

## GENERAL SALES CONDITIONS INCLUDING ACCREDITED TESTS

### Article 1 Preamble

- 1.1 The terms and conditions here below shall have effect between the parties identified as follows:  
“Complife”: the company Complife Italia S.r.l., with registered office in Garbagnate Milanese (MI), Via Guido Rossa 1, VAT 11093320155, as the party in charge of the execution of the service;  
“Client”: the legal entity that requires the execution of the services included in those offered by Complife.
- 1.2 The relationships between Complife and the Client are regulated by the present General Sales Condition, assumed to be known to the Client because they are published on the website [www.complifegroup.com](http://www.complifegroup.com), or because they are specifically accepted by the Client with its signature at the end of the present document.
- 1.3 Any exceptions or additions to the present terms and conditions should be agreed in writing by both parties, and they will be accepted by Complife only if reported in the order confirmation.
- 1.4 In case of contrast between the present general conditions and the specific conditions agreed by the parties, the specific conditions prevail.
- 1.5 The individual agreement are concluded in accordance with specific written conventions, with the acceptance of the sales offers made by Complife or in any other way considered suitable to the circumstances, as long as it is provided in written form.

### Article 2 Object of the contract

- 2.1 The relationship between Complife and the Client may involve several services, including microbiological and/or chemical-physical tests on the materials provided by the Client, *in-vitro* and *in-vivo* safety and efficacy tests, technical consulting and regulatory support, provided also at the Client's site.
- 2.2 The individual services chosen by the Client will be indicated in the sales offers made by Complife.

### Article 3 Offers

- 3.1 Each sales offer will be valid for the length of time specified in it. The contract will be considered finalized when Complife receives a formal acceptance, undersigned by the Client, of the proposed offer as well as of the terms and conditions and of any further documents required. The validity of the agreement refers to the current year.
- 3.2 In derogation to the above clause 3.1, in any case the offer will be considered tacitly accepted by the Client in all of its parts when Complife receives the Client's samples on which the services mentioned in the offer are to be performed.

### Article 4 Certification and accreditation

- 4.1 Complife Quality Management System is certified to be compliant to the ISO 9001 standard.
- 4.2 Complife Test facilities are certified to be compliant with the principles of Good Laboratory Practice (GLP) by the Italian Ministry of Health according to EU Directive 2004/9/EC to carry out tests in compliance with GLP for what concerns the executions of non-clinical trials (chemical-physical tests, analytical chemistry tests, microbiological experiments, toxicity studies and *in-vitro* compatibility studies) for the purposes covered by the regulation and aimed at evaluating products' effects on man, animals and environment.
- 4.3 Complife is a CAB (Conformity Assessment Body) Laboratory credited by Accredia according to international standard UNI CEI EN ISO/IEC 17025- Accreditation n° 1318. The accreditation relates to the tests for which Complife has requested and obtained ilk accreditation. The updated list of accredited tests is available on ACCREDIA web site [www.accredia.it](http://www.accredia.it).

Accreditation implies verification of the Complife laboratory technical competence in relation to the accredited tests and its quality management system, according to the ISO/IEC17025:2005 requirements. Complife and ACCREDIA

### COMPLIFE Italia S.r.l.

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have stipulated an accreditation agreement which details all mutual duties ruling accreditation. By means of accreditation, ACCREDIA ensures the technical competence of personnel, the adequacy of facilities and equipment and the suitability of building. Accredia performs periodical sample checks on all the accredited tests and on the laboratory quality management system. The ACCREDIA Mark does NOT mean that ACCREDIA accepts responsibility for the results of the test or for any opinion or interpretation that may derive from this, nor that ACCREDIA gives its approval to a test sample or to a product.

