Bios Organic Standard and Natural Standard for Beauty Products

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Content

1. INTRODUTION

BIOS s.r.l. (BIOS) is an organisation founded in 1999 with the aim of certifying products, processes and services - *as a voluntary scheme* - in conformity with the relevant national and international regulations.
BIOS is authorised by the Italian Ministry of Agriculture and Forestry for the certification of organic production according the to Reg. CE 834/07 and 889/08.
To provide these services as well as the certification according to the Global scheme G.A.P. for fresh fruit and vegetables and their supply chains according to the ISO 22005, BIOS acquired the accreditation UNI CEI EN ISO 17065 granted by Accredia. The remaining control and certification services are provided following the same criteria and requirements.
Operating since 1999, Bios has grown over the years also thanks to international business activities.
BIOS guarantees a control and a certification of organic production that is objective, on time and reliable to companies and consumers. These guidelines are at the core of BIOS activities and organisation. Companies that certify with BIOS as well as produce and transform organic agriculture, know that they can rely on valuable assets of knowledge and expertise, delivering an efficient and effective service. The same quality principles are applied to BIOS voluntary product certification with the following objectives:

- to promote the culture about quality and certification in the farming, food and cosmetic sectors;

- to operate according to UNI CEI EN 17065 criteria committing to achieve and maintain the ACCREDIA accreditation (organic farming sector);
- to operate (with reference to operators that request such service) according to international standards criteria, committed to obtain and maintain the requested accreditation;
- to create working conditions so that all company decisions at BIOS can be understood by all staff via providing relevant training and information to carry out their work correctly;
- to achieve customer satisfaction by providing an efficient, impartial, objective and confidential service complying with the relevant rules;
- to provide credibility to clients and the market in general;
- to be a professional, reliable and independent guarantee for the consumer.
- to ensure that all personnel involved in the certification process, at all responsibility levels, are free of conflict of interests via a constant and documented methodology;
- to carry out a process of constant improvement of BIOS qualitative standards with medium term objectives set by the Board of Directors, also as a result of regular reviews;

To achieve such objectives, BIOS requires necessary to operate via the promotion of internal human resources, looking after their development, training and mutual trust, making sure every BIOS operator is involved, and is able to speak openly. BIOS also promotes a positive relationship with the companies certified.

BIOS:

- is a Limited Company, in operation since 13th of May 1996
- has its Headquarters in Marostica (VI) in via Montello n,6
- has a social capital of 33.000 Euros
- is registered in the Vicenza Companies Registry no. 190571/1996
- is registered at Vicenza R.E.A. no. 239399
- Tax number IT 00916890247
- is accredited by Accredia (Accreditation Certificate 056B) and complying with UNI CEI EN ISO 17065/2012 as a certification body for farming produce and food obtained via organic methodology as per Reg. CE 834/07, to provide certification according to the Global Scheme G.A.P. for fresh fruit and vegetables and the relevant supply chains according to ISO 22005.

2. GENERAL

The present certification rules show the production and product procedures to companies wishing to produce organic and natural cosmetics and/or cosmetic raw materials according to the BIOS standard for Organic and Natural Beauty Products (BCos01).
Such standard describes accurately the requirements to acquire a complaint product and to communicate such status on the label, the product technical data sheet and any other consumers or market information material.
BIOS examines every aspect of the production process in order to obtain a product certifiable according to the standard.

In certifying beauty products BIOS aims at:

- ensuring transparent, impartial, clear and truthful information to the consumer. The information provided needs to reach the consumer's natural disposition towards natural substances that respect the environment where we live.
- contributing to boost organic farming multi-functionality, which is not only raw materials production but also various functions and benefit for the human being.
- contributing to a real environmental safeguard
- promote cosmetics produced utilising organic raw materials and chemical substances that are either naturally derived or from green chemistry that fulfil health and environmental sustainable criteria
- contribute to develop commercial opportunities for BIOS certified beauty products.

3. SCOPE AND AREAS OF APPLICATION

The present regulations define the rules applied by BIOS in its certification services in relation to the BIOS standard for organic and natural beauty products.
The purpose behind BIOS control and certification activities is to give an independent assurance with suitable level of trust (via an initial evaluation and audits) regarding such products that not only comply with the mainstream regulations and good manufacturing practise but also with the latest BIOS standard.
The supplier remains responsible for the manufacturing compliance with the relevant regulations and the reference standard.
The certification can be extended to other international or national regulatory bodies depending on the notifications received by BIOS.
The technical part of the regulation is applied to cosmetic products as defined by the European Cosmetic Directive 1223/2009 and/or similar products with similar functionality and characteristics if intended for animals.

