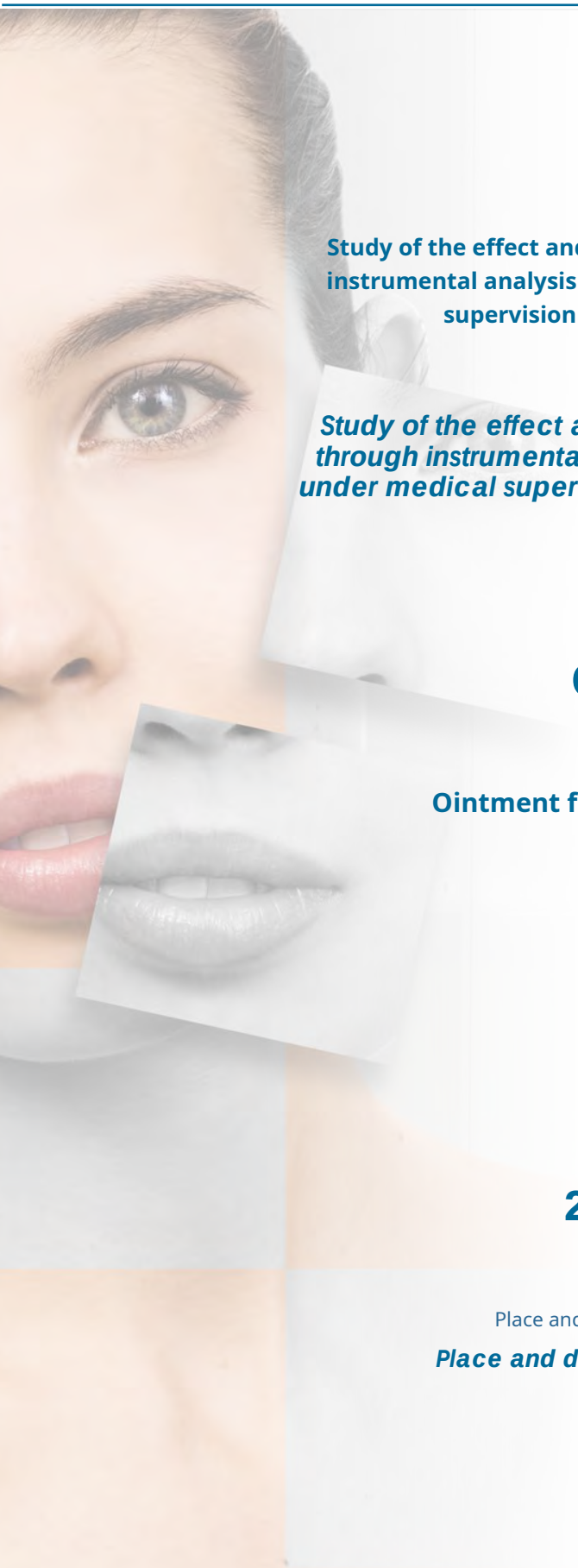


Study of the effect and cosmetic properties of a product through instrumental analysis performed by professionals under medical supervision and consumer self-assessments.

Study of the effect and cosmetic properties of a product through instrumental analysis performed by professionals under medical supervision and consumer self-assessments.

Crystal srl

Ointment for very dry skin REF 1111213L

Report

2130M17F1-1

Place and date of issue: MILAN - 11/04/2022

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www.biobasiceurope.it
VAT no. 11930080152

INTRODUCTION

The clinical trial protocols are audited and approved by the Technical Scientific Committee (TSC) of Bio Basic Europe S.r.l., whose functions, compositions and procedures are described in the document "Statute - Regulation" (Ann. C). The TSC ascertains the protocol's completeness, confirms the adequacy of the documentation and the conformity of the procedures and methodologies followed in designing and developing the research project, in compliance with the applicable legislation. The protocol is audited by at least the following mandatory members of the TSC:

a) The Chairman and/or the Vice Chairman of the TSC
b) The University of Pavia Director of Research
c) The Investigator/Medical Director of the CDC Dermo Clinical Research Institute
d) The expert of Bio Basic Europe S.r.l. depending on the issue on which the opinion is formulated

The final report is signed by the Investigator/Medical Director of the CDC Dermo Clinical Research Institute and, subsequently, by the Safety Assessor, who attests the document's validity, affixing a digital signature.

PERSONS RESPONSIBLE FOR SIGNING THE PROTOCOL

Safety Assessor
CLAUDIO ANGELINETTA, Vice Chairman of the Technical Scientific Committee, Chemist/Cosmetic Chemist, Degree in Chemistry, Specialisation in Cosmetic Sciences and Technologies, University of Milan.

Investigator
Dr. FERNANDO MARCO BIANCHI M.D., Bio Basic Europe S.r.l. CDC Dermo-Clinical Research Institute Health Director, medical surgeon specialist in dermatology and venereology.

LEGAL AND CONTRACTUAL INFORMATION

- *The protocols are drafted in accordance with the applicable legislation, the guidelines of the Technical Scientific Committee and the provisions of the research contracts in force between Bio Basic Europe S.r.l. and the University of Pavia (contract dated 01/09/2019 and further renewals with the L. Spallanzani Faculty of Biology and Biotechnologies).*
- *In accordance with the applicable regulatory framework and the Helsinki declaration* (Regulation (EC) no. 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetic products), *the volunteers are adequately informed of the purpose, the methods and the characteristics of the clinical study, the beneficial effects and the possible side effects. Each volunteer signs the informed consent form as a sign of acceptance, which is managed and archived in accordance with the internal procedures of the Quality Management System of Bio Basic Europe S.r.l.*
- *This clinical trial was conducted at the CDC Dermo Clinical Research Institute, in accordance with the guidelines dictated by the Technical Scientific Committee.*
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- *Based on the experience of Bio Basic Europe, it is recommended to check, once every three years, its harmonisation with any regulatory update.*
- *This final technical report was drafted by: ANTONELLA PRATICO', Bio Basic Europe Clinical Test Reporting Coordinator, Master's Degree in Natural Sciences, University of Milan, II Level Master's Degree in Evaluation and control of the toxicological risk caused by environmental pollutants.*

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ABSTRACT

The primary objective of this clinical trial is to assess whether the cosmetic product Ointment for very dry skin REF 1111213L has a moisturizing effect. The activity of the product was evaluated by analysing the increase in skin moisturization. The trial also had the following secondary objective: to assess the perceived pleasantness and effect of the product.

