



ETB-BISLIFE

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GENERAL TERMS AND CONDITIONS (OF DELIVERY) OF THE ETB-BISLIFE FOUNDATION

These general terms and conditions (of delivery) come into force on 01-01-2024, replace all previous general terms and conditions (of delivery) of the ETB-BISLIFE Foundation and its legal predecessors, and can also be accessed at www.etb-bislife.org.

Article 1 – Definitions

In these general terms and conditions (of delivery), the following definitions shall apply:

General Terms and Conditions: the present general terms and conditions (of delivery).

ETB-BISLIFE: The ETB-BISLIFE Foundation, listed in the commercial register of the Chamber of Commerce under number 70564000, granted recognition by the Ministry of Health, Welfare and Sport as an organ bank and tissue establishment within the meaning of Article 9 of the Bodily Material (Safety and Quality) Act.

Client: the counterparty of ETB-BISLIFE.

Party: ETB-BISLIFE or the Client.

Parties: ETB-BISLIFE and the Client jointly.

Services: a) activities in the field of taking possession after acquiring, processing, preserving, storing and distributing Donors' Bodily Material; b) related activities in the field of information provision, training, knowledge development and knowledge utilisation; and c) all further actions which are related to the above under a) and b) or which may be conducive thereto.

Bodily Material: the constituents of the human body in the broadest sense.

Donor: a person or mortal remains, by or in respect of whom consent has been given under the Organ Donation Act for – or in respect of whom there is no objection to – the removal of Bodily Material from him or her.

Implantation: the introduction or insertion of Bodily Material into the body of another person (the recipient) for the purpose of their treatment on medical grounds.

Bodily Material Laws and Regulations: European directives 2004/23, 2006/17, 2006/86, 2012/39, 2015/565 and 2015/566, the Organ Donation Act, the Bodily Material (Safety and Quality) Act, the Requirements Decree on Bodily Material 2006 and the Regulation on Safety and Quality of Bodily Material.

In writing: in these General Terms and Conditions, "in writing" also means electronically, provided that the identity of one or more Parties can be established with a sufficient degree of certainty.

Article 2 – Applicability

1. These General Terms and Conditions apply to all Services provided by ETB-BISLIFE, to all offers and quotations of ETB-BISLIFE, to all assignments accepted by ETB-BISLIFE, to all work to be performed by ETB-BISLIFE, to all agreements between the Parties and to all other legal relationships existing between the Parties.
2. If and to the extent that the Parties wish to deviate from these General Terms and Conditions, the deviations must be agreed in writing. The provisions of these General Terms and Conditions not waived in the aforementioned manner shall apply in full.
3. The applicability of general terms and conditions and/or other conditions of the Client is excluded, unless the Parties have expressly agreed otherwise in writing.