5. GENERAL RULES INTRODUCTION

The present certification rules are the only set of regulation applied by BIOS to certify and register beauty products.
Any company wishing to acquire such certification and registration by BIOS must comply with it.
When the present set of rules and regulations is reviewed, the certified/registered companies can choose between the reviewed version and the previous one until the next review. At the time of the certification renewal it is necessary to comply with the most recent version.

6. CERTIFICATION AREAS OF APPLICATION

The BIOS certificate states that the product fulfils the present regulations criteria and the technical rules for cosmetic products.
The certificate is valid for three years. Following the release of the certificate, it is a requirement to have at least one inspection per year.
The BIOS certificate is valid providing the certified company:

-keep the conditions that granted the certificate;
-notifies any changes affecting the product quality within one month;
-respects the payment terms.

The certified company can request to extend the certificate to new products at any time. In such case BIOS has a specific program to verify and evaluate documents depending on the request.
If the extension is approved, the initial certificate gets updated accordingly or it gets replaced with a new certificate. The standard can be modified and if this involves additional costs, BIOS will communicate the new fees to the certified company. Any complaint by a third party in relation to certified products compliance must be recorded and addressed by BIOS during an inspection, to be notified to the Committee of Certification Deliberation (CDC).

7. TERMS AND DEFINITIONS

Definitions:

- **Applicant:** the company requesting the BIOS certification and product registration
- **Company:** organisation, a group of people and structures with defined responsibility, authority and connections.
- **Certified company:** a company whose quality control is BIOS certified
- **Product:** term applied in the broad sense of the word to include processes and services.
- **Monitoring:** following the documents re-examination and the the certification verification, the monitoring checks will be performed over a period of three years from the certification contract engagement.

8. REFERENCE DOCUMENTS:

- Reg. (CE) no. 1223/2009
- UNI CEI EN ISO 17065
- ISO CEI EN 19011
- ISO CEI EN 22716
- D220 Certification rules by BIOS
- BCos01 technical regulations for the certification of beauty products
- Regulations by Committee of Certification Deliberation (CDC)

The regulations references mentioned above are the ones valid at the moment. The most recent versions must be applied in any case during the certification process.

9. GENERAL RULES DETAILS

Any company wishing to obtain BIOS certification and registration must comply with the present set of rules.
General criteria to achieve certification:

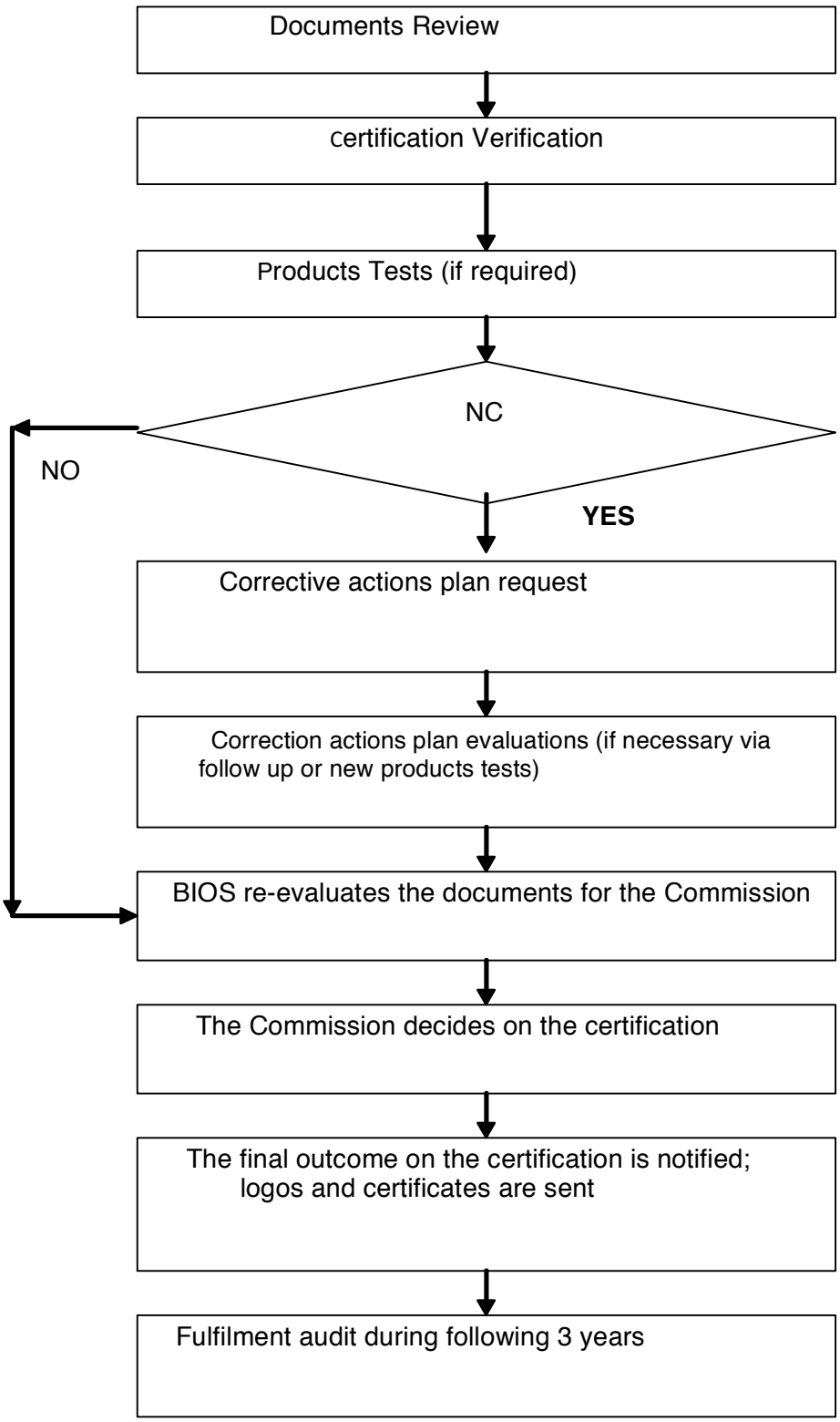
- to submit the BIOS application form;
- to arrange and update the control plan, providing evidence for the criteria requested for the product/process according to D240 and BCos01;
- to include and keep up to date records of the required compliance in the management quality control system as described in D240 and BCos01;
- to accept the initial inspection visit and the following monitoring visits;
- to maintain the product conformity, not only in accordance to the current cosmetic directive but also to BIOS D240 and BCos01;
- to supply all documents requested by BIOS to evaluate the product conformity at any time;
- to fill out and to constantly keep up to date every document that BIOS considers essential for the compliance with the sets of rules of regulations;
- to accept in every part the present set of rules and the technical regulation BCos01.

The certification system is based on the inspection visit and approval of the production plant management and control system of the requesting company in view of BIOS rules and regulations; monitored constantly via the periodic verification of the compliant processes and quality control system, as well as testing of samples taken from the market and production/transformation site.
The aim of the BIOS certification is to give the certified company, as well as the market, a form of reassurance that the product fulfils some specific criteria.
BIOS, being a control and certification body that is third party, impartial and independent, ensures that the product complies with the current set of rules D240 and BCos01.
The trademark BIOS COSMESI is BIOS property and can only be used on the cosmetic product label literature and technical data sheet only after the conformity (D240 and BCos01) certificate is issued.
BIOS is not allowed to provide any consultancy services to companies it controls and certifies.
The staff at BIOS and the professional experts commissioned to inspect can only deal with matters related to the compliance of D240 and BCos01.
If any non-conformities are found, BIOS gives a recommendation on how to overcome these, maintaining impartiality about the company's suggested corrective actions.
The outcome on the conformity is given by the CDC.

In Italy BIOS operates with staff and documents in Italian.
For control and certification activities abroad, BIOS is committed to operate (when necessary) in English, or in the local language utilising professional translators familiar with the certification and control processes.
The same principle applies to writing and distribution of documents relevant to the acquisition and maintenance of the certification (standards, sets of rules and regulations, application forms etc.)
The certification documents are issued in bilingual version, i.e. English and Italian. When the product is sold in countries where English is not common, BIOS commits to translate the certification documents into the local language or another language known in the country.

In order to promote the access to useful information to people interested in BIOS cosmetic standard, BIOS commits to provide all non confidential materials and information via direct request or via www.certbios.it.
To increase the system transparency, BIOS reserves the right to make public non confidential information regarding its activities such as the list of certified companies/products, the certification fees, sanctions and test results.
To provide a constant flow of information to consumers on the BIOS www. certbios.it the following documents are made available:

- essential documents for the certification;
- updates related to BCos01 and D240;
- the list of certified companies/products along with the business name.