A clinical study was therefore conducted, and the test product was assigned to 20 enrolled subjects. They applied the product to the body. Specific endpoint variables were analysed at baseline (before product use) and 15 and 30 minutes after application.

The results demonstrate a moisturizing effect of the product, which was the primary objective of the study: after product use, an improvement was observed in all primary endpoints studied. In parallel, good product pleasantness and effect were perceived.

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The results demonstrate a moisturizing effect of the product, which was the primary objective of the study: after product use, an improvement was observed in all primary endpoints studied. In parallel, good product pleasantness and effect were perceived.

Along with this phenomenon, it was also observed : a good pleasantness and effect of the product were perceived.

OBJECTIVES

Primary objective

The aim of this study is to assess whether the cosmetic product Ointment for very dry skin REF 1111213L has a moisturizing effect.

Primary endpoints:

- Skin moisturization (quantitative endpoint)

Secondary objectives

The secondary objectives were designed to substantiate and confirm the primary objective.

A series of sensory self-evaluations were collected from the enrolled subjects to assess the effect and pleasantness of use of the product.

Secondary endpoints:

- Subjective evaluations (quantitative discrete endpoint)

Primary objective

The aim of this study is to assess whether the cosmetic product Ointment for very dry skin REF 1111213L has a moisturizing effect.

Primary endpoints:

- *skin moisturization (quantitative endpoint)*

Secondary objectives

The secondary objectives were designed to substantiate and confirm the primary objective.

Furthermore, a series of sensory self-evaluations were collected by the enrolled subjects, with the aim of evaluating the effect and pleasantness of use of the product.

Secondary endpoints:

- *subjective evaluations (quantitative discrete endpoint)*

STUDY CHARACTERISTICS

Study design

The effect of the product was evaluated by comparing the results obtained after the application with the baseline data.

The perceived pleasantness and effect were evaluated by analysing the results obtained after the application of the product.

Sample size

Based on Bio Basic Europe experience, by considering the type of product, the objectives of the trial and taking into account any possible drop-out, the sample size is composed of 20 subjects.

Eligibility criteria

The subjects participating in the study were screened under medical supervision and enrolled according to the following inclusion criteria:

- *both male and female sex;*
- *very dry skin*
- *sensitive skin*
- *history of atopy and psioriasis*
- *age between 18 and 60 years;*
- *good general health status/absence of psychological and/or cognitive disorders;*
- *absence of dermatological and allergological pathologies (cosmetological or to other specific excipients) or other pathologies (such as irritative reactions of unknown origin);*
- *absence of ongoing pharmacological treatments which may affect the outcome of the test;*
- *non-participation in other clinical trials in the previous 30 days;*
- *informed consent obtained.*

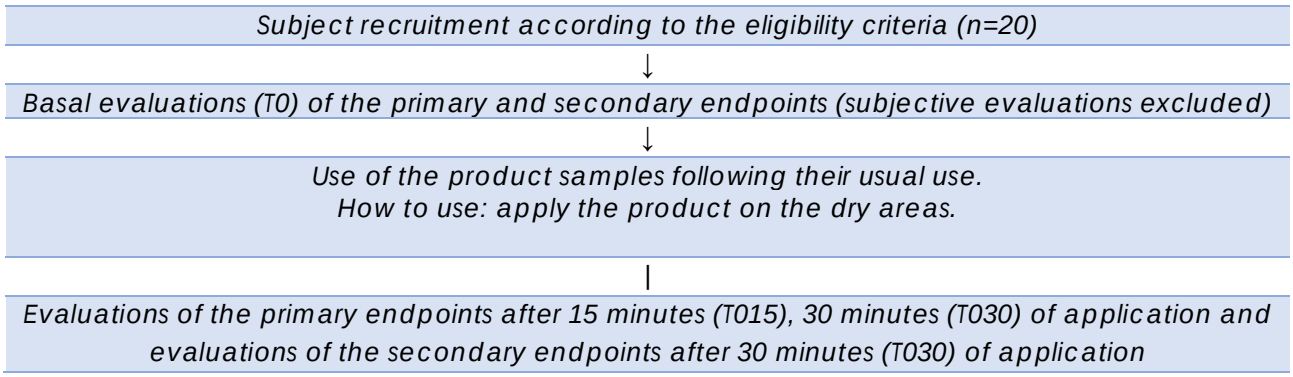
Randomization

Not applicable.

Blindness

The subjects received the product without packaging or indications regarding the manufacturer's brand in order to avoid the distortions caused by the conditioning effect of the awareness of the product.

Trial scheme



Criteria for the subject withdrawal

The following rules were imposed on a possible subject withdrawal which may occur during the trial:

- *breach of one of the inclusion/exclusion criteria;*
- *development of adverse effects.*

Endpoints

- *Quantitative endpoints*

o *Skin moisturisation (instrumental analysis)*
Measured by CORNEOMETER CM 825 (A.U. arbitrary units)

The instrument measures the skin capacitance (quantification of the ability of the skin to collect electrical charge) by application of a high frequency electrical field.
The measurement is based on the principle that skin capacitance depends on the changes in dielectric constant, which are proportional to the water content in skin. With increasing hydration in the stratum corneum, its dielectric constant grows and therefore its capacitance; to clarify, the more the skin is hydrated, the more the stratum corneum becomes a good electric conductor.
Hence the instrument can indirectly detect skin hydration level, using arbitrary units.

- *Quantitative discrete endpoints*

The subjects enrolled in the trial are asked to fill in a survey, which consists of numerical rating scale questions.

Specifically, it is used the 11-point Numerical Rating Scale (NRS), which ranges from 0 to 10 (0 is the minimum value and 10 the maximum one). The answerers are asked to indicate the numeric value which best describe their response.

The basal measurements are carried out in the treatment sites following a rest period of at least 20 minutes in an air-conditioned room with controlled and regulated temperature and humidity (temperature = 21°C +/- 2°C and humidity 40%-60%).

