



FINAL REPORT

EFFECTIVENESS EVALUATION OF A MAKE-UP REMOVER AGAINST WATERPROOF AND NOT WATERPROOF MAKE-UP (In vivo short term test- 20 volunteers)

STUDY N°	KH266/14-01
SPONSOR	LABORATOIRE DR PAUL ET KARIN HERZOG SA Route de Taillepied, 1 1095 Lutry - SWITZERLAND
SAMPLE	Finest Chocolate Cleansing-Ref. E52C 100ml
REPORT DATE	22/07/2014
REPORT N°	REL/1273/2014/CLI/SAB

The results reported herein do exclusively refer to the tested sample

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www.abich.it

**Corporate Offices and
laboratories:**

Via 42 Martiri, 213/B
28924 – Verbania (VB) Italy
Pho +39 0323 586239/496041
Fax +39 0323 496877
e-mail: info@abich.it

**Clinical and cosmetic
testing:**

Via Bruno Buozzi, 4
20090 – Vimodrone (MI)
Italy

Headquarter:

Via 42 Martiri, 213/B
28924 – Verbania (VB) Italy
CF/VAT/Reg. Imp. VCO: 01864020035
R.E.A.: 189901
Cap. Soc. € 16.000,00 i.v.



Direttore dello studio/ Study Director:

Dr. Samuele Burastero, _____

Medico specialista in allergologia e immunologia clinica, Ricercatore presso l' Istituto Scientifico Ospedale san Raffaele / *Medical Doctor, Board Certified Specialist in Allergology and Clinical immunology, Researcher at the Scientific Institute San Raffaele Hospital*

Indirizzo/Address: Istituto Scientifico Ospedale san Raffaele
Via Olgettina, 58
20132 – Milano (MI)
Italy

Assicurazione Qualità/ Quality Assurance:

Roberta cattaneo, _____

Indirizzo/Address: Abich S.r.l.-Clinical and Cosmetological Trials Center
Via Bruno Buozzi, 4
20090 - Vimodrone (MI) - Italy

Direttore del Centro Studi clinici/ Clinical Study Center Director:

Dr. Stefano Todeschi, _____

Biologo e specialista in Patologia Clinica/ *Biologist and Specialist in Clinical Pathology*

Indirizzo/Adress: Abich S.r.l.-Clinical and Cosmetological Trials Center
Via Bruno Buozzi, 4
20090 - Vimodrone (MI) - Italy

Altre figure professionali coinvolte nello studio/ *Other professionals involved in the study:*

Dr.ssa Giulia Caccia – Biologa/ Biologist _____

Dr. Juri Masuri – Biotecnologo/ Biotechnologist _____

Dr.ssa Mariana Tritapepe – Biologa/ Biologist _____



AUTHENTICITY OF RESULTS

I hereby declare that the study concerned by this report was carried out under my responsibility, according to the experimental protocol and the quality plan of Abich S.r.l. I also state that, where applicable, all procedures were compliant with the principles of Good Clinical Practice.

All relevant observations and data recorded during the test are reported in this study report. I certify the re-reading of this report and I do agree with its content.

The Study Director

Dott. Samuele Burastero

Corporate Offices and laboratories:

Via 42 Martiri, 213/B
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Fax +39 0323 496877
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1. SUMMARY

On behalf of the Company **LABORATOIRE DR PAUL ET KARIN HERZOG SA** on the test substance **Finest Chocolate Cleansing-Ref. E52C** an *in vivo* study was conducted to evaluate its efficacy in removing the make up waterproof and not waterproof.

The make up (black eye pencil and black mascara) was applied on 20 female volunteers, with normal or sensitive skin, by the Abich Specialized personnel and than it was removed in two phases in controlled conditions with the product under study.

On the right eye the make up not waterproof was applied while on the left eye the make up waterproof was applied.

Market leader products were used to make up (brand L'Oréal).

The two phases of the make up removal were always carried out by the same Abich technician using a known quantity of product for each eye and making the same movements and pressure with the special towel provided by the Sponsor (silk towel designed by Karin Herzog).

At the end of each phase the experimenter has filled in a questionnaire relative to an objective evaluation of the visual efficacy of the product's power to remove make-up waterproof and not waterproof using a judgment scale from 0 to 10.

The volunteers at the end of the test have filled in a questionnaire relative to a subjective evaluation of the product pleasantness, of its organoleptic characteristics and to a general satisfaction assessment of the tested product.

Moreover to support the product efficacy and its visible effect in the make up removal photos of the examined areas were made before the make up application (T0), after the make up application (T1), and after the first and the second passage with the product (T1° passage and T2° passage).

This study has been carried out in compliance with the most recent recommendations of the Helsinki Declaration (64th WMA General Assembly, Fortaleza, Brazil, October 2013) and has followed the "Guidelines for the Assessment of Skin Tolerance of Potentially irritant Cosmetic ingredients", COLIPA, 1997, for the inclusion/exclusion criteria.

The study was performed in the facilities of the Abich Clinical study Center, Via Buoizzi, 4, 20090-Vimodrone, MI, Italy.

The study started the 18th June, 2014 and ended the 7th July, 2014.



2. TEST SUBSTANCE

The test substance consists of a brown gel.

Name: **Finest Chocolate Cleansing-Ref. E52C 100ml**

Batch/ Formule code: **5521015**

Sample Code Abich: 4421/14-01

INCI composition: see annex

Pao / Expiration date: Pao 5M

Storage conditions: room temperature

The characterization of the test substance is under responsibility of the Sponsor.

3. VOLUNTEERS RECRUITMENT (PANEL)

The study was performed on 20 healthy volunteers, females, of age between 18 and 65 years, with normal or sensitive skin, who have been identified from the volunteers database of the Abich Clinical and Cosmetological Trials Center.

