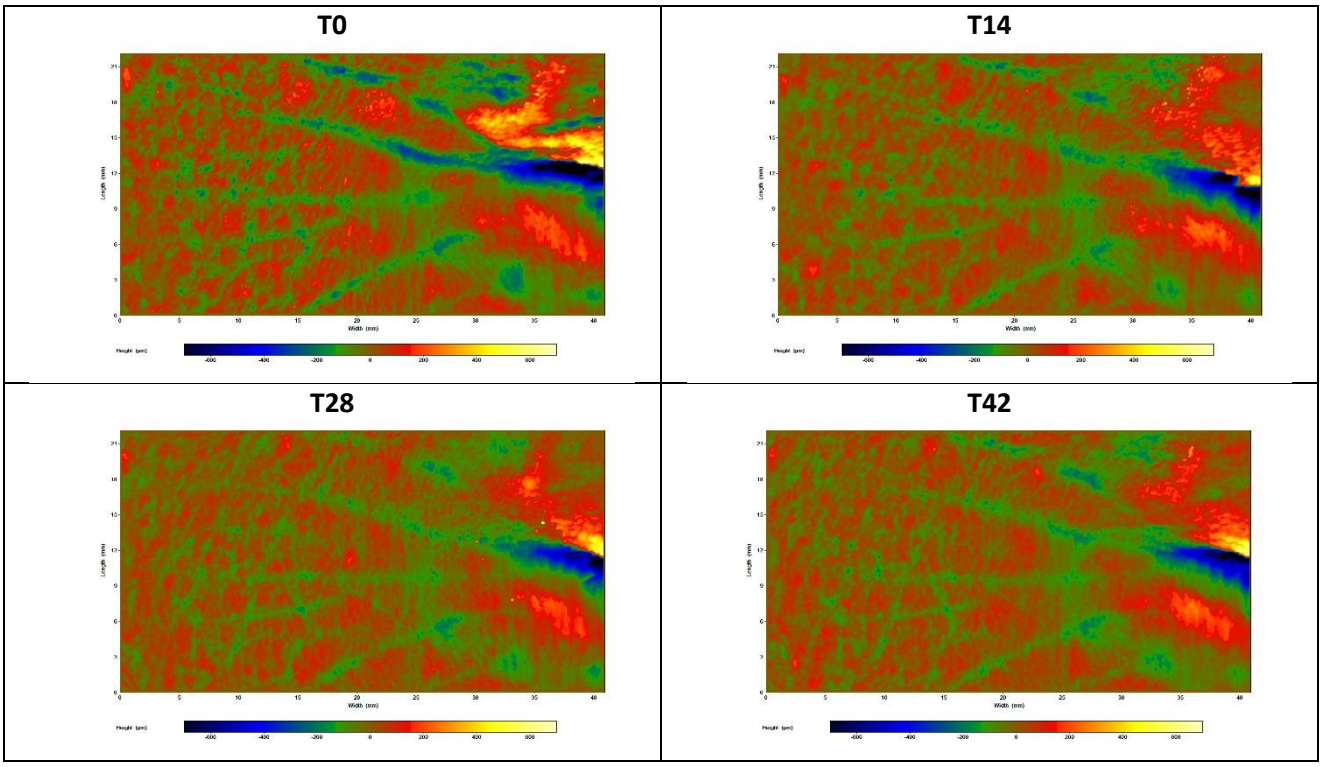
	

COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504

WRINKLE DEPTH – PRIMOS PICTURES – Volunteer 26



COMPLIFE Italia S.r.l.
info@complifegroup.com
complifeitalia@legalmail.it
complifegroup.com
GARBAGNATE MILANESE (MI), Via Guido Rossa 1, 20024 I +39.02.990.25138
SAN MARTINO SICCOMARIO (PV), Via Monsignor Angelini 21, 27028 I +39.0382.25504