#### **Article 5 Protection of health and safety in the workplace**

- 5.1 In carrying out its activities Complife applies and complies with all the requirements and duties provided on health and safety matters in the workplace pursuant to all applicable legislation, such as Italian Decree D. Lgs 81/2008 (Code on safety in the workplace).
- 5.2 The Client must notify to Complife any possible risk and/or danger, even though only potential, concerning the manipulation of the sample and, in case, a Material Safety Data Sheet and/or information about the composition of the sample must be enclosed with the sample.
- 5.3 If a Complife employee carries out its activities at the Client's site, the Client must inform Complife of the specific risks existing in its operational environment and also of the prevention and emergency measures adopted.

#### **Article 6 Price and payment**

- 6.1 Prices and payment methods are indicated in the sales offer.
- 6.2 Any delay in the payment of the due amount will imply, in addition to any determination of the seriousness of the failure, the application of overdue interests on the amount to be paid as to D. Lgs. 231/2002 (Administrative Responsibility of legal entities, companies and associations including those without legal personality).
- 6.3 In case of early interruption of the test on Client's request, an amount calculated on the basis of the activities done until the time of the request will be charged.
- 6.4 Any customs clearance charges for the samples are at Client's expense, except different arrangements between the parties.

#### **Article 7 Sampling and delivery**

- 7.1 Unless otherwise agreed, the Client should rely on its own staff to arrange the sampling, under its exclusive responsibility and according to adequate procedures in terms of correct manual operation and statistical significance, ensuring the minimum quantity necessary for the carrying out of the studies/tests mentioned in the sales offer. The type of container used for samples and the packaging for the transport must be suitable to maintain the sample's condition (detailed information about the correct execution of sampling can be found on the website [www.complifegroup.com](http://www.complifegroup.com)).
- 7.2 Unless otherwise indicated, the Client sends the sample, fixing with Complife the correct methods of transport. The sample must be delivered in such a way not to cause sample variations which could invalidate the analytical outcome. Client is responsible for sample delivery, unless Complife arranges for the withdrawal through its personnel. In any case the tests carried out by Complife will always refer only to the sample condition at the time of delivery.
- 7.3 Each sample must be identified with the following information: code or identification name of the sample, batch number, category (cosmetic, food, medical device etc.), typology and/or description of the product (if not indicated on the packaging), name of the Client.
- 7.4 Samples sent to Complife shall be preceded or accompanied by a written Request of Analysis reporting the date, the identification data of each product, the required tests (method) and the reference to the related sales offer. For the request of chemical and microbiological tests the format "Sample Sending Form", prepared by Complife, should be preferably used in order to be uploaded through Complife web platform "Lab Extended".
- 7.5 The Client is responsible for any inaccuracies or deficiencies in the information provided to Complife.
- 7.6 In case of incorrect or lacking indications, any additional charge and/or any delays in the tests delivery shall be borne by the Client.
- 7.7 During the service performance, the Client shall assure, where necessary, its full collaboration through all of its employees, assistants or third parties without any charge for Complife. This collaboration shall take place must be conducted in accordance with all the current legal requirements, as well as with the rules regarding safety conditions in the workplaces as well as the regulations for injury prevention cited in the Article 5 above.

#### **Article 8 Test start date and report delivery date**

- 8.1 Generally, microbiological tests start within the next working day after the acceptance of the sample by Complife, it is Complife duty to ensure the appropriate conservative treatments of the sample in the meanwhile. The times for carrying out all other tests, including *in-vivo* and *in-vitro* security and efficacy tests and studies, are agreed during the offer definition.

- 8.2 Samples on hold before acceptance by Complife will be properly kept in a quarantine area that ensures their preservation.
- 8.3 *In vivo* safety and efficacy tests will be carried out on the number of volunteers reported in the offer; in case of volunteers drop out the inclusion of more volunteers is not planned.
- 8.4 The delivery date to Client of Test report / Study reports is indicated in each specific offer, in relation to the provided test/study typology.