The subjects with sensitive skin were recruited according the following principle: subject whom have shown moderate erythema following a treatment with a solution of SLS 1,5%.

Before the beginning of the study each volunteer has read and signed an informative form (informed consent form, C.I.). Each volunteers has had the opportunity to ask any kind of questions regarding the study to which was given an exhaustive answer. The volunteer was explained the aim of the test, the procedure and the possible risks related.

Only after signature of the informed consent the participation in the study was permitted. Only volunteers in good general health conditions were included in the study.

The originals of these informed consent forms were archived at the Abich Clinical and Cosmetological Trials Center. All patients signed a consent allowing to treat personal data according to the Italian law (Testo unico sulla privacy. D.Lgs 196/2003).

The following criteria of exclusion were applied:

- Women pregnancy or nursing condition;
- Subjects with blemishes, marks, including tattoos, scars, sunburns on the test site(s) which could interfere with scoring;
- medication (local and/or systemic) which may affect skin response;
- signs of irritated skin on test site(s);
- any active skin disease which may interfere with the aim(s) of the present study;
- participation in other simultaneous studies which that might interfere with the test evaluation or participation in a previous study without an appropriate rest period between studies;
- non-assessed as suitable by the Medical Doctor.

After study start, the following withdrawal criteria were applied:

- volunteers who did not follow the conditions as described in the Study Information Sheet;
- volunteers who suffered any illness or accident or developed any condition which could affect the outcome of the study;
- volunteers who did not longer wish to participate in the study.



Panel:

Vol N°	Vol. code	Skin type
1	veca393	Normal
2	alfo132	Normal
3	sttr104	Sensitive
4	anir531	Normal
5	vaca375	Sensitive
6	anvi256	Sensitive
7	mavi242	Normal
8	kadi493	Sensitive
9	mace462	Sensitive
10	bamu461	Normal
11	elmo96	Normal
12	gica358	Sensitive
13	vaza10	Sensitive
14	depi513	Sensitive
15	roca405	Normal
16	sife108	Sensitive
17	stpi387	Sensitive
18	sean395	Normal
19	lada314	Normal
20	gito475	Normal

4. DISCLAIMER

According to COLIPA guidelines, the test was performed with the assumption that the Sponsor under its responsibility provided to the personnel of Abich S.r.l. Clinical and Cosmetological Trials Center truthful information on any ingredient of the test product endowed with potential toxicological relevance.

On the basis of such information, a general assessment of the toxicological information concerning the product was preliminarily carried out and ethical implications as to its use during the present study have been considered.

5. MATERIALS AND INSTRUMENTS

The following instruments and materials were used:

- Canon EOS350D MACRO®: digital reflex camera equipped with 19-55mm objective (Canon Italia, Milano).
- Waterproof and not waterproof make up: mascara and eye pencil of black color (L'Oréal).
- Silk towels.
- Semi-analytical balance Sartorius Mod. BA710S, measuring range 0.001g – 3100 g, precision +/- 0.001mg.

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6. EXPERIMENTAL DESIGN

6.1 Structure of the study

The study was performed in an open observational modality.

6.2 Aim of the study

The present study is finalized to evaluate the efficacy of the product in exam in the removal of make up waterproof and not waterproof.

The test was conducted in controlled conditions in the facilities of Abich Clinical and Cosmetological Trials Center.

The make up was applied on each volunteer by the same technician and after a drying period of 15 minutes it was removed using a known quantity of the product under study with the help of special towels.

6.3 Environmental conditions

The study was performed in standard environmental conditions for each observing time specified, maintaining temperature and humidity constant.

6.4 Tested skin areas

The product under study was used at the level of the face, in particular on the periorcular area.

6.5 Evaluated skin areas

The photos and the objective assessments of the product efficacy are relative to the right eye (not waterproof make up) and to the left eye (waterproof make up).

6.6 Product application

The two phases of make up removal with the product under study were always carried out by the same Abich technician using special towels provided by the sponsor.

A quantity of product equal to a hazelnut sized was used and it was firstly warmed between the fingertips. The product was after combined with warm water and massaged onto the face and in particular on the eye area with circular motions for 10 to 15 second. During the first phase of the make up removal the product was removed with the towel wetted with warm water. Than a second passage with the towel was carried out.

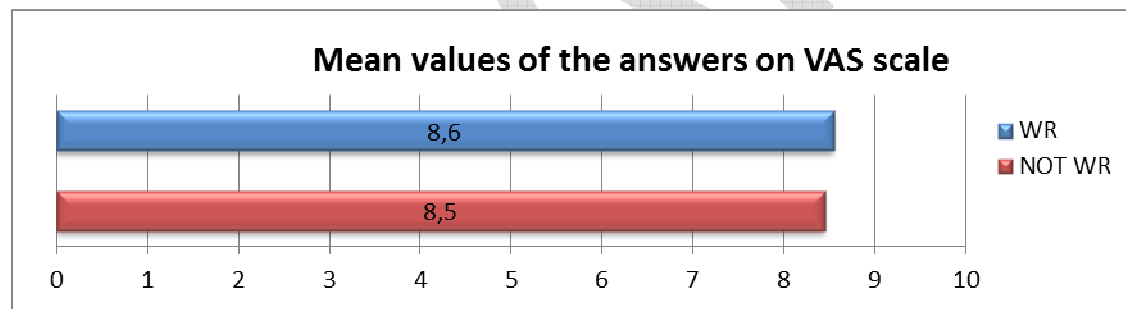


7. RESULTS RELATIVE TO THE OBJECTIVE ASSESSMENT MADE BY ABICH SPECIALIZED PERSONNEL

Here below are reported all the questions and answers referred to each volunteer of the questionnaire relative to the objective efficacy evaluation toward make up waterproof and not waterproof; the answers were expressed using the VAS judgment scale (from 0 to 10)
 For the graphic representation of the answers the mean of the scores of all volunteers was calculated.