Data analysis and statistical analysis

- *Quantitative endpoints*

  The data on the quantitative endpoint were described using the normal position and dispersion measurements: mean and standard deviation/median and interquartile range.

  A Shapiro-Wilk test was used to verify the normality of the quantitative endpoint variable.

  When the assumptions were fulfilled, a parametric one-way repeated measures analysis of variance model was applied in order to evaluate the effect of the treatment over time. When the sphericity assumption was violated, the Greenhouse-Geisser correction was applied.

  When the result was significant, post-hoc tests were performed.

  In particular, the most appropriate parametric (Student's t test) or non-parametric test (Wilcoxon signed rank test/Sign test) with Bonferroni corrections were used to compare the observation times of interest.

  When the assumptions were violated, a non-parametric approach was applied.

  A non-parametric repeated measures analysis of variance model (Friedman test) was used to evaluate the effect of the treatment over time.

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  In particular, after having verified the symmetry of the distribution of the differences between the paired evaluations, the most appropriate non-parametric test for paired data (Wilcoxon signed rank test/Sign test with Bonferroni corrections) was applied to compare the observation times of interest.

  A significance level of <0.05 was considered.

  Analyses were performed using RStudio Version 1.4.1106 © 2009-2021 RStudio, PBC.

- *Quantitative discrete endpoints*

The data on the quantitative discrete endpoints were described using the median. For each self-evaluation question, the percentage frequencies of each score were calculated.

Finally, the percentage frequencies of the responses were summarized: responses ≥7 and ≥6 were considered respectively as fully positive and positive.

The conclusions about the self-assessment test were drawn from an overall analysis of the medians of responses to all the questions, as shown in the table below:

Overall median	Conclusion
<6	Insufficient pleasantness and perceived effect
6-6.5	Sufficient pleasantness and perceived effect
7-7.5	Moderate pleasantness and perceived effect
8-8.5	Good pleasantness and perceived effect
9-10	Excellent pleasantness and perceived effect

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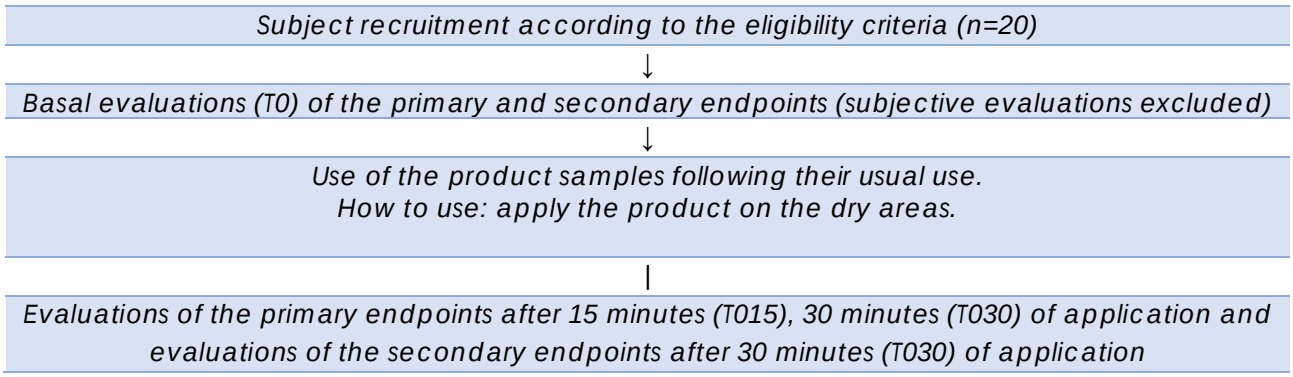
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RESULTS

During the trial, no subject developed undesirable effects or breached the established inclusion/exclusion criteria. Furthermore, there were no drop-outs. Therefore, the analysis refers to a sample of 20 subjects.

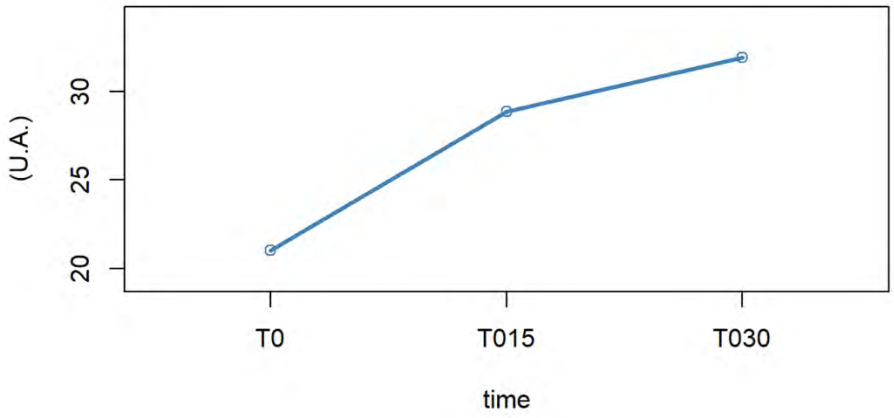
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Skin moisturization

Descriptive analysis

Survey times	Mean	±	Standard deviation	Median	IQR		
T0	21,0	±	3,7	21,4	18,7	-	22,8
T015	28,9	±	4,0	28,5	25,8	-	31,2
T030	31,9	±	4,9	31,0	28,3	-	33,7

Skin moisturization



Compared with the baseline value (T0), skin moisturization increased by:

- 37% after 15 minutes from product application;
- 52% after 30 minutes from product application.

Compared to the baseline value (T0), it can be observed an increase of the variable skin moisturization of:

- *37% after 15 minutes from the product application;*
- *52% after 30 minutes from the product application.*

One-way repeated measures ANOVA

F	df	p-value	significance
61,72	2;38	<0,001	**yes**

One-way repeated measures ANOVA used to evaluate the effect of time on skin moisturization

The table, which presents the analysis of variance, shows a statistically significant effect of time: the treatment had a significant effect on skin moisturization (at least one mean skin-moisturization value at the different observation times differs from the others).

The table, which represents the result of the analysis of variance, shows a statistically significant effect of the variable "time": the treatment had a significant effect on the variable skin moisturization (at least one mean of the variable skin moisturization acquired at all time points is different from the others).