Article 3 – Agreement

1. Any offer or quotation is always without obligation, even if it contains a deadline for acceptance. The purpose of the deadline for acceptance is solely to indicate that the offer or quotation expires as soon as it has not been accepted within the time period stated therein.
2. An agreement between the Parties shall only come into effect when (i) both Parties have signed a written document to that effect or (ii) ETB-BISLIFE has confirmed the agreement has been established to the Client in writing. If deemed necessary by ETB-BISLIFE, payment guarantees may be required in advance.
3. ETB-BISLIFE will endeavour to take great care in performing the Services.
4. ETB-BISLIFE is authorised to engage third parties to perform the Services. If such third parties wish to limit their liability, ETB-BISLIFE is authorised to accept such limitations also on behalf of the Client.
5. Any delivery times will be established in consultation between the Client and ETB-BISLIFE. Delivery times are always indicative and should never be considered as strict deadlines.
6. ETB-BISLIFE shall make every effort to ensure that the Services comply with the arrangements agreed in writing, the specifications stated by ETB-BISLIFE in the offer and the Bodily Material legislation and regulations applicable on the date the agreement was concluded.
7. The Client is obliged to act in accordance with all applicable legislation and regulations when executing any agreement between the Parties and, where applicable, to take care of all necessary permits and consents.
8. In cases where ETB-BISLIFE supplies Bodily Material:
 - (a) the Client is obliged to immediately report to ETB-BISLIFE any (suspected) serious adverse events or side effects involving the supplied Bodily Material, as referred to in the Bodily Material legislation and regulations;
 - (b) the Client is obliged to keep an accurate central archive or logbook of the Bodily Material supplied by ETB-BISLIFE for at least 30 (thirty) years after Implantation – including a description of the final use or destruction of the Bodily Material – such that the specific use of the Bodily Material is documented and the Bodily Material can be traced from the Donor to final destination;
 - (c) if there is a patient record, the Client is obliged to record all delivered and implanted Bodily Material in the relevant patient record and to keep this information accessible for at least 30 (thirty) years after Implantation;
 - (d) the Client shall provide ETB-BISLIFE with all relevant information in order to facilitate the traceability of the delivered Bodily Material and to ensure quality control and safety of the delivered Bodily Material;
 - (e) the Client is obliged to use the Bodily Material solely in accordance with the enclosed leaflet and conditions determined in advance by ETB-BISLIFE. Furthermore, unless otherwise agreed in writing with ETB-BISLIFE, the Client is obliged to use the Bodily Material exclusively in its own institution. Without ETB-BISLIFE's prior written consent, the Client is not allowed to make the Bodily Material available to third parties or to use it for purposes other than Implantation;
 - (f) the Client warrants that it has the required medical expertise and knowledge required for judicious Implantation of the delivered Bodily Material.
9. ETB-BISLIFE will endeavour to supply the Client with the desired quantity of Bodily Material, but can never guarantee this. In this regard, the Client also recognises and accepts that Bodily Material is sourced from Donors, so that the availability of Bodily Material depends, inter alia, on the availability of suitable Donors, the willingness of

these Donors to donate and the correct removal of the donor tissue by the relevant surgical removal organisations.

Article 4 – Price

1. Unless otherwise agreed in writing, the performance of the Services shall be subject to the rates set out in the ETB-BISLIFE's price list. The Client is familiar with this price list. In addition, transport costs will be charged.
2. Before the end of each calendar year, ETB-BISLIFE will set the price list for the following new calendar year, without requiring the Client's consent. ETB-BISLIFE will inform the Client in writing of any new price list and is entitled to charge the new rates for deliveries taking place in the new calendar year.
3. In addition to the above, ETB-BISLIFE shall be entitled to implement an increase with immediate effect if, in its opinion, circumstances arise that have an upward influence on the rates then applicable. ETB-BISLIFE will inform the Client in writing of such an increase and is entitled to charge this increase through to the Client for the next delivery.

Article 5 – Payment

1. The Client shall pay invoices sent by ETB-BISLIFE in euros within 30 (thirty) days of their date, without suspension or set-off.
2. If the Client fails to pay the amounts due within the agreed period, the Client will automatically be in default, without ETB-BISLIFE being obliged to send the Client a notice of default. From that moment, the Client shall owe the statutory commercial interest and shall be obliged to reimburse the costs for obtaining extrajudicial satisfaction, the latter amount being fixed at 15% of the amount owed by Client.

Article 6 – Non-compliance

1. In the event that the Client suspects that Services do not comply, it shall inform ETB-BISLIFE by means of a written communication, including the reasons for this suspicion, sent to ETB-BISLIFE, where possible accompanied by photographs of the alleged non-compliance and any other relevant information. The Client shall give such notice within 36 (thirty-six) hours of delivery of the relevant Service in respect of any immediately observable defect and, in respect of any non-immediately observable defect, within due time after the Client has discovered or reasonably should have discovered non-compliance, but always within 12 (twelve) months of delivery of the relevant Service. After the expiry of the applicable period, the Client can no longer claim this non-compliance.