1. From 0 to 10 after the first passage with the test product how much it resulted effective in the make up removal?

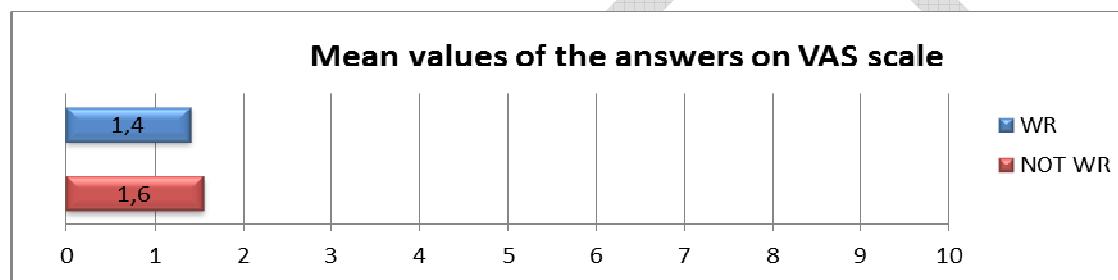
Make up	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	MEDIA
NOT WR	8	9	9	8	8	9	10	8	10	8	8	8	7	8	8	8	9	9	9	8	8,5
WR	9	9	10	8	8	10	10	7	9	8	9	8	8	8	7	9	9	9	8	8	8,6





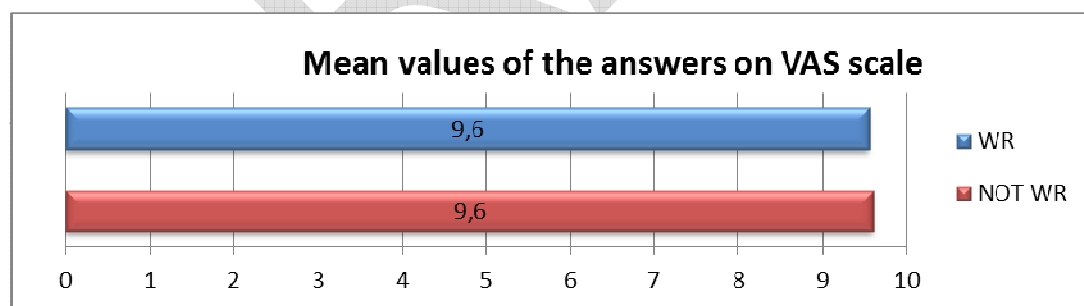
2. From 0 to 10 how much the test product leaves residues of make up after the first passage?

Make up	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	MEDIA
NOT WR	2	1	1	2	2	1	0	2	0	2	2	2	3	2	2	2	1	1	1	2	1,6
WR	1	1	0	2	2	1	0	3	0	1	1	2	2	2	3	1	1	1	2	2	1,4



3. From 0 to 10 after the second passage with the test product how much it resulted effective in the make up removal?

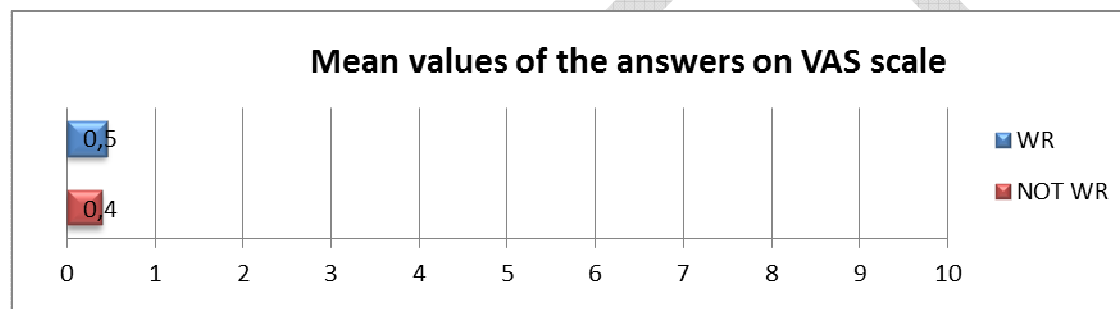
Make up	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	MEDIA
NOT WR	9	10	9	10	10	10	10	9	10	10	9	8	9	10	10	10	10	10	10	9	9,6
WR	9	10	10	9	9	10	10	9	10	10	9	9	9	10	9	10	10	10	10	9	9,6