#### **Article 9 Test Methods**

- 9.1 Complife is committed to performing the contract agreed services in compliance with the applicable regulations on the basis of commonly applied and approved the technical rules.
- 9.2 In case the Client does not specify the test method to be used, Complife will select the method that best suits the Client's needs, preferably one published as international, national or regional standard by renowned technical organizations, as well as on scientific publications; if this is not possible, Complife will use its analytical procedures, already validated. Validation of the specific Client's samples typologies and specimen must be requested during the offer definition.
- 9.3 The proposed test method/protocol is indicated in the offer, hence it is considered accepted by the Client. When the methods and protocols described in the offer are intellectual property or "Reserved Information", as specified in article 15 below of Complife, they can be reproduced and/or shared by Client with third parties (totally or partially) only after agreements between Client and third parties which guarantee the same level of confidentiality, as specified in art. 15 below. Any breach, even partial, of this condition will consequently determine a compensation action for damages.
- 9.4 On Client's request, Complife provides clarifications on the methods and procedures that will be used.
- 9.5 If the test method is required by the Client, Complife is committed to inform it in case the proposed method is considered inappropriate or obsolete.
- 9.6 The sample is managed by Complife Client Service which arranges the collection, if agreed, identifies the sample with a unique code and put it into the analyses/test cycle, provides information about the state of samples and/or about the state of the analyses/tests and publishes the test report on the web portal (only in case of chemical and microbiological tests) and/or sends it to the Client. Any request regarding clarifications or the interpretation of results will be forwarded to the competent Technician by the Client Service. The results reported on the Test Report, identified by the sample's code, are representative only of the tested sample.
- 9.7 Samples tested are kept for a maximum of 30 days after the Test Report issue date, while all of the records relating to the performed activities are kept for at least 10 (ten) years, except different law provision or specific agreements.
- 9.8 Samples not accepted for reasons due to the Client's responsibility (incomplete documentation, missed payments, non-compliance of the sample, etc.) are kept by Complife for the same period (30 days).
- 9.9 The Complife Laboratories staff is allowed to use exclusively for the performance of its office duties all the data, information and circumstances of which it becomes aware during the carrying out of its task and it is required to comply with the regulations contained in the UE Regulation 679/2016 and subsequent changes and additions.

#### **Article 10 Test Reports**

- 10.1 Complife is responsible only for the results referred to the samples subjected to testing.
- 10.2 Test Reports related to chemical and microbiological tests are released in pdf format, preferentially uploaded into the Client's special private section arranged on Complife web portal; in alternative they are sent to the email address provided by the Client.

Reports of microbiological studies (for instance challenge test), chemical studies (for instance stability studies), *in vitro* and *in vivo* safety and efficacy tests are sent in pdf format to the email address communicated by the Client. Reports of *in vitro* and *in vivo* safety and efficacy tests are written in English; requests for test reports in dual language must be notified before the offer issue.

The request of hard copy Test Reports must be notified by the Client while formulating the request for an offer.

Changes to Test Reports (RdP and paper reprints) based on Client's request and not due for reasons attributable to Complife are subject to a separate charge of € 5,00/each for analytical test report, € 25,00/each for microbiological and/or chemical study report and € 50,00/each for *in vitro* and/or *in vivo* clinical test report.
- 10.3 In case of tests involving the supply of images, their format and resolution will depend on the camera used for the acquisition of images. The quality of the captured images (brightness, framing, format, resolution, etc.) is functional to the assessment purposes defined in the study protocol. Therefore the quality of images is selected according to technical/scientific purposes and not for marketing use. Specific requests related to the images quality must be previously agreed with Complife. Images are filed in the original format for a maximum of six months from the report date of first emission. After images will be converted in a compressed format. The image compression may result in a loss of resolution.

- 10.4 It is possible for the Client to use the Test Reports in order to demonstrate to interested third parties the performed test and its results. The use, in whole or in part, of Tests Report and Study reports, with the explicit use of COMPLIFE name or logo, for advertising and promotional purposes could be allowed upon request of authorization to Complife.
- 10.5 The violation of the above duty will result in the application of a penalty equal to ten times the expected burden on the invoice, unless paying compensation for damage.
- 10.6 Complife retains Test Reports and Study Reports for 10 (ten) years, according to current legislation provisions.

