

General Terms & Conditions

for irradiation, laboratory testing and packaging services

provided by BBF Sterilisationservice GmbH, Willy-Rüsch-Straße 10/1, 71394 Kernen im Remstal, Germany for companies within the meaning of Section 14 of the German Civil Code (BGB), legal persons under public law or a special fund under public law

(version from: March 2023)

1. General information and scope of application

All deliveries, services and offerings (hereinafter referred to jointly as services) of BBF Sterilisationservice GmbH (hereinafter referred to as BBF) are performed on the basis of these General Terms & Conditions and are part of all business transactions carried out by BBF and the client. These General Terms & Conditions apply exclusively and unless other conditions or provisions have been explicitly agreed. They apply to all future contracts and business transactions with the client. The business conditions of the client or third parties do not apply, even if BBF does not expressly contradict them again or makes reference to a written document that contains or references the business conditions of the client or a third party.

2. Deliveries, services and offerings

- 2.1 BBF provides services as single services within the client's production process, in the form of the irradiation of goods within an irradiation cycle and/or the laboratory testing of samples, and/or packaging. BBF assumes no liability for contractual work services, and in particular not for those that bring about the desired outcome of the irradiation, such as the sterilisation (sterility/removal of impurities) of the goods, or the usability of the test results obtained from the samples. BBF provides statements as part of the objective application of its expertise, and in particular assumes no liability for any disadvantages experienced by the client as a result of compliance or lack of compliance with the certification/approval regulations that apply to the goods (e.g. the non-issuance, withdrawal, revocation or suspension of a certificate/an approval). The client bears the risk relating to the usability of the deliveries, services and offerings provided by BBF. The contractual relationship is limited by the specific order.
- 2.2 For the provision of services, BBF takes the information, documents, samples, materials and goods provided by the client as a basis. This includes, for example, the radiation dose specified by the client and the packing order/the dose distribution mapping or any specific test instructions/study plans provided by the client (hereinafter referred to as client materials). The validations are performed by the client and are within its field of responsibility. If the client requires the performance of non-validated irradiation processes, the client acknowledges that compliance with the required target dose within the irradiation container cannot be guaranteed and that the measured value at the routine measurement point may deviate from this amount. BBF does not check the client materials and accepts no liability with regard to the suitability, correctness and completeness of these materials or with regard to the resulting consequences. BBF has the right to reject goods and samples that are not in proper condition and/or are unsuitable for the provision of the service, without the client being able to derive any claims from this. The client materials do not extend or restrict BBF's scope of duties or agreed services. The client acknowledges that, through the provision of services, BBF neither assumes the position of the client or a third party nor releases either from their

obligations or takes on such obligations. This applies in particular to (but is not limited to) the client's obligations as a manufacturer and distributor as well as to reporting obligations, observation obligations and other control obligations.

- 2.3 In the case of (laboratory) tests, BBF creates a report that describes the test results but that does not contain an evaluation of the results of the (laboratory) test. In the event of any non-conformances (OOS results), BBF will make reference to these without mentioning any possible solutions. The report only makes statements on the results of the (laboratory) tests performed on the specific samples, and not on the remaining deliveries/lots. Reports are created and transmitted in electronic form (in particular via remote data transmission). The client accepts that reports created and transmitted in electronic form may be lost, modified or falsified, that they are not protected against access by third parties and that BBF accepts no liability for the confidentiality and integrity of electronic communication that leaves BBF's area of responsibility. The same applies to damage that occurs in connection with or as a result of computer viruses. If the client prefers a different type of transmission, this must be expressly agreed upon.
- 2.4 BBF provides the services with the required care in accordance with the agreement. The agreed specifications of the client are taken into account. If no such specifications have been agreed, BBF will perform the services in accordance with the recognised rules of technology and with the level of care that is customary for the industry, in compliance with the applicable regulations and trading practices.
- 2.5 BBF is entitled to assign services to subcontractors, which requires the prior approval of the client. In the event of such an assignment of services, BBF may disclose to the subcontractor all of the information, documents, materials and goods that are required for the provision of services, including the client materials.

3. Contract conclusion

- 3.1 BBF is bound to quotations for 14 days (from the date of the quotation). All orders must be made in writing; remote data transmission is sufficient. The acceptance of the quotation is binding, and can take the form of either the acceptance or the sending of goods.
- 3.2 The orders are individual orders, and BBF is entitled to provide the client with partial services if these partial services are usable and reasonable for the client within the framework of the intended contractual purpose.