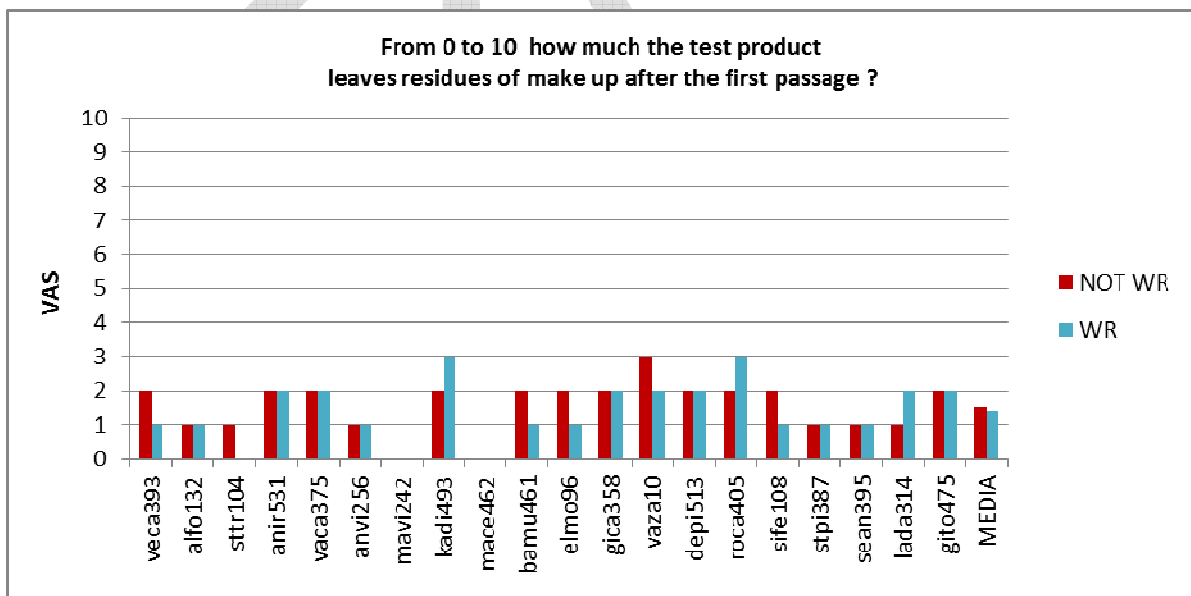
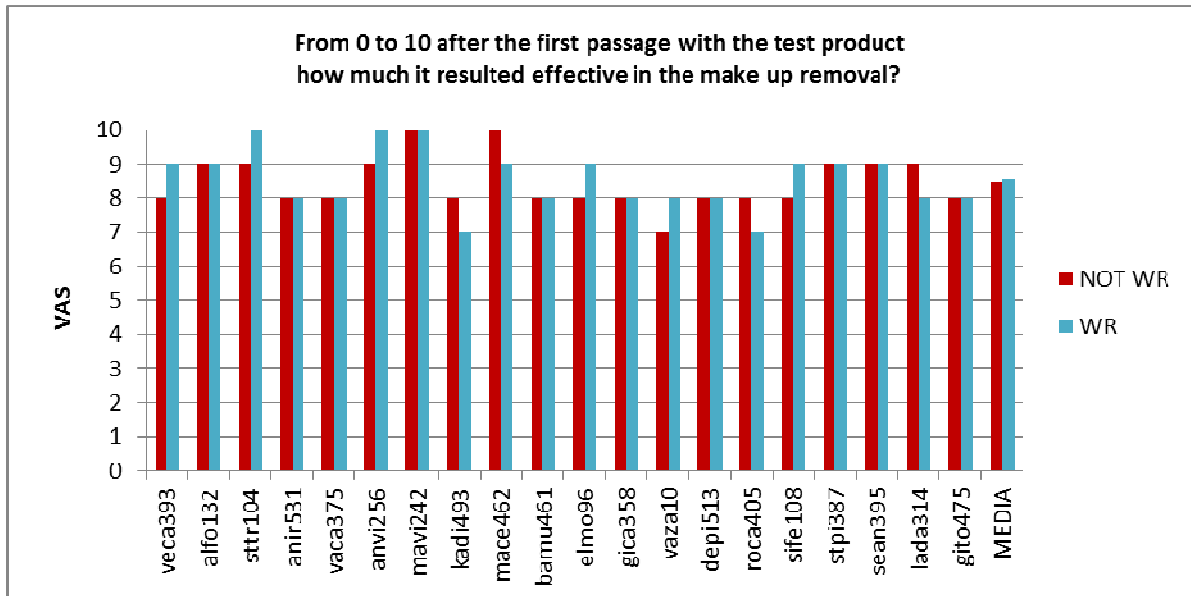
4. From 0 to 10 how much the test product leaves residues of make up after the second passage?