10. RULES TO GRANT CERTIFICATION

The applicant must follow the following rules in order to achieve certification:

a) To comply with the BIOS cosmetic standard along with its sets of rules and NC= non-compliance

technical regulations.

b) To have completed the certification process successfully.
c) To allow BIOS staff to access the company's premises and all the relevant production sites.
d) To authorise BIOS staff to access all the relevant documents and records, such as technical documents, invoices, and any other document required by the certification process.
e) To maintain/improve the conditions that granted the certification during the period the certification is valid.
f) As soon as any irregularity or non-conformity of the product, that are related to the granting of the certification, appears, BIOS must be notified and the company considers if it is necessary to withdraw or downgrade the non compliant product certification status.
g) To pay BIOS the full certification fee irrespectively of the inspections outcome: the payments will need to be received also during the period of suspension.
h) To inform BIOS of any legal action involving the processes and/or products that are certified by BIOS.
i) To comply with any decision taken by BIOS (for example in case of any possible non-conformity, suspension or revocation of the acquired certification).
j) To produce and keep all key records regarding the certified products. The records need to be updated on a daily basis providing objective evidence regarding the product conformity with the BIOS Standard. The records can be kept on paper or on a computer, providing the system has regular back ups and files cannot be modified. The records for certified products must be clearly distinguished from the ones for non certified products.
k) To take care of complaints regarding the BIOS certified products.
l) To keep a suitable traceability for the product at any stage of the manufacturing process. The control performed by BIOS is based on the presence of objective evidence such as the correct identification of raw material suppliers, production batches, raw material specifications, manufacturing and other processes, the product buyers., etc. The objective evidence must be relevant to any aspect of the certified product and must always be available to BIOS.
m) To keep documents providing objective evidence of the purchased raw material conformity in relation to its organic status and production (for example raw material suppliers trading schedule, organic certificates, invoices, etc.).

11. CERTIFICATION PROCESS

Upon receipt of the application form the certification and evaluation process by BIOS is the following:

12. CERTIFICATION REQUEST

The company requesting certification accepts the set of rules D240 and BCos01 for cosmetic products and fills the relevant forms provided by BIOS including:

- a copy of the receipt of payment to BIOS for the certification
- an electronic copy of the label of the product to be certified;
- the completed application form containing the products description and place of manufacture;
- qualitative formulations for the products requesting certification and the technical data sheets for all the raw materials used in their production;
- challenge-tests and patch-tests performed to verify the product safety and dermatological compatibility;
- clinical tests or references of scientific articles to substantiate any product claim;
- quality control plan for the products to be certified.

The documents supplied by the applicant are subject to an initial review. The outcome of the second review will be communicated to the applicant to give enough time to implement any measures, if required, prior to the inspection.
On request the second review of the documents can be done at the applicant site.
On request it is also possible to perform the documents review as well as the certification verification; in this instance only one report will be released to the company, containing the findings for both. BIOS reserves the right to decide, case by case, to accept the request to conduct the documents review at the same time as the certification verification.
A representative from BIOS headquarters will evaluate the case within two weeks from the documents receipt. BIOS reserves the right to request further documents in order to evaluate the company and products conformity. The documents evaluation will give one of the following outcomes:

- positive
- positive with non-conformities
- negative

In case of positive outcome the inspection visit is arranged.
In case of positive outcome with non-conformities, the applicant can submit an action plan to BIOS within 15 days from the report delivery. Alternatively the company can give the action plan during the inspection visit. If the company does not take any action within the given period, the application gets cancelled.
In case of negative outcome it will not be possible to proceed with the inspection visit or product certification.