Wilcoxon signed rank test

p-value and significance		
	T0	
T015	<0,001	**yes**
T030	<0,001	**yes**

Post-hoc tests for pairwise comparison of skin moisturization at all observation times

The post-hoc tests showed statistically significant differences among the means of the paired comparisons.

Post-hoc tests showed statistically significant differences among the means of the paired under comparisons.

Questions	Median of responses	% Frequency of responses	
		positive	fully positive
Do you think the product deeply moisturizes your skin? 8 95% 95%			
Do you think the product makes your skin softer and smoother? 8 95% 95%			
Do you think the product is gentle and suitable for your skin? 8 95% 90%			
Do you find the product texture pleasant? 7.5 85% 80%			
Do you find the product's fragrance / olfactory note pleasant? 8 95% 85%			
Do you think the product is easily absorbed by dry skin? 8 90% 90%			
Do you think the product provides relief from itching in dry, delicate areas? 8 95% 75%			
Overall opinion on the product 8 90% 90%			
Would you buy it? 8 90% 90%			

Summary table of the medians calculated from the responses to the self-evaluation questionnaire and the percentage frequencies of positive and fully positive responses

The summary table shows that 85%-95% of enrolled subjects gave a positive response to the questions and 75%-95% gave a fully positive response 30 minutes after product use. Overall, the medians indicate that the subjects perceived good product pleasantness and effect.

CONCLUSIONS

The results obtained demonstrate the primary objective of the study: the moisturizing effect of the product OINTMENT FOR VERY DRY SKIN REF 1111213L. An improvement was observed in all primary endpoints studied after product use. In parallel, good product pleasantness and effect were perceived.

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Investigator

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Safety Assessor / Technical Scientific Committee Vice Chairman

Dr. Claudio ANGELINETTA



BIBLIOGRAPHY

[1] "Regulation (EC) no. 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetic products".

[2] "Declaration of Helsinki - ethical principles for medical research involving human subjects adopted by the 18th wma general assembly, Helsinki, Finland, june 1964, and consecutive amendments (last amendment: 64th wma general assembly, Fortaleza, Brasil, Oc".

[3] "GUIDELINES FOR COSMETIC PRODUCT CLAIM SUBSTANTIATION Revising and expanding the Colipa Guidelines on Efficacy (2001/rev. 2008) 22 May 2019 Cosmetics Europe – The personal care association".

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PRODUCT INFORMATION - INGREDIENT LIST

INCI

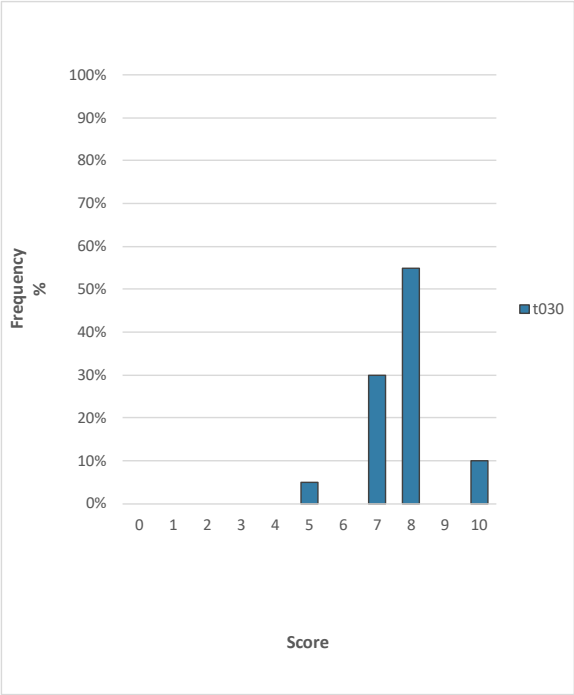
BUTYROSPERMUM PARKII BUTTER (BUTYROSPERMUM PARKII (SHEA) BUTTER), CAPRYLIC/CAPRIC TRIGLYCERIDE, CERA ALBA (BEESWAX), ORYZA SATIVA BRAN OIL (ORYZA SATIVA (RICE) BRAN OIL), CANNABIDIOL, PRUNUS AMYGDALUS DULCIS OIL (PRUNUS AMYGDALUS DULCIS (SWEET ALMOND) OIL), BORAGO OFFICINALIS SEED OIL, LINUM USITATISSIMUM SEED OIL (LINUM USITATISSIMUM (LINSEED) SEED OIL), CAMELLIA OLEIFERA SEED OIL*, HIPPOPHAE RHAMNOIDES FRUIT OIL, TOCOPHEROL, LECITHIN, ETHYL LINOLENATE, ETHYL LINOLEATE, ASCORBYL PALMITATE, PARFUM (FRAGRANCE)
*From organic farming

Skin moisturization (A.U.)			
Vol. n°	**T0**	**T015**	**T030**
1	28,0	37,2	35,2
2	26,0	31,2	46,0
3	17,9	25,4	23,9
4	19,0	34,0	40,0
5	23,9	34,8	33,3
6	19,0	25,9	32,0
7	18,9	23,2	35,4
8	25,5	31,2	32,4
9	22,3	31,2	30,8
10	21,8	28,5	27,7
11	15,6	32,6	30,8
12	21,4	28,2	30,7
13	16,3	22,0	32,0
14	21,4	28,4	27,5
15	26,0	30,1	35,0
16	14,7	24,7	30,1
17	21,4	30,6	28,3
18	18,1	26,6	31,1
19	20,8	25,3	27,3
20	22,4	26,0	28,2

Do you think the product deeply moisturizes your skin?

