

General Terms and Conditions for the Supply of Goods and Services of Protec GmbH & Co. KG

as of July 2023

1 Object and Scope

- 1.1** All our offers and orders are subject exclusively to the following *General Terms and Conditions for the Supply of Goods and Services* even where they are not expressly referred to later in permanent business relations. Opposing or deviating conditions of the customer shall apply only if we have expressly accepted them in writing.
- 1.2** Our *General Terms and Conditions for the Supply of Goods and Services* shall apply only in relation to entrepreneurs within the meaning of § 14 BGB (German Civil Code) and only if the contract relates to the operation of the enterprise, as well as in relation to legal persons under public law and special public funds within the meaning of § 310 para. 1 BGB.
- 1.3** Unless otherwise agreed in the particular case, all foreign business transactions shall be subject to INCOTERMS 2020.
- 1.4** To the extent referred to in our confirmation of the order, further business conditions - such as our *General Software License Conditions*, our *General Maintenance Conditions for Systems*, our data protection agreement according to §28 GDPR (General Data Protection Regulation) as well as fulfillment of requirements according to Medical Device Directive (MDD), respectively Medical Device Regulation (MDR) as from 26 May 2020, including our Quality Assurance Agreement ("QSV_LuL") - may be applicable in addition to the present *General Terms and Conditions for the Supply of Goods and Services*. Within the limits of their scope of application, such conditions shall prevail over the provisions set forth in the present *General Terms and Conditions for the Supply of Goods and Services*.

2 Offers, Conclusion of Contract

- 2.1** All offers provided by us are subject to confirmation. Orders shall not be deemed accepted until confirmed by us in writing. Our confirmation of the order is binding with regard to the content of the contract unless written objection is received by us within 14 days of our confirmation of the order. Verbal subsidiary agreements must always be confirmed by us in writing to be valid.
- 2.2** We unrestrictedly reserve all of our rights, title and interest in and to service-, and product- and programme descriptions, drawings, test programs, and any other documentation made available to the customer within the framework of our offer. These documents may be made available to third parties with our prior consent only. The product information and technical data contained in such documentation, as well as in brochures, advertisements and other information and advertising material, has been compiled with due care, but does not constitute guarantees as to quality (*Beschaffheitsgarantien*) unless expressly designated as such. We reserve the right to make modifications for technical reasons even after the conclusion of the contract if these modifications do not materially affect the agreed function of the delivery item or object of the service.

3 Prices, Payment Conditions

- 3.1** Our prices are ex factory Oberstenfeld excluding packing, freight, insurance and statutory value added tax. In the absence of an agreement to the contrary, the customer will be billed separately for travel costs and expenses.
- 3.2** Subject to the confirmation of the order providing otherwise, our invoices are payable in the currency designated in the invoice net within 30 days of the date of the invoice. For deliveries abroad, terms of payment shall be at our discretion - either by payment in advance, or by irrevocable and confirmed letter of credit at the customer's expense. Differing conditions for foreign business transactions require a separate agreement.
- 3.3** Bills of exchange or checks are accepted only on account of payment; the time of payment shall be the point in time the bill or check is collected, in the case of bill

of exchange or check proceedings the point in time of release from liability. The customer shall bear all costs and expenses of discounting or collecting the bill.

- 3.4** The customer shall be in default if he fails to effect payment after receipt of a reminder that has been issued after the due date. Furthermore, default already occurs without further reminder 30 days after due date and receipt of the invoice. In the event of a delay in payment (*Zahlungsverzug*), we are entitled to charge interest for delay at the statutory rate. We reserve the right, subject to provision of evidence, to assert a higher damage caused by such delay or default.
- 3.5** In the event of delay in payment on the part of the customer, we are entitled, without prejudice to further statutory rights, to exercise, without prior notice, a right of retention over all outstanding deliveries and performances or to request prior payment and/or provision of security. We are furthermore entitled in any such case to demand immediate settlement of all outstanding claims against the customer for payment and, regardless of the maturity dates of accepted bills of exchange, to request payment in cash against restitution of these bills. The same shall apply in the event that, after acceptance of the order, we obtain knowledge of facts that give rise to justified doubts about the customer's ability to pay.
- 3.6** The customer is not entitled to set off counter-claims where they have not been expressly admitted by us or recognized by declaratory judgment. The customer shall be entitled to exercise a right of retention only to the extent that its counter-claim results from the same contractual relationship. The customer shall have no right of retention because of partial performances under § 320 para. 2 BGB.

4 Passing of Risk, Delivery and Delivery Period

- 4.1** As regards deliveries of goods, the risk passes to the customer as soon as the goods leave our factory or the warehouse; if the goods are to be collected by the customer, the risk passes with the customer's notification that the goods are ready for collection. The costs and risk of dispatch are always borne by the customer. In the absence of the customer's written instructions, we will determine the manner of dispatch. Transport insurance will be taken out only on the customer's express

instructions and at its own expense. Should there be a delay in dispatch due to circumstances for which the customer is responsible, then the risk passes to the customer upon notification that the goods are ready for dispatch. In this case, we are, however, willing to take out the insurance policies requested by the customer at the latter's cost. FCA in accordance with INCOTERMS 2020 shall apply for deliveries abroad.