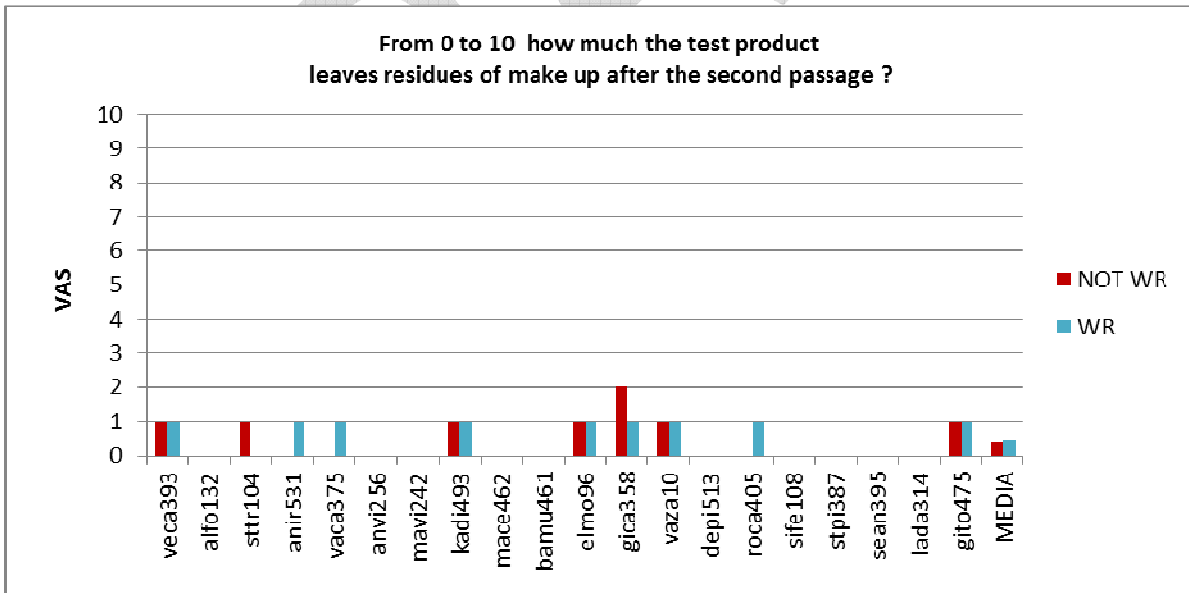
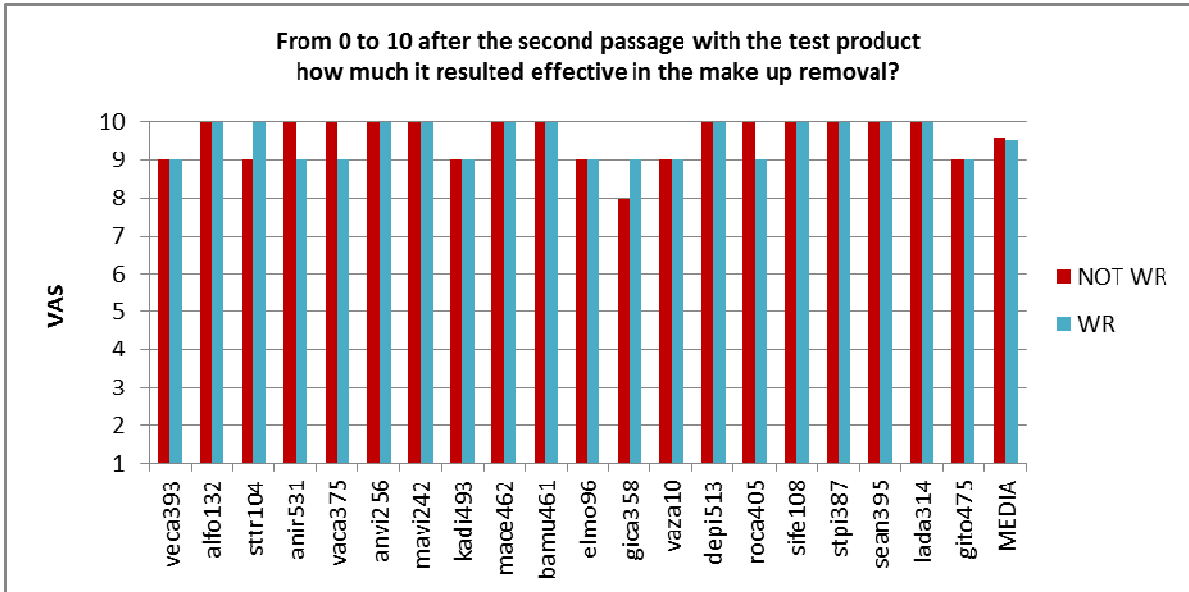
Make up	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	MEDIA
NOT WR	1	0	1	0	0	0	0	1	0	0	1	2	1	0	0	0	0	0	0	1	0,4
WR	1	0	0	1	1	0	0	1	0	0	1	1	1	0	1	0	0	0	0	1	0,5





The same answers are graphically represented here below by inter-group comparison (waterproof make up-WR versus not waterproof make up-NOT WR) to better compare the different efficacy of the product toward the two types of make up.







8. RESULTS RELATIVE TO THE SUBJECTIVE ASSESSMENT MADE BY THE VOLUNTEERS

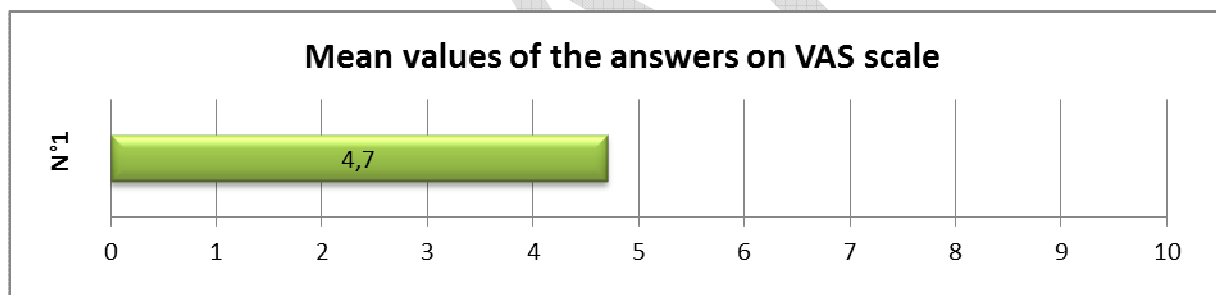
Here below are reported all the questions and answers of each volunteer relative to the subjective evaluation of the product pleasantness, of its organoleptic characteristics and to a general satisfaction assessment of the tested product.

The answers were expressed using the VAS judgment scale (from 0 to 10).

For the graphic representation of the answers the mean of the scores of all volunteers was calculated.

1. From 0 to 10 how much the tested product leaves a freshness sensation on your skin?

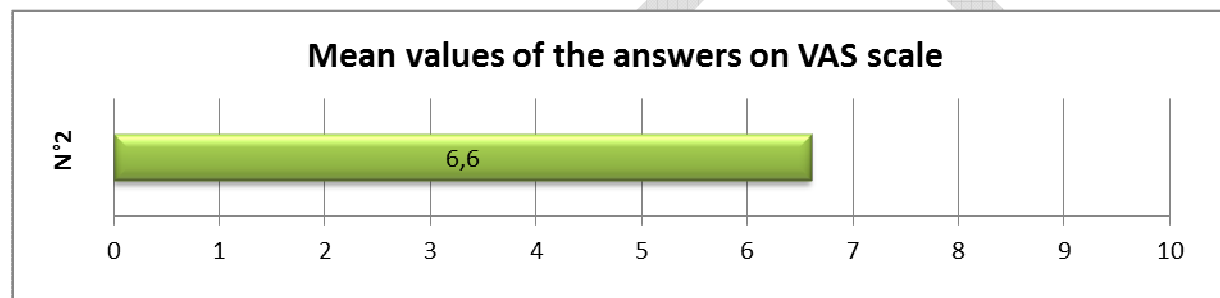
Question	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	Mean
n°1	7	8	8	4	7	6	5	8	8	8	6	2	2	1	2	2	6	2	2	0	4,7