13. CERTIFICATION VERIFICATION

The certification verification is a systematic evaluation and/or of samples aimed at verifying the compliance with the BIOS sets of standard and regulations.
During the verification, BIOS will assess the company according to the Beauty Products Standard criteria.
The verification team will be assigned and will check the validity of what is present in the documents and compare it against the standard requirements.
The certification verification is done at the company premises and in other manufacturing or processing sites, if necessary.
The verification consists of inspecting relevant sites, interview with personnel and documents review.
The certification verification starts with a meeting with the applying company senior managers and the verification team. During the meeting the participants introduce themselves and the certification details are described.
Afterwards the verification is carried out as planned previously by BIOS and the company, keeping in mind any modifications suggested during the initial meeting.
The certification verification ends with a final recap meeting with the senior managers and the BIOS verification

team. During the final meeting the verification team gives a presentation on conclusions and any possible non-conformities. The verified company signs off the non conformities (NC) and has the opportunity of expressing any concern or comment regarding the non conformities that are found.
In case of non conformity the company must provide an action plan to rectify them within 15 days. The decision regarding the certification is not taken by the verification team but by the CDC.

14. PRODUCTS TEST

In some cases it may be necessary to perform tests on the product in order to verify its compliance with the standard.
The number, type and frequency of tests will be set by BIOS based on the sampling procedures and instructions and according to the BIOS Impartiality Protection Committee (CSI).
Sampling and tests will be appointed to professional laboratories accredited with EN17025.
The laboratories will provide test results to BIOS first who will then pass them on to the company.
If, as a result of these, non-conformity is discovered, BIOS will inform the company expecting an action plan within 10 working days. It is not possible to proceed with the certification without non conformity resolution.

15. NON-CONFORMITIES CLASSIFICATION

Non-conformities can be classified as follows:

- major: unacceptable condition that affects the global conformity of the whole system. It must provide an immediate resolution within 60 days from detection, after which the certification process needs to start over;
- serious: unacceptable condition related to a specified requirement that does not affect the system performance and conformity. It must provide a corrective action;
- minor: despite highlighting a shortfall relating to a requirement it does not affect the passing. A corrective action needs to be considered.

The presence of essential non conformities and/or important ones that have direct implications on the product compliance, result in the removal of the conformity references for the product in question (batches and quantities).

16. NON CONFORMITIES RESOLUTION

Before being presented to the CDC, the company must provide evidence regarding the non conformity resolution (even with a follow up verification, if necessary) and must send an action plan to correct the non conformity. The corrective actions are then approved by BIOS.

17. CERTIFICATION DOSSIER

BIOS personnel prepares a dossier summarising the certification process which will be presented to the CDC. This dossier contains:

- the documents required by the certification and the contract;
- the documents regarding the action plan of the verifications;
- test results and verification reports;
- a suggestion regarding the corrective actions and possible evidence of their resolution;
- an assessment regarding the company compliance.

The certification dossier is presented at the first available meeting of the CDC and not later than 90 days from the date of the verification.

18. COMMITTEE FOR THE CERTIFICATION APPROVAL (CDC)

The CDC evaluates the certification dossier. The CDC members meet regularly at least every 90 days. At every meeting the CDC examines all certification dossiers submitted and decides if the certificate is granted and in what conditions, or if it is refused and why.
Certification is denied when the CDC considers that the company degree of conformity is below the requirements set out in the standard. This assessment is based on the following elements:

- Presence of essential non-conformity;
- A large number of important and marginal non-conformities, casting a shadow on the company ability to manage the product quality;
- The proposed corrective actions and the lack of evidence supporting the non-conformity resolution.

The CDC takes its decision according to the relevant set of rules.

19. ISSUING OF THE CONFORMITY CERTIFICATE AND DESPATCH OF THE LOGO TO THE CERTIFIED COMPANY

Once the certificate is issued, it gets a registration number on the certificate itself. The certificate is compiled according to International requirements applicable to certification and accredited bodies.
Typically the certificate contains:

- the reference to the standard used to determine the conformity status;
- the business name and address of the company certified;
- the area of application of the certification (products and requirements);
- the validity period.

The CDC decision will be communicated to the company in writing along with the certificate and the logo that the company is allowed to use on the label.
Once the certification is granted the company will be able to:

- make public the certificate of conformity;
- advertise the certification in all the marketing materials (i.e. web, leaflets, brochures, adverts, headed paper, business cards, etc.) providing that the certification is referred only to the products with certification;
- market the certified products with label carrying the claim and logo allowed by this sets of rules;

The conformity claim and the BIOS logo can only be used with the products that have certification granted.

20. ALTERATION OF THE CERTIFICATION PROCESS

When the present certification rules gets reviewed, the companies registered/certified can choose between using the updated version and the previous one until the next certification renewal.
The certified company can request changes to the certification granted such as:

- business name
- production units
- certified products

The certified company can request at any time to cancel the control system by giving BIOS at least one month notice from the termination date . After the termination date the conformity certificate expires automatically and products labelled according to the present set of rules must be used of within 18 months maximum.
Starting from the termination date the company will have to:

- stop labelling products showing this standard compliance;
- stop printing marketing material showing this standard compliance;
- stop advertising the expired certificate;
- upon BIOS request inform all clients aware of the certification that the certification has expired.