Vol. n°	Judgement t030
01	8
02	7
03	7
04	8
05	10
06	8
07	8
08	7
09	7
10	8
11	8
12	8
13	8
14	5
15	7
16	8
17	7
18	8
19	8
20	10
Median	8,0

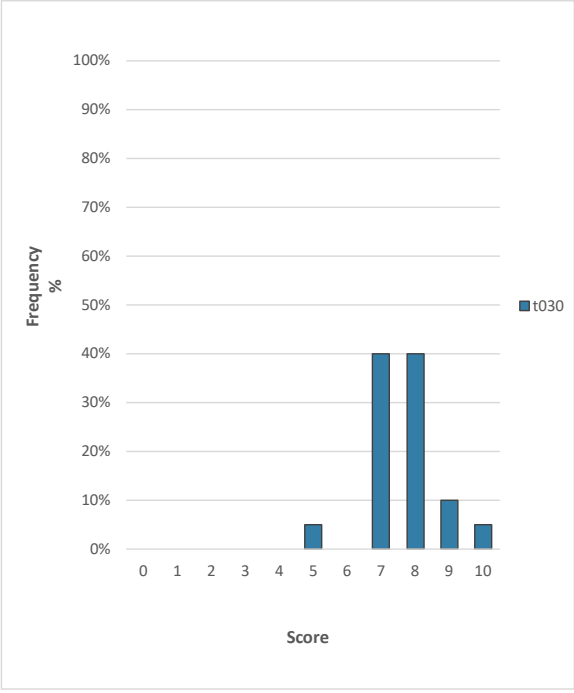
Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	0%
5	5%
6	0%
7	30%
8	55%
9	0%
10	10%



Do you think the product makes your skin softer and smoother?

Vol. n°	Judgement t030
01	7
02	8
03	7
04	8
05	10
06	8
07	8
08	7
09	7
10	8
11	9
12	7
13	8
14	5
15	7
16	8
17	7
18	7
19	8
20	9
Median	8,0

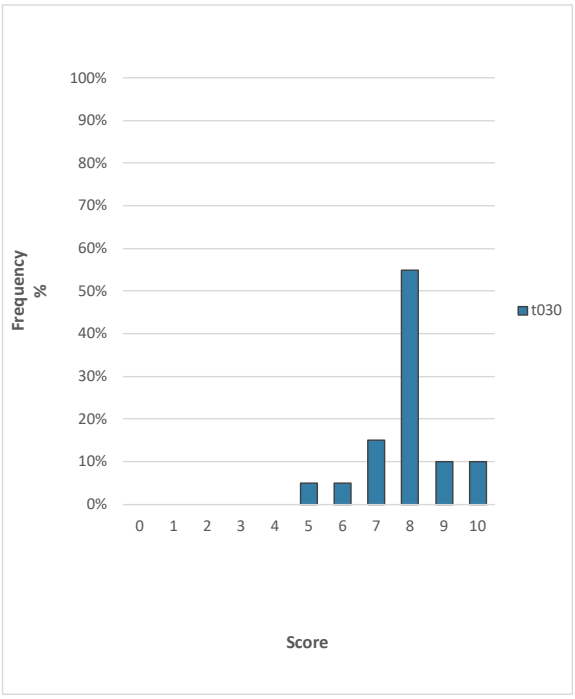
Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	0%
5	5%
6	0%
7	40%
8	40%
9	10%
10	5%



Do you think the product is gentle and suitable for your skin?

Vol. n°	Judgement t030
01	10
02	8
03	7
04	8
05	10
06	8
07	7
08	8
09	6
10	7
11	9
12	8
13	8
14	5
15	8
16	8
17	8
18	8
19	8
20	9
Median	8,0

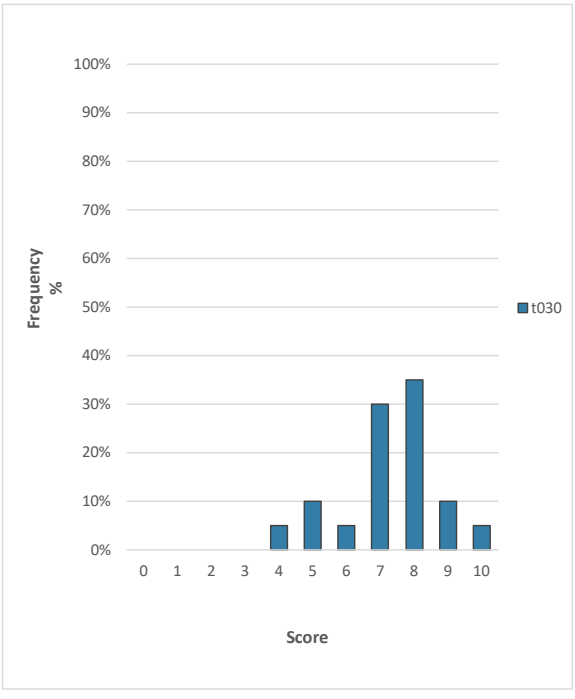
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1	0%
2	0%
3	0%
4	0%
5	5%
6	5%
7	15%
8	55%
9	10%
10	10%



Do you find the product texture pleasant?

Vol. n°	Judgement t030
01	10
02	8
03	7
04	8
05	6
06	7
07	8
08	8
09	5
10	5
11	9
12	7
13	8
14	4
15	7
16	7
17	8
18	8
19	7
20	9
Median	7,5

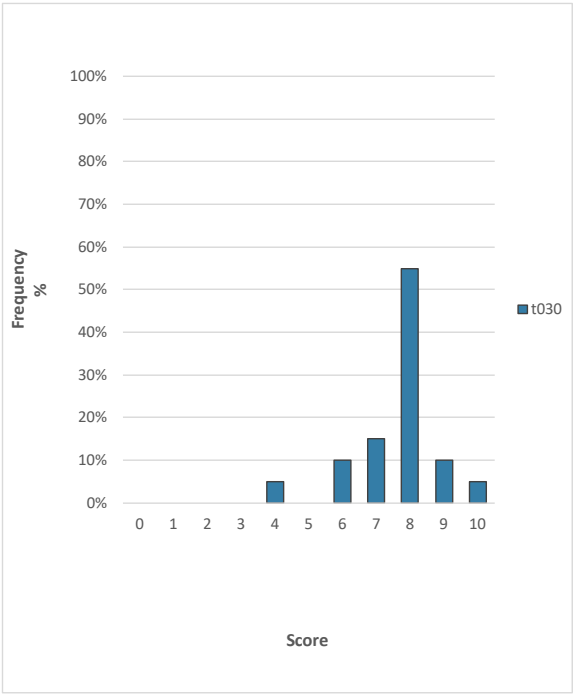
Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	5%
5	10%
6	5%
7	30%
8	35%
9	10%
10	5%



Do you find the product's fragrance / olfactory note pleasant?