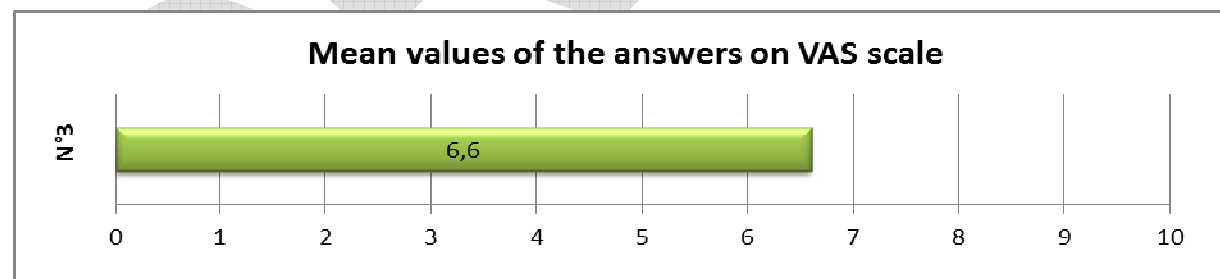
2. From 0 to 10 how much the tested product leaves a tonic skin?

Question	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	Mean
n°2	9	8	7	5	7	6	8	7	9	10	7	9	5	3	5	4	7	5	5	6	6,6



3. From 0 to 10 how much the tested product leaves a bright skin?

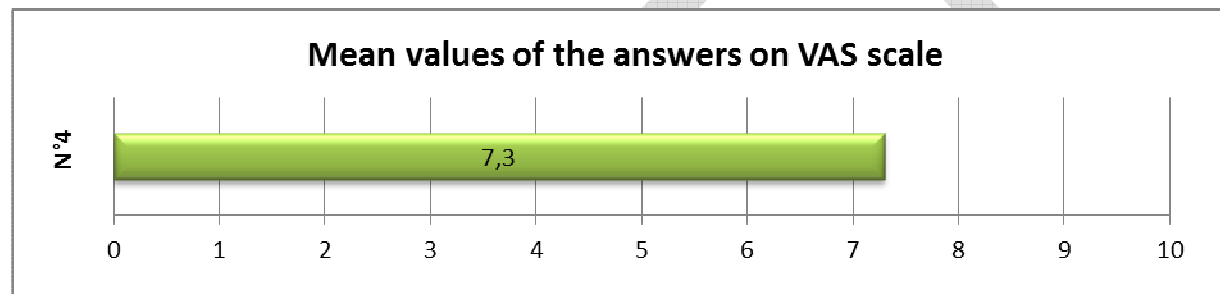
Question	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	Mean
n°3	8	8	7	7	7	6	6	8	9	8	7	8	5	3	5	7	7	5	5	6	6,6





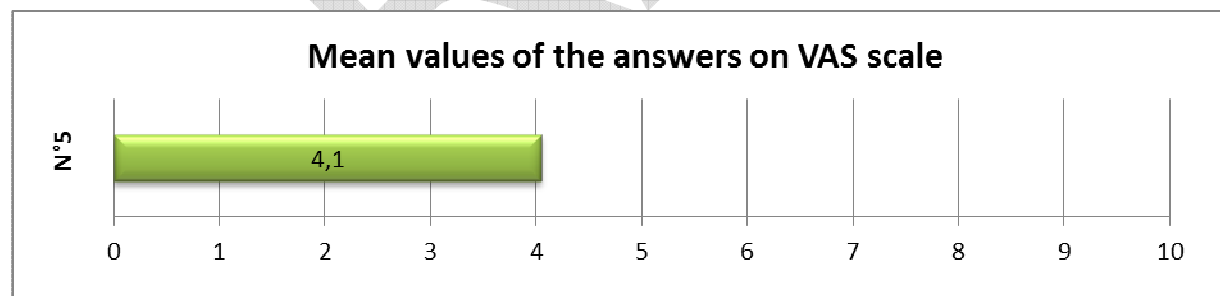
4. From 0 to 10 how much the tested product leaves a soft skin?

Question	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	Mean
n°4	8	9	6	8	7	8	8	8	9	10	7	8	6	6	7	7	7	6	5	6	7,3



5. From 0 to 10 how much the tested product leaves the skin oily?

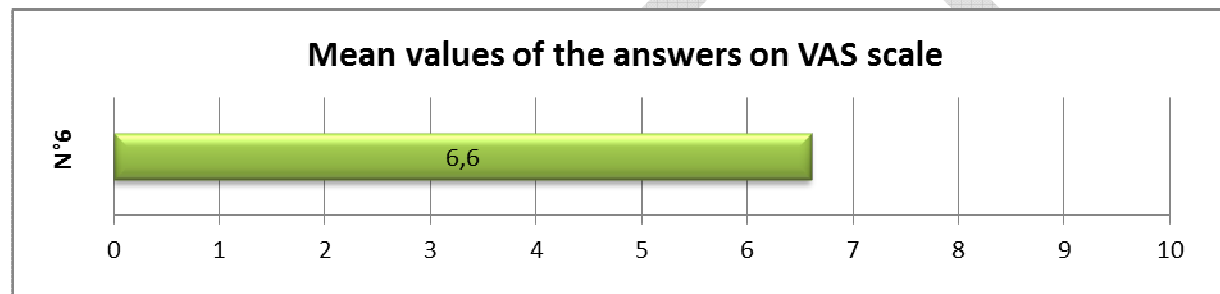
Question	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	Mean
n°5	1	1	1	6	6	6	1	2	3	4	6	6	6	8	4	0	0	8	4	8	4,1