- 4.2** No. 4.1 shall also apply when we perform an installation of the goods delivered to the customer, unless it concerns a supply and installation obligation under a contract for works and services, in which case the risk shall pass upon acceptance only.
- 4.3** Unless expressly agreed in writing, the indication of deadlines for the provision of goods and services shall be non-binding. Firmly agreed delivery or service times begin upon receipt of our confirmation of the order at the earliest but not before the timely and proper fulfillment of the collaboration duties of the customer, in particular clarification of all technical questions and, with respect to foreign orders, only upon payment in advance or provision of a confirmed letter of credit. In the case of deliveries of goods, the delivery period shall be deemed met if, at its expiry, the good to be delivered has left the factory or the warehouse or the customer has been notified of the good's readiness for collection or dispatch. This does not apply if the respective contract requires acceptance of the good or provides for the obligation to install the same.
- 4.4** We will endeavor to comply with agreed delivery or service times. Should we be in delay (*Verzug*) in delivery or in the performance of a service, the customer shall be entitled – provided that it proves to our satisfaction that it has incurred a loss due to the delay – to claim lump-sum default damages in the amount of 0.5% of the order value for each full week of default, however no more than 5% of the order value altogether. The assertion of further claims for damages by the customer because of the delay in delivery or in the performance of the service shall be excluded. This does not apply if delay is due to wrongful intention or gross negligence on our part or on the part of our agents, or if we are mandatorily liable for a violation of life, body, or health; this does not involve a change in the burden of proof to the customer's disadvantage.

- 4.5** The customer's statutory right of rescission in the event of a delay in delivery or in the performance of a service remains unaffected but requires that we are responsible for the delay. The customer shall be obligated to declare at our request within a reasonable period whether it will rescind the agreement upon expiry of such period because of the delay in delivery or in the performance of the service or whether it will insist upon delivery or the performance of the service.
- 4.6** We will be released from our delivery or service obligations in the event of operational breakdown (e.g., power shortage and shortage of raw materials, strikes) and other force majeure events for which we are not responsible, as well as in the event of late delivery of supplies to ourselves, for the period during which such factors affect the running of operations. The same shall apply if such circumstances happen to our suppliers. To the extent that we are released from our delivery or service obligations, we will grant back advance performances made by the customer, if any. Further claims for damages of the customer shall be excluded.
- 4.7** Partial deliveries and the partial performance of services shall be permissible to the extent reasonable.

5 Copyrights, License Conditions for Software

- 5.1** The customer shall be obligated to observe the existing copyrights and other intellectual property rights in respect of the delivery item or the work created within the framework of the performance of our services, especially rights in computer programs (software) and to impose this obligation also on its own purchasers.
- 5.2** In the event of the delivery of software of other manufacturers (third-party software), the customer may use the supplied software only in accordance with the license conditions of the manufacturer currently in force, and provided that the customer is authorized to resale the software, it shall impose the same duties on any purchaser to whom it resells the software,

5.3 Unless otherwise agreed, the use of any software manufactured by us (Protec Software) shall be governed by our *General Software License Conditions*. If the customer makes Protec Software available to third parties (final customers), it is under obligation to ensure that our *General Software License Conditions* are brought to the knowledge of – and are recognized by – the respective final customer.

6 Retention of Title

6.1 As regards deliveries of goods, we retain our title to the goods supplied until all our claims resulting from the business relationship with the customer have been discharged in full, regardless of the cause in law. With respect to current accounts, the title retained is regarded as security for our offset balance at any given time.

6.2 In the event of a conduct of the customer that is not in conformity with the contract, especially in the event of a delay in payment, impending suspension of payment, unsatisfactory information as to the customer's solvency or financial position, if judicial executions or protests in respect of bills of exchange occur, or if an application for the institution of insolvency proceedings against the customer's assets has been filed, we are entitled to take back the goods delivered. The customer is obliged to return the goods. We are not required to rescind the contract in order to be able to take back the goods and/or assert the retention of title. These acts or the attachment of the goods delivered by us does not constitute a rescission of the contract, unless we expressly declare so in writing. After taking back the goods delivered, we are entitled to sell or otherwise dispose of the same. The proceeds resulting from such sale or other disposition, less reasonable costs thereof, shall be credited towards the customer's liabilities.

6.3 The customer shall be obligated to treat the goods delivered with due care and to sufficiently insure them against damage at our request for the duration of the retention of title. The customer assigns to us already now any claims it may have against the insurance company up to the amount of our underlying claim. In the event of attachments or other interventions by third parties, the customer must immediately notify us in writing so that we can assert our title. To the extent that the third party is not willing or able to reimburse us for the judicial and extra-

judicial costs incurred by us in connection with the enforcement of our property rights, the customer shall be liable for the loss incurred by us.