Vol. n°	Judgement t030
01	7
02	8
03	7
04	8
05	10
06	6
07	8
08	8
09	6
10	8
11	8
12	9
13	8
14	4
15	8
16	8
17	7
18	8
19	8
20	9
Median	8,0

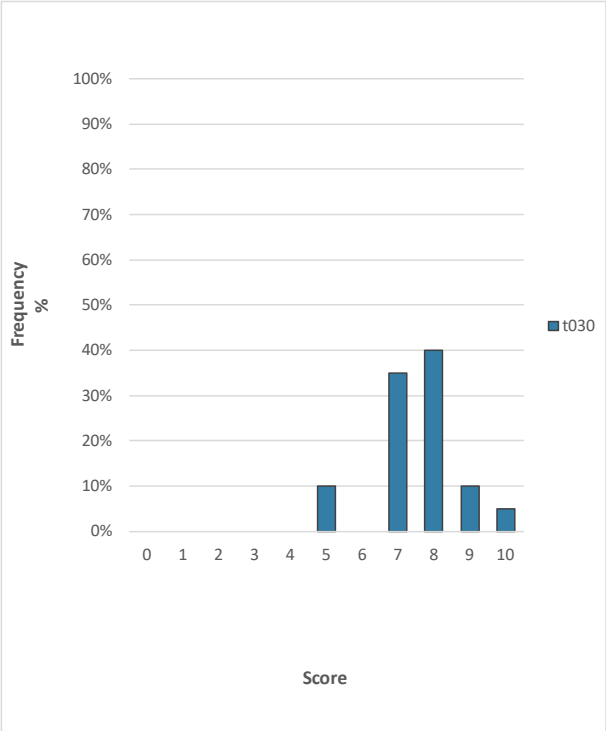
Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	5%
5	0%
6	10%
7	15%
8	55%
9	10%
10	5%



Do you think the product is easily absorbed by dry skin?

Vol. n°	Judgement t030
01	10
02	7
03	5
04	8
05	9
06	7
07	7
08	7
09	7
10	8
11	8
12	8
13	8
14	5
15	7
16	8
17	8
18	8
19	7
20	9
Median	8,0

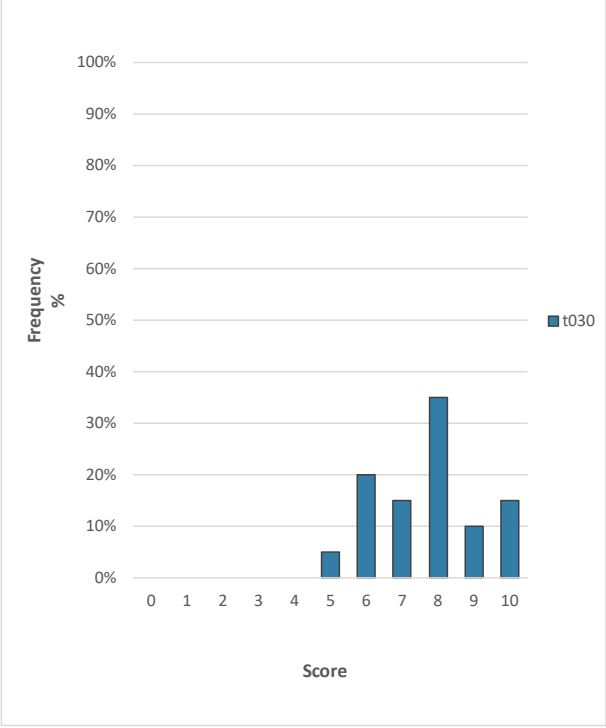
Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	0%
5	10%
6	0%
7	35%
8	40%
9	10%
10	5%



Do you think the product provides relief from itching in dry, more delicate areas?

Vol. n°	Judgement t030
01	10
02	6
03	8
04	8
05	8
06	10
07	8
08	8
09	8
10	7
11	8
12	6
13	10
14	5
15	7
16	9
17	7
18	6
19	6
20	9
Median	8,0

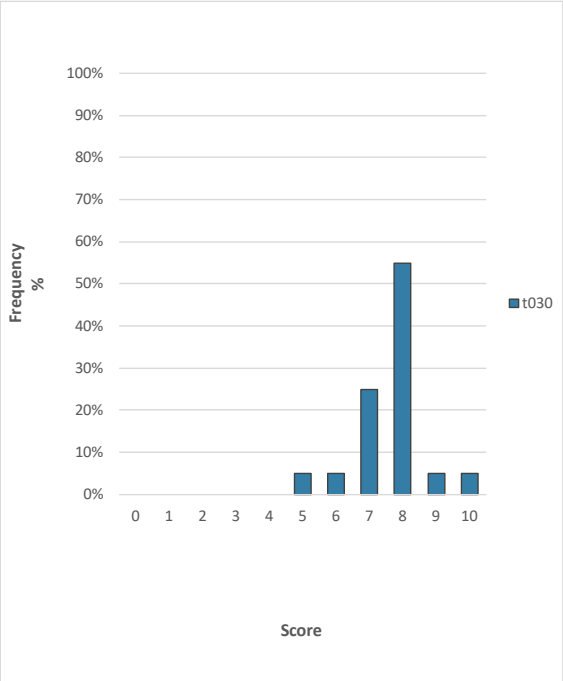
Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	0%
5	5%
6	20%
7	15%
8	35%
9	10%
10	15%



Overall opinion on the product

Vol. n°	Judgement t030
01	8
02	8
03	7
04	8
05	10
06	8
07	8
08	7
09	6
10	8
11	7
12	8
13	8
14	5
15	8
16	7
17	8
18	7
19	8
20	9
Median	8,0

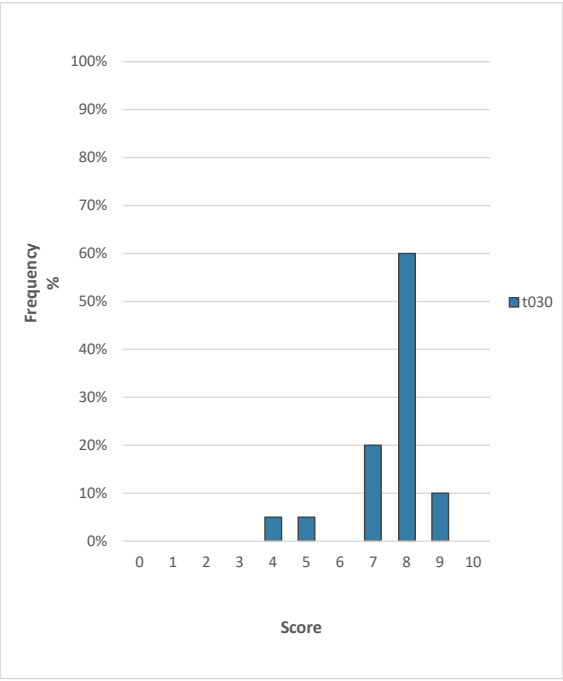
Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	0%
5	5%
6	5%
7	25%
8	55%
9	5%
10	5%



Would you buy it?