4. The client's obligations (duty to cooperate)

- 4.1 The client must support BBF in the provision of services, in particular by ensuring the timely and complete provision of the client materials (in particular the irradiation dose or specification number for the irradiation and the packing order/the dose distribution mapping or any specific test instructions/study plans) and other information and materials, and by ensuring compliance with the requirements regarding the technical processability of the goods/samples. The client must inform BBF immediately of any circumstances that would make the provision of services by BBF difficult or impossible.
- 4.2 The client bears the costs incurred by BBF for the additional outlay that arises as a result of BBF having to repeat services due to delayed, incorrect and/or incomplete information or other cooperation steps or obligations of the client that have not been properly performed or as a result of these services being delayed (e.g. missing client materials such as samples or test instructions) or if additional services are required (e.g. re-testing). BBF is also entitled to charge for additional outlay such as that incurred in the case of a standstill/failure of the irradiation facility (e.g. for maintenance work) that is caused by the client failing to properly perform cooperation steps (in particular a failure

to observe the packaging information). The incurred additional outlay must – where possible – be invoiced in accordance with the agreed contract prices (unit price, hourly rates, personnel costs, system downtime etc.); if no agreement has been made in this regard, the customary remuneration must be paid. BBF is entitled to charge for such extra additional outlay, even if a fixed/maximum price has been agreed.

5. Performance period, deadlines, delay

- 5.1 Agreed performance deadlines are only binding for BBF if they have been expressly agreed. They are extended (i) if the client does not perform its obligations (or duty to cooperate), or if it performs these obligations or duties improperly or late and (ii) as a result of BBF lawfully claiming rights of retention to its own service as a result of outstanding remuneration payments. The enforcement of rights from Item 4.2 remains unaffected.
- 5.2 The performance period begins on the day on which all commercial and technical issues relating to the provision of services have been clarified, and all relevant conditions have been met, in particular the deliveries of goods and the provision of any down payments.
- 5.3 The performance deadline is met when, by the expiry of said deadline, BBF has informed the client that it is ready to dispatch the goods or when the goods have been handed over to the freight forwarder/sender as directed.
- 5.4 BBF accepts no liability for impossibility or delay of performance if this is due to force majeure or other incidents that were unforeseeable at the time the contract was concluded (e.g. operating disruptions of all kinds, strikes, lawful lockouts, labour shortages, shortages of energy or raw materials, difficulties in the procurement of materials or energy, difficulties in the procurement of necessary official approvals, or official measures) for which BBF is not responsible. If such incidents make it significantly more difficult or impossible for BBF to provide the services and if the obstacle is not just temporary in nature, the contracting parties are entitled to withdraw from the contract by means of a written declaration.
- 5.5 In the event of temporary obstacles/hindrances, the performance deadlines are extended by the period of the obstacle/hindrance plus a reasonable restarting time.
- 5.6 If BBF defaults on a service or becomes unable to provide a service, irrespective of the reasons, then BBF's liability is limited to damage compensation in accordance with Item 9 of these General Terms & Conditions.

6. Incoming and outgoing transportation, transfer of risk

- 6.1 The goods/samples requiring handling must be delivered in packaging that allows for safe and easy handling by BBF and that is suitable for reuse for the return transport. The client must reimburse BBF for the costs of any necessary repackaging and/or the intermediate storage of the goods requiring handling.
- 6.2 The client must deliver the goods requiring handling at its own cost and risk, by the specified deadlines and with any necessary duty paid. The client must ensure that the goods match the parameters on which the validation is based. This includes in particular the framework conditions specified by BBF, e.g. the basis weight and/or dimensions such as the diameter, wall thickness etc. The irradiation of the goods is performed (unless expressly agreed otherwise between BBF and the client) in an irradiation box specified by BBF (= standard box, 554 x 457 x 457 mm, capacity 110 l). The client must deliver the goods (or have them delivered) to BBF in the agreed box in accordance with the defined and qualified loading configuration/packing order. If a standard box is used, its weight must not exceed 25 kg when filled evenly and homogeneously with the goods intended for irradiation. The enforcement of rights from Item 4.2 remains unaffected.
- 6.3 BBF is obligated to store the delivered goods for the client with the care that BBF applies to its own property. BBF is only liable for intent and gross negligence. BBF's liability in the event of damage to the client's goods, including the packaging, is limited in its extent in accordance with Item 9.3 below.
- 6.4 The client must collect the handled goods, including packaging, from BBF, Kernen im Remstal, Germany at its own cost and risk (EXW Incoterms 2020). If the goods are sent at the request of the client, the risk for the accidental loss of the goods is transferred to the client at the time at which BBF hands over the goods to a freight forwarder or another institution assigned with carrying out the shipment. The transport costs are borne by the client. The client is solely responsible for taking out insurance to cover breakage and transport risks. If the collection or desired shipping of the goods is delayed, the risk of accidental loss is transferred to the client at the latest 2 days after the time at which the handled goods are ready to be collected or shipped and BBF has informed the client of this.
- 6.5 The storage costs following the transfer of risk are borne by the client. If the goods are stored by BBF at its own premises, the storage costs are invoiced separately based on actual expenditure (storage payment EUR 2.00 net per day per pallet) (this applies to packaging and sterilisation services; subject to change).