#### **Article 11 Tests subcontract**

- 11.1 With the acceptance of the present general conditions, the Client authorizes Complife to subcontract to third parties the whole work or part of it for technical and/or logistic reasons.
- 11.2 Complife is responsible towards the Client of the activities assigned to third subcontractors, whose competence have been verified. This responsibility no longer persists if the third laboratory is indicated by the Client.
- 11.3 In case of accredited tests, the subcontract can only take place - prior consent of the Client - to other laboratories that have accredited the same tests in object.

#### **Article 12 Complaints**

- 12.1 Any complaint shall be addressed to: "Complife – Quality Assurance" ([qualityassurance@complifegroup.com](mailto:qualityassurance@complifegroup.com)) and must include the timely and motivated indication of remarks and exceptions.
- 12.2 Claims and notifications in written form regarding the non-compliance of the Study report(s) and/ or Test report(s) with the Client's requirements that the Client submits to Complife will be evaluated if filed within 60 days from the date of receipt of the respective document(s) by the Client.

#### **Article 13 Information on the processing of personal data**

In compliance with the provisions of EU Regulation 679/2016 (hereafter, "GDPR") and in particular art. 13 of the Regulations, Complife guarantees that the processing of personal data carried out by any means of processing both computer and paper, will be carried out in compliance with the rights of data subjects, with particular reference to confidentiality, protection of personal identity and dignity and the right to the protection of personal data.

##### 13.1 Data Controller and Data Protection Officer (RPD / DPO)

The Data Controller is Complife Italia S.r.l., with registered office in Garbagnate Milanese (MI) Via Guido Rossa 1

The contact details of the Data Controller are as follows:

- by e-mail to [info@complifegroup.com](mailto:info@complifegroup.com)

- by post to the following address: Complife Italia S.r.l., via Guido Rossa, 1 20024, Garbagnate Milanese (MI)

The Data Protection Officer (RPD / DPO) can be contacted by writing to [info@complifegroup.com](mailto:info@complifegroup.com)

##### 13.2 Purposes and methods of processing

Your personal data will be processed to comply with legal / regulation obligations imposed by national or community legislation, for the fulfillment of the administrative and accounting obligations and for the fulfillment of contractual obligations for the purposes of carrying out the activity related to this supply agreement.

The data will be processed using mainly computerized methods.

##### 13.3 Legal basis of processing

The processing of your personal data complies with the provisions of art. 6, par. 1, letters b) and c) of the GDPR as necessary for the execution of a contract of which the interested party is a party and for the fulfillment of legal and regulatory obligations.

##### 13.4 Optional / obligatory nature of the provision of data

The provision of personal data is necessary for the fulfillment of legal and contractual obligations and failure to provide them could make it impossible to perform the aforementioned activities

##### 13.5 Circulation of data

For the pursuit of the aforementioned purposes, your personal data may be disclosed to professional offices, consultants and professionals working to support administrative, accounting and tax compliance and may be disclosed within the companies belonging to the Complife Group.

##### 13.6 Data transfer abroad

For the pursuit of the aforementioned purposes, your personal data may be made available to other companies of the Complife Group, in the EU and outside the EU.

##### 13.7 Retention of personal data

Your personal data will be stored for a period of time not exceeding that necessary for the purposes for which they are collected and subsequently processed and in any case, in compliance with the deadlines set by the regulations in force from time to time applicable.