Vol. n°	Judgement t030
01	8
02	8
03	4
04	8
05	9
06	8
07	8
08	7
09	7
10	7
11	8
12	8
13	8
14	5
15	7
16	8
17	8
18	8
19	8
20	9
Median	8,0

Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	5%
5	5%
6	0%
7	20%
8	60%
9	10%
10	0%



The results reported in this document refer exclusively to the tested sample, whose safety was assessed beforehand.

The results reported in this document are to be referred exclusively to the tested sample, whose safety was previously assessed.

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Annex C

TECHNICAL SCIENTIFIC COMMITTEE STATUTE - REGULATION

ART. 1 INTRODUCTION

The Technical Scientific Committee of "Bio Basic Europe S.r.l." is an independent and impartial work group, constituted in accordance with interdisciplinarity criteria and with autonomous decision-making powers, whose task and responsibility is to ascertain the compliance of the methodologies and validate scientific and clinical research protocols. The TSC is called upon to formulate operating proposals and opinions on Bio Basic Europe S.r.l. research projects at the CDC Dermo Clinical Research Institute of Milan, at the microbiological, chemical/physical and in vitro analysis laboratories of the Technical Scientific Park of the University of Pavia, or at laboratories, medical clinics and Hospital Institutes that collaborate with the company. The TSC acts in compliance with the ethical principles contained in the Helsinki declaration, with the Clinical and Laboratory Best Practice Standards and with all applicable national and European related regulatory frameworks, as well as with the recommendations and guidelines of the main competent international organizations and institutions.

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ART. 2 INDEPENDENCE OF THE TECHNICAL SCIENTIFIC COMMITTEE

The independence of the TSC is guaranteed:

- by the lack of hierarchical subordination of the TSC to the principal;
- by the presence of experts who are not employed by the principal;
- by the absence of conflicts of interest of TSC members with regard to the trials proposed.

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- *by the presence of experts who are not employed by the principal;*
- *by the absence of conflicts of interest of TSC members with regard to the trials proposed.*

ART. 3 FUNCTIONS OF THE TECHNICAL SCIENTIFIC COMMITTEE

In brief, the TSC performs the following functions:

- It assesses clinical trial protocols and scientific protocols, ascertaining conformity of procedures and compliance with all mandatory regulatory frameworks, expressing its opinion and validating in particular:
  - clinical trials and laboratory analyses assessing cosmetic products, nutraceutical products, medical and diagnostic devices, medical/surgical aids, detergents, hazardous substances, biocides and chemical substances in general;
  - protocols assessing the adoption of new clinical and scientific operating procedures;
  - observational studies and monitoring.

- It may propose information, training and refresher initiatives for the operators involved in the trials, as well as workshops on pertinent scientific topics.

In brief, the TSC performs the following functions:

- *It assesses the clinical trial protocols and the scientific protocols, ascertaining the conformity of the procedures and the compliance with all mandatory regulatory frameworks, expressing its opinion and validating in particular:*
  - *clinical trials and laboratory analyses that assess cosmetic products, nutraceutical products, medical and diagnostic devices, medical/surgical aids, detergents, hazardous substances, biocides, and chemical substances, in general.*
  - *protocols that assess the adoption of new clinical and scientific operating procedures.*
  - *observational studies and monitoring.*
- *It may propose information/training/refresher initiatives for the operators involved in the trials, as well as workshops on pertinent scientific topics.*

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ART. 4 COMPOSITION OF THE TECHNICAL SCIENTIFIC COMMITTEE

The TSC is composed of members who are internal and external to Bio Basic Europe S.r.l., with multidisciplinary skills, so that it can guarantee the qualifications and experience required to assess the scientific, methodological and ethical aspects of the protocols presented. The members of the TSC have proven skills and qualifying experience in the sector covered by the study.

For this purpose, at least the following persons participate in all TSC meetings:

a. The Chairman and/or the Vice Chairman of the TSC
b. The University of Pavia Director of Research
c. The Investigator/Medical Director of the CDC Dermo Clinical Research Institute*
d. The expert of Bio Basic Europe S.r.l. depending on the issue on which the opinion is formulated

*For in vitro, microbiological and chemical/physical tests, member c. is replaced by member d., namely one of the Bio Basic Europe members specialising in the relevant subject.

In general, the TSC work group comprises at least:

e. one chemist/cosmetic chemist
f. one toxicologist
g. one pharmacist/pharmacologist
h. one physician
i. one biologist
j. one biostatistician
k. one microbiologist/virologist/expert in genetics
l. one clinician

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- ***c.*** *The Investigator/Medical Director of the CDC Dermo Clinical Research Institute**
- ***d.*** *The expert of Bio Basic Europe S.r.l. depending on the issue on which the opinion is formulated*

**In the specific case of in vitro, microbiological and chemical/physical tests, member c. will be replaced by member d., or by one of the members who specialise in topics pertinent to Bio Basic Europe.*

In general, the TSC work group comprises at least:

- ***e.*** *one chemist/cosmetic chemist*
- ***f.*** *one toxicologist*
- ***g.*** *one pharmacist/pharmacologist*
- ***h.*** *one physician*
- ***i.*** *one biologist*
- ***j.*** *one biostatistician*
- ***k.*** *one microbiologist/virologist/expert in genetics*
- ***l.*** *one clinician*

MANAGING MEMBERS OF THE TECHNICAL SCIENTIFIC COMMITTEE

• Prof. ORNELLA PASTORIS
TSC Chair and Scientific Director, “Lazzaro Spallanzani” Faculty of Biology and Biotechnologies, University of Pavia
• Dr. CLAUDIO ANGELINETTA
TSC Vice Chair, Chemist/Cosmetic chemist
• Dr. FERNANDO MARCO BIANCHI, M.D.
Medical Director of the CDC Dermo Clinical Research Institute, specialising in dermatology and venereology

MEMBERS AFFILIATED WITH THE UNIVERSITY INSTITUTES AND RESEARCH CENTRES

• Prof. GIULIANO MAZZINI
National Research Council, Pavia Institute of Molecular Genetics, expert in genetics
• Prof. FIORENZO PEVERALI

National Research Council, Pavia Institute of Molecular Genetics, expert in genetics

MEMBERS AFFILIATED WITH BIO BASIC EUROPE S.R.L.