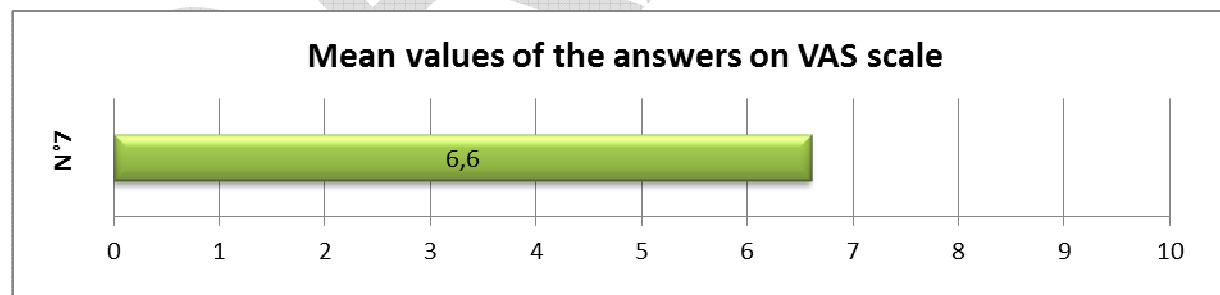
6. From 0 to 10 how much the tested product leaves an hydrated skin?

Question	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	Mean
n°6	9	8	7	8	8	7	7	7	6	8	7	7	6	5	5	6	6	5	4	6	6,6



7. From 0 to 10 how much did you like the product perfume?

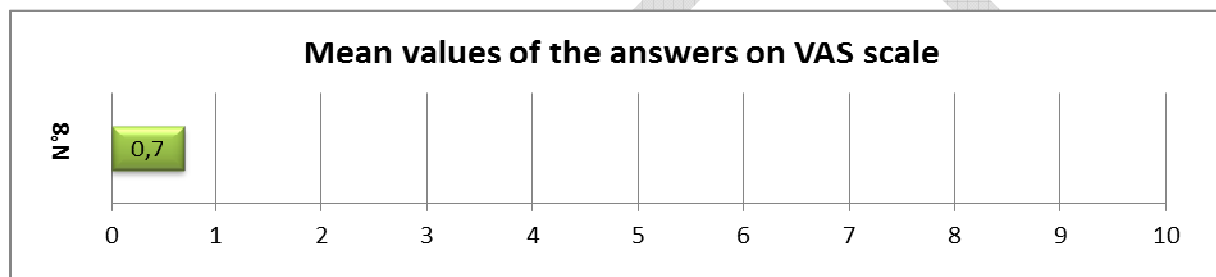
Question	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	Mean
n°7	6	2	9	6	8	8	10	7	9	9	9	3	7	0	0	4	7	10	8	10	6,6





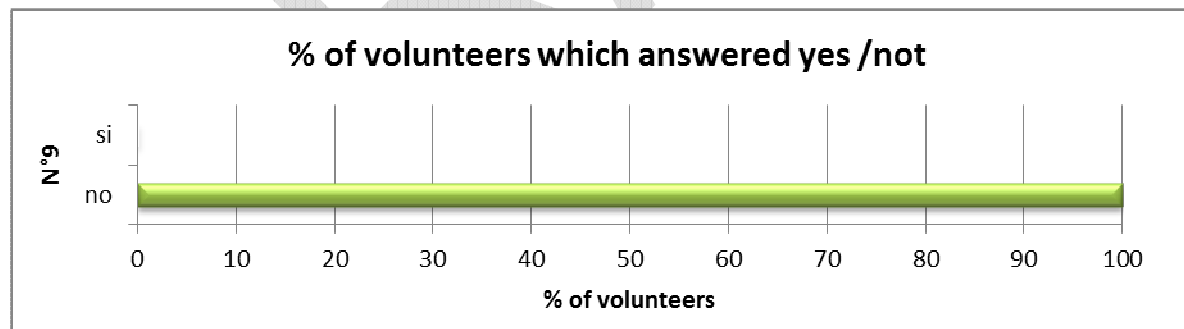
8. After the product use did you feel a burning sensation to the eyes? How much from 0 to 10?

Question	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	Mean	
n°8	0	0	0	0	0	4	0	0	0	0	3	0	2	0	2	0	0	0	0	3	0	0,7



9. Did you noticed other adverse effects after the product use (irritation, redness, lachrymation etc...)?

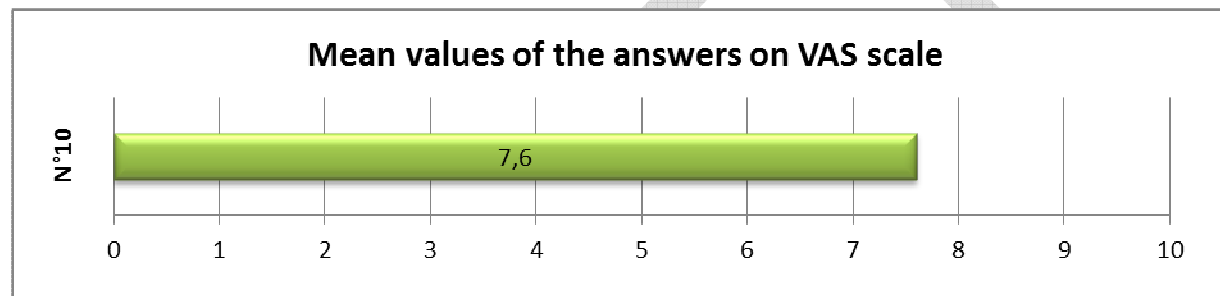
Question	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	Mean	
n°9	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	no	10 no