7. Prices and payment conditions

- 7.1 All prices are listed in euros and are net prices that apply on an "ex works" basis and are exclusive of packaging and any applicable statutory VAT. Any duties, fees, taxes and other public charges must be paid by the client. Transport packaging and all other packaging in accordance with the German Packaging Ordinance will not be taken back by BBF and will become the property of the client, with the exception of pallets. In the event of a consignment purchase at the request of the client, the client bears the actually incurred transport costs ex warehouse.
- 7.2 If the agreed prices are based on BBF's list prices and if the delivery is due to take place more than four months following the conclusion of the contract, BBF's list prices that are valid at the time of delivery apply (less an agreed percentage discount or fixed discount in each case).

- 7.3 Unless agreed otherwise, the invoice amount is due within 14 days of invoicing. Receipt of the payment by BBF is taken as the date of payment. Cheques are only classed as payment once they have been cashed.
- 7.4 If the client does not make a payment when the payment is due, it enters into arrears. From the time of entering into arrears, interest of 9 percentage points per annum over the base interest rate of the European Central Bank must be paid on outstanding amounts from the day that payments become due. The right to apply higher interest rates and assert claims for further damage in the event of arrears remains unaffected.
- 7.5 The client is entitled to rights of set-off or retention only to the extent that its claim is undisputed or ascertained as legally valid.
- 7.6 If, after the conclusion of the contract, it becomes apparent that BBF's claim to payment is jeopardised due to a lack of ability to perform on the part of the client (e.g. due to an application for the opening of insolvency proceedings), BBF is entitled to only provide or perform outstanding deliveries or services following advance payment or the provision of security and to withdraw from the contract in accordance with the statutory regulations – possibly after the setting of a deadline. In the case of contracts relating to the manufacturing of single items (one-off production items), BBF can declare its withdrawal from the contract immediately; the statutory regulations regarding the lack of necessity to set a deadline remain unaffected.

8. Qualitative performance impairment (warranty)

- 8.1 Reports by BBF (in particular relating to conducted tests) are created based on the client materials and are intended exclusively for use by the client. They cannot be invoked by third parties. BBF also assumes no liability in this regard. This applies in particular to damage incurred by third parties as a result of incorrect or erroneous information in reports created by BBF or the results communicated to the client. The client is solely responsible for the evaluation, use and usability of the reports. BBF also assumes no liability in this regard.
- 8.2 BBF is not liable toward the client or third parties for damage or costs incurred as a result of delayed, incorrect and/or incomplete client materials or information or other cooperation steps that have not been performed or not been performed properly, or obligations of the client that have not been met, not been met properly, or not been met by the specified deadlines. The same applies in the event of changes to the validated processing parameters in the event that the client does not communicate these changes or communicates them late, or if the client forgoes a validation. BBF also accepts no liability for (i) the up-to-dateness and lawfulness of the client materials or for (ii) damage to client materials that occurs as a result of incidents and circumstances for which BBF is not responsible, e.g. break-in, theft, fire, water, force majeure.
- 8.3 In the absence of an express written agreement to the contrary, BBF accepts no liability toward the client or third parties for the error-free state or suitability for use of a client's product in relation to which BBF is providing a service. A (laboratory) test carried out by BBF and a report that is based on such a test does not release the client or third party from product liability. BBF accepts no liability for damage caused by the product and/or its use/application. The related (indirect or direct) liability of BBF for consequential damage is also excluded. This includes, for example, lost profits, lost business, lost business opportunities, a decrease in company value or costs incurred in connection with a market action. BBF's liability for costs incurred by the client as a result of claims made against the client by third parties (in particular product liability claims) is excluded.
- 8.4 If the service provided by BBF is defective, BBF can initially choose to either provide a supplementary performance by remedying the defect (rectification) or to provide a defect-

free item (replacement delivery). The client acknowledges and is aware that the services performed by BBF (in particular irradiation) can usually only be performed once. In the event of a defective service performance by BBF, the client must therefore provide BBF with new goods and samples for the supplementary performance free of charge. BBF is also obligated to bear the necessary costs for the purpose of supplementary performance (transport, travel, labour and material costs). If a client's demand for defect rectification turns out to be unjustified, BBF can request that the client reimburse the costs that have been incurred as a result.