Clinical research experts:

• Dr. DANIELA GANDINI
Bio Basic Europe Safety Clinical Test Reporting Contact Person, expert in in vivo safety tests
• Dr. ANTONELLA PRATICO'
Bio Basic Europe Clinical Test Reporting Coordinator, expert in clinical research
• Dr. GAETANA RIZZI
Bio Basic Europe Medical Device and Food Supplement Clinical Tests Reporting Contact Person, expert in clinical research
• Dr. ROBERTA VILLA
Bio Basic Europe Statistical Analysis Coordinator and Efficacy Clinical Test Reporting Contact Person, expert in clinical statistics

Other experts:

• Dr. MARA FOPPIANI
Head of Bio Basic Europe Microbiology Laboratory, expert in microbiology and virology
• Dr. ELIANA REGOLA, PhD
Bio Basic Europe Laboratory Test Coordinator, expert in microbiology and virology
• Dr. FRANCESCA VALLOTTO
Coordinator of the Regulatory Department of Bio Basic Europe, expert in cosmetic chemistry and toxicology
• Dr. RICCARDO VICINI, PhD
Head of Bio Basic Europe Vitro Laboratory, expert in pharmacology and toxicology

CLINICAL INVESTIGATORS

• Dr. MAURIZIO BARBIERI CARONES, M.D., specialising in gynaecology
• Dr. ANTONELLA COLOMBO, M.D., specialising in dermatology and venereology
• Dr. ALESSANDRA DI BENEDETTO, M.D., specialising in dermatology and venereology
• Dr. TIZIANA DIVINO, M.D., specialising in aesthetic medicine and dermosurgery
• Dr. EVELYN FALCONI KLEIN, M.D., specialising in dermatology and venereology
• Dr. GIORGIO GRASSI, M.D., specialising in ophthalmology
• Dr. ANDREA RAMONI, M.D., specialising in ophthalmology
• Dr. LUCA VETTORUZZO, M.D., specialising in dentistry and dental prosthesis

In the case of evaluations pertaining to areas not covered by its members, the Chairman of the TSC may convene experts who are not members of the TSC for specific consultations. In the case of resignation or departure for any reason of one of the mandatory members, the Chairman ensures prompt replacement.

In the case of evaluations pertaining to areas not covered by its members, the Chairman of the TSC may convoke, for specific consultations, experts who are not members of the TSC. In the case of resignation or of the exit on any grounds of one of the mandatory members of the TSC, the Chairman of the TSC ensures that they are promptly replaced.

ART. 5 FUNCTIONS OF THE CHAIRMAN

The Chairman exercises the following functions:

• he/she is the official representative and spokesperson of the TSC
• he/she is the contact person for any critical issues of a clinical/scientific nature that arise during the activity of the TSC
• he/she decides on possible supplementation of the TSC composition and replacement of members who have been deprived of office and/or have resigned
• he/she convenes, moderates and conducts the TSC meetings
• he/she guarantees the decisions adopted by the TSC

The Vice Chairman replaces the Chairman in all functions in case of absence or temporary impediment. He/she assists the Chairman, who may confer specific assignments. The Chairman uses the services of a Scientific Secretary for administrative/scientific activities. The Secretary participates in meetings with advisory and support functions and takes the minutes.

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- *he/she is the contact person for any critical issues of a clinical/scientific nature that arise during the activity of the TSC*
- *he/she decides on the possible supplementation of the TSC's composition and on the replacement of members who have been deprived of their office and/or have resigned*
- *he/she convokes, moderates and conducts the meetings of the TSC*

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- *he/she supervises the decisions adopted by the TSC*

The Vice Chairman replaces the Chairman in all his/her functions in case of absence or temporary impediment. He/she assists the Chairman who may confer specific assignments thereto. The Chairman uses the services of a Scientific Secretary for the performance of activities of an administrative/scientific nature. The Secretary participates in the meetings with advisory, supporting functions and takes the minutes.

ART. 6 DUTIES OF THE MEMBERS

The Members of the TSC:

- are personally responsible for the activities under their remit carried out in the TSC;
- are bound to secrecy with regard to actions related to their activity in the TSC;
- must communicate any bias or lack of impartiality that may affect their participation in the TSC.

The Members of the TSC:

- *are personally responsible for the activities under their remit carried out in the TSC*
- *are bound to secrecy with regard to the actions related to their activity in the TSC*
- *must communicate any bias and lack of impartiality that may have an impact on their participation in the TSC*

ART. 7 VALIDATION OF THE PROJECTS

The TSC is called upon to express opinions on and ascertain the completeness of scientific and clinical protocols by Bio Basic Europe S.r.l. It certifies the adequacy of the documentation and the conformity of the procedures and methodologies followed in designing and developing the research project, in compliance with applicable rules and regulations. Each protocol, once confirmed by the mandatory members of the TSC as indicated in Art. 4, is signed by the Investigator/Medical Director of the CDC Dermo Clinical Research Institute, or by the Head of the Laboratory in the case of test reports, and thereafter by the Safety Assessor/Vice Chairman of the TSC, who attests the validity of the document with a digital signature. Each protocol approved by the TSC is archived and made available to all TSC members.

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TSC Chairman and Scientific Director, University of Pavia	TSC Vice Chairman	The Investigator and Medical Director of the CDC Dermo Clinical Research Institute
		