### 13.8 Right of access to data and other rights

In relation to the processing of your personal data, the Client (the Interested Party) has the right at any time to obtain confirmation of the existence or otherwise of the same data and to know its content and origin, verify its accuracy or request integration or updating or correction. The interested party has the right to request cancellation of data processed in violation of the law or in case of revocation of consent and limitation of treatment in the event of a dispute, as well as to oppose their treatment for legitimate reasons or in any case and discretionally for all those purposes based on consent. The interested party also has the right to obtain the release of the personal data being processed in a format compatible with standard computer applications to allow transfer to other platforms of his choice also through direct transmission where this is technically feasible (the right to data portability).

These rights may be exercised by contacting the Data Controller:

- by e-mail to [info@complifegroup.com](mailto:info@complifegroup.com)

- by post to the following address: Complife Italia S.r.l., via Guido Rossa, 1 20024, Garbagnate Milanese (MI)

In case of failure or partial acknowledgment of the aforementioned requests, he / she will have the right to lodge a complaint or appeal to the Guarantor for the protection of personal data.

### Article 14 Data of Volunteers pursuant EU Regulation 679/2016

14.1 The data of the volunteers indicated in the clinical studies including the image related to parts of the body, are collected pursuant to the provision of EU Regulation 679/2016.

14.2 All personal and sensible data of the volunteers, including digital images and pictures, cannot be used in contexts that jeopardize their personal dignity and decorum. It is also forbidden to accompany the images with references in the personal details.

14.3 Pursuant to the article 7 of EU Reg. 679/2016 "The data subject shall have the right to withdraw his or her consent at any time" and that the data subject can exercise the rights referred to in Chapter III of the EU Regulation 679/2016. In particular, the volunteer has the right to obtain from the data controller the deletion of personal data concerning him without undue delay and the data controller is obliged to cancel the personal data without undue delay. In this case, if Complife were to receive a request for cancellation - pursuant to art. 17 of EU Reg. 679/2016 - will promptly inform the Client so that the latter can provide for the cancellation of any link, copy or reproduction of personal data of the volunteer from the channels of dissemination used, as required by the same article of the Regulation. The deletion of data must take place within one month, or within three months, taking into account the complexity and the number of requests, from the receipt of the request of the data subject, pursuant to the art. 12 of EU Regulation 679/2016. Upon completion of the cancellation, the Client will promptly inform Complife so that it can communicate it to the data subject.

14.4 In case of non-compliance with the requests of the volunteer, according to the art. 14.3 above, by Complife and by the Client, pursuant to art. 12, paragraph 4 of EU Reg. 679/2016, the data subject will have the right to lodge a complaint with a supervisory authority and to bring a judicial appeal.

### Article 15 Confidentiality

15.1 In view of the high sensitivity of the data and information exchanged between the Parties, they undertake to keep secret and shall not disclose to third parties or used themselves, directly or indirectly, even after the execution of the tasks and / or after the termination of the contract for any reason, the knowledge and information acquired in operation and / or a result of the activities, in order to (but not limited to):

15.1.1 Characteristics physical and chemical of the Costumer's products and/or compositional of the raw materials used in the Costumer products;

15.1.2 Features, application procedures, methods, timing, sequencing, technical characteristics, technical process of the production by the Client and of the study provided by Complife;

15.1.3 Commercial and industrial activities developed by the parties;

15.1.4 Technical research policy of new machinery/equipment, new processing, new chemicals formulations, new products/services;

15.1.5 Any other information and/or that the parties will know during the activity of this agreement or as well as the instrumental information ones (as indicated in the point from 15.1.1 to 15.1.4 above, "Reserved Information")

15.2 The Reserved Information should be used by the parties only and exclusively for the aims of the activity indicated in this agreement and within the agreed deadlines;

15.3 The Parties undertake, at the end of the activity of this agreement, to return or destroy promptly each type of support and/or document (original and in copy) that contain the Reserved Information known during the development of the activity, notwithstanding what indicated in the articles 9.7 and 9.8 and 10 above. The

document owned by the Costumer will be protected by Complife for a minimum period of six months from the date of the receipt.