- 8.5 In order for the client to make a warranty claim, it must have issued a complaint without delay and in accordance with Section 377 of the German Commercial Code.
- 8.6 If the contractually compliant provision of the service in the form of the application of the irradiation dose specified by the client in its order to the item being irradiated is not achieved as part of the supplementary performance, or is not achieved by the end of the reasonable extension period to be expressly defined by the client, or if this is impossible or unreasonable for practical reasons or if BBF allows the extension period to expire to no avail, the client is entitled to withdraw from the contract, or can request a reduction of the remuneration. These rights are limited to the specific order. There is no right of withdrawal in the event of negligible defects.
- 8.7 In the event of a breach of duty that does not consist of a defect, the client can only withdraw from the contract if BBF is responsible for the breach of duty.
- 8.8 Additional claims, in particular for damage compensation or compensation for futile expenses, are determined in accordance with Item 9.
- 8.9 The limitation of warranty claims is one year from the transfer of risk.

9. Liability for damage compensation

- 9.1 BBF's liability for damage compensation, regardless of the legal grounds, and in particular due to impossibility, delay, defective or incorrect delivery, breach of contract, breach of duties during contractual negotiations and unauthorised action, is limited in accordance with this Item 9, insofar as it is at fault.
- 9.2 BBF accepts no liability in the case of simple negligence provided that such negligence does not constitute a breach of essential contractual obligations. Essential contractual obligations include the obligation to provide the delivery object on time and free from significant defects, as well as obligations concerning consultancy services, protection and care that are intended to enable the client to use the delivery object in accordance with the contract or that exist for the purposes of protecting the life and limb of the client's personnel or protecting its property against major damage. Any further liability is excluded regardless of the legal nature of the asserted claim. This limitation of liability also applies to bodies, legal representatives, employees or other vicarious agents of BBF.
- 9.3 If and insofar as BBF is liable in accordance with the previous Item 9.2, this liability is limited to damage that BBF has foreseen as the possible consequence of a breach of contract on conclusion of the contract or that BBF should have foreseen when applying due care. Indirect damage and consequential damage that occurs as a result of defects in the delivery object are also only eligible for compensation of such damage as is typically expected during the intended use of the delivery object. In terms of the amount, BBF's liability in the event of gross negligence is limited to twice the amount of the effected individual order for each claim or to a maximum total of EUR 10,000.00 per year of the contract, or in the event of simple negligence, to a maximum of the value of the

affected individual order for each claim or to a maximum total of EUR 5000.00 per year of the contract.

- 9.4 If BBF provides technical information or advice and if this information or advice is not part of BBF's contractually agreed scope of services, this information and advice is provided under exclusion of any liability.
- 9.5 The limitations of liability in this Section 8 do not apply to BBF's liability as a result of intentional or grossly negligent conduct, to guaranteed characteristics, to injury to life, limb or health or to BBF's liability in accordance with the German Product Liability Act.
- 9.6 If the client is entitled to claims for damages in accordance with this Item, these claims become invalid after one year has elapsed following the transfer of risk, unless a mandatory legal provision stipulates longer periods of limitation.
- 9.7 If BBF is liable with others as a joint and several debtor, it is always the final liable entity and only if the liability of the others does not cover the asserted claim.

10. Industrial property rights, copyrights and expertise

- 10.1 The client recognises the industrial property rights and the expertise of BBF.
- 10.2 All industrial property rights, including expertise, remain the sole property of BBF. Subject to any mandatory provisions that arise from applicable law or any written agreements to the contrary, the client is not granted any rights to the industrial property or expertise of BBF.
- 10.3 Work results such as inventions made by BBF or its vicarious agents in connection with the fulfilment of the contract are the exclusive property of BBF.

11. Termination

- 11.1 An order can be terminated at any time up until the start of the service provision, and thereafter only for good cause. The termination notice must be issued in writing. If the client terminates the contract before the start of the service provision, BBF is entitled to claim a lump-sum payment of 10% of the net invoice amount. The client is not barred from providing evidence that the extent of the damage was actually lower than this agreed lump sum. In the event of later termination, BBF is entitled to claim payment for the actually performed service, including the additional calculatory profit.
- 11.2 In the event that BBF terminates the contract for good cause and without giving notice, the client must reimburse BBF for the costs incurred by BBF as a result of the termination without notice. In particular, a good cause would be if the client does not carry out the required cooperation steps, if notice is received of insolvency proceedings on the client's assets, and if the client is in arrears for over one month.

12. Data processing

BBF stores and processes personal data within the context of performing the services and processing the business relationship with the client.

13. Final provisions

- 13.1 The place of performance is the BBF headquarters in Kernen im Remstal. The place of jurisdiction is the BBF headquarters. BBF is also entitled to file a suit at the client's headquarters. German law (German Civil Code, German Commercial Code) is exclusively applicable, excluding all international jurisdictions and the regulations of international private law.

- 13.2 Additional verbal agreements require written confirmation in order to be effective. Any amendments or supplements must be made in writing in order to be effective; this also applies to any changes to this clause relating to the written form.
- 13.3 If one provision is or becomes ineffective, either in whole or in part, this does not affect the validity of the remaining provisions. The legally ineffective provision must be replaced by a legally permissible provision that most closely reflects its economic purpose.