Article 7 – Liability

1. If and insofar a failure to fulfil any obligation incumbent upon it under any agreement can be imputed to ETB-BISLIFE, or it is otherwise liable to the Client, its liability to pay compensation for any resulting damage shall be limited to the amount paid out by its insurer, increased by the deductible excess. If the insurer does not pay out in a particular case, ETB-BISLIFE's liability shall be limited to an amount of EUR 500,000 per event and EUR 1,000,000 per year.
2. ETB-BISLIFE shall never be liable for indirect damage, which in any event is understood to include consequential damage, loss of profit, missed savings and damage due to business interruption.
3. The limitations of liability in articles 7.1 and 7.2 do not apply in case of intent or deliberate recklessness on the part of ETB-BISLIFE.



4. ETB-BISLIFE shall never be liable for damage resulting from or related to the circumstance that:
 - (i) the Client has not treated the Bodily Material supplied in accordance with the enclosed leaflet, conditions previously determined by ETB-BISLIFE and/or applicable legislation and regulations; and/or
 - (ii) the Client has wilfully used unsound working methods.
5. The Client indemnifies ETB-BISLIFE and shall fully compensate ETB-BISLIFE for all third-party claims resulting from or related to the circumstance that:
 - (i) the Client has not treated the Bodily Material supplied in accordance with the enclosed leaflet, conditions previously determined by ETB-BISLIFE and/or applicable legislation and regulations; and/or
 - (ii) the Client has wilfully used unsound working methods.
6. The damage referred to in clause 7.5 is hereby fixed at the amount necessary to put ETB-BISLIFE in the position that would have existed if there had been no reason to bring a claim on the grounds of this indemnity. The damage just referred to also includes reasonable costs incurred by ETB-BISLIFE for the prevention, limitation and/or determination of the damage just referred to, including in any case the reasonable costs of external advisors engaged by ETB-BISLIFE.
7. The Parties are obliged to take out adequate insurance against liability arising from any agreement existing between them.

Article 8 – Confidentiality, privacy legislation and regulations, and security

1. The Parties undertake to keep confidential vis-à-vis third parties all information relating to the Bodily Material, so that the person in whom the Bodily Material is implanted cannot find out which Donor the Bodily Material originates from and the family of the Donor cannot find out in whom the Bodily Material has been implanted. This obligation of confidentiality does not apply if there is a legal obligation or court order requiring information be disclosed to a third party.
2. The Parties undertake to comply with applicable privacy laws and regulations, including the General Data Protection Regulation (GDPR) and the General Data Protection Regulation Implementation Act (GDPRIA), in the performance of any agreement existing between them. If and to the extent that proper compliance with these laws and regulations requires further arrangements to be made, the Parties shall consult with each other in good faith to reach such further arrangements.
3. The Party receiving personal data from the other Party shall keep such personal data confidential from third parties. This confidentiality obligation shall not apply if the disclosing Party has given its consent to provide such personal data to third parties, if the provision of the personal data to third parties is logically necessary in view of the purpose for which the personal data was provided and/or for the performance of any agreement between the Parties, or if there is a legal obligation or court order pursuant to which the personal data must be provided to a third party.
4. Each Party is responsible for the security of personal data which falls under its responsibility. The Parties will implement and maintain sufficient and appropriate technical and organisational security measures to protect the personal data, as required by the applicable privacy legislation and regulations.
5. If the Client provides personal data to ETB-BISLIFE, it shall ensure that it only provides personal data that is necessary for compliance with applicable legislation and regulations and the execution of any agreement between the Parties. This personal data will be provided pseudonymised, wherever possible.
6. If and to the extent a Party requires the cooperation of the other Party to comply with applicable legislation and regulations, the other Party shall (within reason) provide such cooperation.



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Article 9 – Applicable law and dispute resolution

1. The legal relationship between the Client and ETB-BISLIFE is subject to Dutch law. Any disputes will be settled exclusively by the competent court in Amsterdam.
2. In the event of a dispute between the Parties, the Parties agree that the ETB-BISLIFE's measurements, tests and values take precedent, subject to evidence to the contrary to be provided by the Client.

Article 10 – Translations

1. The General Terms and Conditions drawn up in Dutch shall prevail over any non-Dutch translation.