- 15.4 The Parties undertake not to start any activity linked to achieve any right, including any license of the features, application procedures, methods, timing, sequencing, technical characteristics, technical process of the production by the Client and of the study provided by Complife.
- 15.5 Each of the Parties shall ensure adequate protection in order to prevent the disclosure of Reserved information and the parties agree to protect the Reserved Information by using the same degree of care as the party uses to protect its own confidential or proprietary information with the same level of secrecy of the Reserved Information received. This level of secrecy should not be less than a reasonable degree of care apply by professional operator of the same field.
- 15.6 The Parties should ensure all necessary precaution to prevent the disclosure of the Reserved Information to their employee or consultants that not need to know the information for their activity.
- 15.7 The parties undertakes to not will communicate the Reserve Information received from the other Party to anyone else than those of its employees or consultants having a need to know the information within the framework of the above-mentioned exchanges. Each of the Parties shall clearly inform the employees as to the confidential nature of the Reserved Information and will compel them to respect all aspects of the confidentiality Agreement.
- 15.8 In case of breach of this provision in full or in part, the party that suffered the violation can terminate the agreement according to the articles 1456 of the Civil Code, without prejudice to all other legal remedies.

**Article 16 Compensation requests**

- 16.1 In case the samples to be tested have anomalous characteristics or behaviors, not due to instrumental defects or because subjected to wrong handling by Complife's personnel responsible for the tests, any compensation expenses for damages committed to people and/or objects will be paid by the Client.

**Article 17 Copyright**

- 17.1 COMPLIFE GROUP® is a registered trademark of Complife. The Client cannot use this trademark without a prior written authorization by Complife.

**Article 18 Termination**

- 18.1 Complife can terminate the contract pursuant to art. 1456 of Italian Civil Law in case of late or failed payment by the Client of the due amount for the services object of this contract, as well as for violation of the rules pursuant to the Model adopted according to the D. Lgs. 231/2001 as further described in Article 18 here below, without the prejudice to the possibility to any other remedy under the law including the right to compensation for any damage incurred.

**Article 19 Organization, Management and Control according to Italian Decree D. Lgs 231/2001 and Code of Ethics**

- 19.1 The Client is aware that Complife adopted and applies a Model of Organization, Management and Control pursuant to Italian Decree D. Lgs. 231/01 (Administrative Responsibility of legal entities, companies and associations including those without legal personality), with its related Code of Ethics - published on Complife website - and disciplinary system; Client declares to have read and understood it.
- 19.2 The Client undertakes to comply with the principles of the aforementioned Model and to abide by its contents, principles and procedures, and, in general, to refrain from any behavior designed to configure the crimes indicated in D. Lgs.231/2001 and in subsequent edits and additions.
- 19.3 The Client also undertakes to enforce among its employees and collaborators all of the principles and behavioral protocols contained in the above mentioned model according to D. Lgs. 231/2001 and its related Code of Ethics.

**Article 20 Competent Court**

- 20.1 For any dispute that may arise concerning the interpretation and execution of the present general terms and conditions, the competence is recognized to the Court of Milan, with the exclusion, by accepted agreement, of any other Court.

Place and Date

CLIENT (Signature and Stamp)

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The Client acknowledges, having read the general conditions, approving them and explicitly accepting in writing the stipulation contained in the following provisions pursuant to and by effect of articles 1341 and 1342 c.c.: Article 2 (Object of the contract); Article 3 (Offers); Article 6.2 (Default interests); Article 7 (Sampling and Delivery); Article 8 (Tests start dates); Article 9 (Test Methods); Article 10 (Test Reports); Article 11 (Tests subcontract); Article 12 (Complaints); Article 14 (Data of Volunteers pursuant EU Regulation 679/2016); Article 16 (Compensation requests);

Article 18 (Termination); Article 19 Organization, Management and Control according to Italian Decree D. Lgs 231/2001 and Code of Ethics; Article 20 (Competent Court).

Place and Date

CLIENT (Signature and Stamp)

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