BIOS can proceed with the company by giving:

- a cautionary suspension of the certificate conformity and of the labels;
- a permanent cancellation of the certificate conformity and of the labels.

In case of non-compliant behaviour of the company certified by BIOS, BIOS will decide the appropriate course of action.
A certificate can be suspended by BIOS only in the following cases:

- a voluntary request by the certified company;
- serious non-conformity or lack of the corrective relevant actions;
- serious violation of the applicable regulations by the certified company;
- missed payment to BIOS for the services provided.

The CDC has the authority of suspending and restricting the application field and/or withdrawing the conformity

certificate.
Such measures are notified immediately to the certified company.
The suspension can be revoked if the company re-establishes the conformity conditions and the compliance within 60 days from the date of the notification of the suspension.

21. FREQUENCY OF MONITORING AND TESTS

The certification contract is valid for three years. The minimum frequency of visits and tests is annually. If the company wishes to postpone an inspection, it must request it in writing explaining the reason two months before the scheduled visit. The decision to accept it or not is BIOS only. The following inspections will be performed according to the approved plan and schedule.
Any inspections or extraordinary tests can be done by the CDC in case of the following situations:

- there is evidence the company conformity is at risk due to complaints or non-conformity being reported by people interested in the certification
- an early verification is required because of non conformities spotted during earlier inspections or other certification activities.

At the same time of the conformity certificate being issued, an inspection plan will be produced and communicated as binding to the certified company.
Two months prior to the inspection BIOS will contact the certified company to schedule the date. The inspections are performed in the same modality as the certification verifications.
When the three years have expired, if the company chooses to renew the certification the third inspection becomes a renewal verification.

22. HOW TO USE THE LOGO AND THE CERTIFICATE OF CERTIFICATION

The certified company can:

- display, duplicate and issue a copy of the certificate;
- copy the BIOS registration logo specifying the certificate number and the reference document, but only on paper documents, marketing and advertising material.

In such case, the following conditions do apply:

- the BIOS logo may be used only in the format and exact colours provided by BIOS.
- the BIOS logo must always be used along with the company name and the unique certification reference number.
- the BIOS logo must be used only with products that have been granted certification;
- the BIOS logo may be used only on promotional material if complying with the above points;
- the certified company must suspend the use of the logo if BIOS considers it unacceptable.
- once the certification expires the certified company must stop using the logo;
- if there is a change in the application field, the certified company must update the certification certificate and/or the logo;
- using BIOS logo inappropriately without proper authorisation and/or a valid certificate following a certification suspension, is classified as a major non-conformity**.**

23. BIOS ORGANIC AND NATURAL COSMETICS LOGOS

NATURAL COSMETIC **ORGANIC COSMETIC**

24. APPEAL

If the company believes that the CDC or BIOS have discriminated against it, it can appeal to BIOS Voluntary Certification Chief who will pass it on to the Appeals Management Committee (CGR).
The appeal must be filed within 30 days from the notification date submitted by BIOS, specifying its reasons and arguments for not agreeing with such decisions.
The BIOS Voluntary Certification Chief has 30 days to summon the CGR.
The appeal will be evaluated by the BIOS CGR within 30 days from its filing.
Any expenses resulting from the appeal will be paid by the losing party.

25. CONFIDENTIALTY AND DATA PROTECTION

All internal personnel, BIOS evaluators and the laboratories involved in the certification process, are under a signed confidentiality agreement as per ISO 17065.
This implies that any information about the applicants and certified companies is kept confidential and there is restricted access to certification documents.
BIOS can make certification documents and records available to the accreditation body.

During the certification verification, follow up or inspection, the applicant and certified company accept the presence of the accreditation body examiners if required, in addition to the BIOS inspector.

26. BIOS OBLIGATIONS

BIOS refuses any responsibility towards any contracting party for direct, indirect or of any kind of damages resulting from the use of the report and/or certificate compiled during the verification process.
BIOS refuses any responsibility for direct or indirect damages resulting from the certificate issued by BIOS.
The company can file a formal complaint against BIOS at any time regarding the services provided by BIOS.