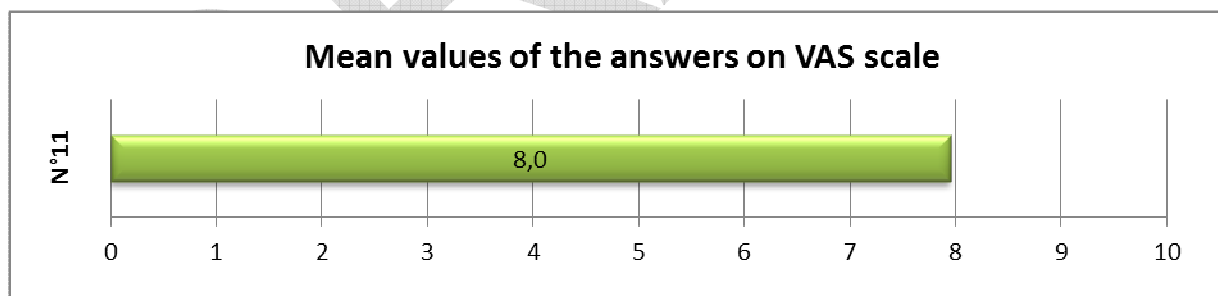
10. What judgment do you give to the product as *make up remover for NOT waterproof make-up*?

Question	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	Mean
n°10	9	9	7	7	10	8	9	8	4	9	6	9	9	7	7	8	6	7	7	6	7,6



11. What judgment do you give to the product as *make up remover for waterproof make-up*?

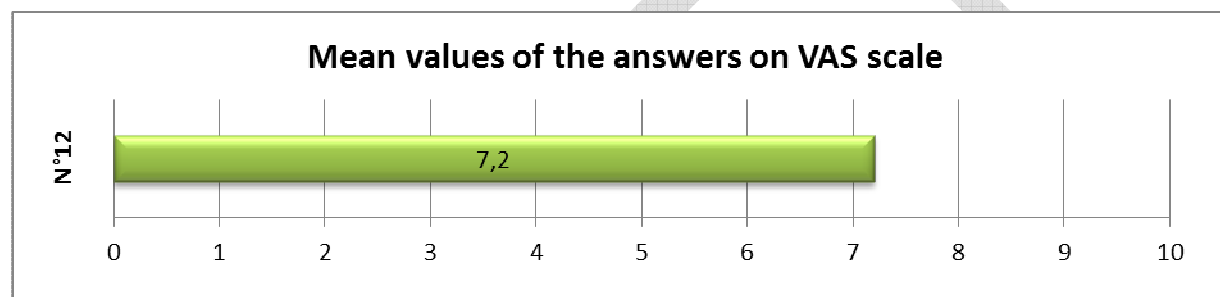
Question	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	Mean
n°11	10	9	8	8	10	8	5	8	10	9	7	10	8	7	7	10	6	7	7	5	8,0





12. What judgment do you give to the cosmetic pleasantness of the product?

Question	veca393	alfo132	sttr104	anir531	vaca375	anvi256	mavi242	kadi493	mace462	bamu461	elmo96	gica358	vaza10	depi513	roca405	sife108	stpi387	sean395	lada314	gito475	Mean
n°12	8	7	9	6	8	8	8	8	10	9	7	6	6	6	6	6	6	7	7	6	7,2





9. PHOTOGRAPHIC OBSERVATIONS (see the CD attached to the present report)

On the attached CD are reported the representative images of the product efficacy in the removal of make up waterproof (left eye) and make up not waterproof (right eye) after a first and a second phase of removal.

10. DISCUSSION AND CONCLUSIONS

On the basis of the results obtained with the adopted experimental conditions it can be concluded that the product under study

Finest Chocolate Cleansing-Ref. E52C

is result effective in removing not waterproof make up and waterproof make up in a very similar way and already after only two passages of removal carried out in laboratory in controlled conditions. Already after the first passage the product was effective in removing more than 50% both of the NOT waterproof make up both of the waterproof make up while after two passages it was able to remove almost all of the two types of make up (waterproof and not waterproof) and above all in a very similar manner and leaving, respectively, a residue of make up equal to 4% (waterproof make up) and 5% (non waterproof make up).

11. DEVIATION

No deviations to the study occurred during the test.

12. FILING

The study protocol, the raw data and the final report will be kept in the archives of Abich Clinical and Cosmetological Trials Center, in Via Buoizzi, 4, 20090-Vimodrone (MI), both in electronic format and in reduced paper format for a period of 10 years from the issue of the final report.

The control sample of the test substance and eventual specific reference material will be kept for 1 month, unless a specific request is provided by the customer.

The Customer, upon drafting a suitable contract, may request either the extension of the conservation of all or part of the materials for a further period or their restitution.



13. BIBLIOGRAPHY

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OECD SERIES ON PRINCIPALES OF GLP AND COMPLIANCE MONITORING
"The application of to GLP principles to short term studies" 15 Sept. 1999.

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"The role and responsibility of the Study Director in the GLP studies" 15 Sept. 1999.



14. ANNEXES

ANNEX 1

Inci list

Petrolatum, Paraffinum liquidum, Glycerin, Cetyl alcohol, Polysorbate 80, Parfum, Propylene glycol, Salicylic acid, Theobroma cacao extract.

DRAFT

Corporate Offices and laboratories:

Via 42 Martiri, 213/B
28924 – Verbania (VB) Italy
Pho +39 0323 586239/496041
Fax +39 0323 496877
e-mail: info@abich.it

Clinical and cosmetic testing:

Via Bruno Buozzi, 4
20090 – Vimodrone (MI)
Italy

Headquarter:

Via 42 Martiri, 213/B
28924 – Verbania (VB) Italy
CF/VAT/Reg. Imp. VCO: 01864020035
R.E.A.: 189901
Cap. Soc. € 16.000,00 i.v.