- 6.4** The customer is entitled to process the goods supplied or combine them with other objects in the proper course of business dealings; such right may be revoked at any time. Any processing or combination is deemed to be on our behalf without commitment on our part. In the event of such processing or combination, the customer gives us co-ownership in the new or combined item in the same proportion as the ratio of the invoice value of the goods in which title is retained to the total of the invoice value of all alien goods used including processing costs. In all other respects, the provisions applicable to goods supplied subject to a retention of title shall likewise apply to the item created through processing or combination.
- 6.5** The customer may dispose of the goods in which we have title or co-ownership in the proper course of business dealings on its usual terms; this applies, however, only as long as the customer is not in delay in payment. In the event of resale, the customer assigns to us already in advance the claims arising against its purchasers or any third party in the amount of the value of our respective invoice (including VAT) plus a security surcharge of 10 %. We herewith accept the assignment.
- 6.6** The customer shall be entitled to collect the claims assigned to us under no. 6.5 above until revoked by us; such revocation is permitted at any time. We will exercise this right of revocation only with good cause. The customer shall, upon request, be obligated to notify the third party debtors of the assignment to us and to supply us with the information and documents required for the collection.
- 6.7** The customer may not transfer the goods in which we have a title or co-ownership by way of security or pledge the same, may not assign the claims resulting from the resale to a third party or make an offset nor agree a ban on assignment with its purchasers with respect to such claims. In the event of a global cession by the customer, the claims assigned to us are to be expressly exempted therefrom.
- 6.8** If the value of our existing securities exceeds our claims against the customer in total by more than 10 %, we will be obligated to release the securities exceeding

this limit at the customer's request; the individual objects to be released will be chosen by us.

7 Defects as to the Quality of Deliveries and Works

- 7.1** As regards deliveries of goods, the customer shall carefully examine the delivered good promptly upon receipt and notify us of defects, if any, forthwith in writing. Defects shall be deemed to have been timely objected to if notification thereof occurs within seven days as of the receipt of the delivered good or, in the event of hidden defects, within seven days of their discovery. Work services shall be accepted by the customer promptly after performance; acceptance may not be refused due to immaterial defects.
- 7.2** If the delivery item is defective and the defect has been timely notified (for deliveries) and in case of acceptance of performance of work services with undetected defects, the customer is first entitled to a rectification of the defect within a reasonable grace period to be determined by the customer. Subsequent performance, whether removal of the defect or substitute delivery/performance, shall be at our choice. Replaced parts become our property and must be returned to us. In the event of unjustified complaints with respect to defects, we are entitled to claim compensation from the customer for the expenses incurred by us.
- 7.3** If we fail to deliver subsequent performance in accordance with no. 7.2 even upon multiple attempt, the customer can – at its choice and without prejudice to claims, if any, for damages or for reimbursement of expenses according to no. 10 below – either demand compensation for the delivery or service performed (reduction) or remedy the defect and demand reimbursement of the necessary expenses (only for work performance) or, if the violation of duty on our part is not only insignificant, rescind the contract.
- 7.4** Customer claims for defects shall be excluded if the defect is the result of fact that our delivery or service item

- has been changed on its own initiative, in particular by installing third-party parts or, in the case of software, by re-programming, or
- was not used in accordance with the respectively valid product or program description, user manual or other product-specific documents, in particular unsuitable attachments, accessories or unsuitable components were used, or
- has been operated by inadequately or insufficiently trained specialist personnel or has not been properly maintained or
- was used outside the intended use or
- continued to be used after the end of the product life cycle or
- has been improperly treated or used, which is the case in particular in the case of a willfully impaired function.

7.5 Any claims for defects become time-barred within 12 months of delivery (as regards deliveries of goods) or of acceptance (as regards work services). This period of limitation (*Verjährungsfrist*) also applies to claims for damages or for reimbursement of expenses in connection with defects to the extent that they do not rest upon wrongful intention or gross negligence nor lead to violation of life, health, or body. Said period does not apply, however, to the extent that a longer limitation period is compulsorily prescribed by law, as, for example, in §§ 438 para. 1 no. 2 BGB (buildings, objects for buildings), 479 para. 1 BGB (recourse claims for the purchase of consumer goods), 634 a para. 1 no. 2 BGB (defective building works). The limitation period applicable to the original delivery item or the original object of our service shall equally apply to replacement parts and other services regarding subsequent performance.

8 Supplemental Provisions for the Purchase, Leasing and Programming of Software

- 8.1** The object of the contract is software generally corresponding to the information contained in the respective product or programme description. Subject to a guarantee, if any, expressly given in our confirmation of the order, the information contained in the product or programme description shall not be deemed guarantees as to quality (*Beschaffheitsgarantie*) within the meaning of §§ 443 and 639 BGB.
- 8.2** A software defect is deemed to exist if the software does not fulfill the functions set forth in the product or programme description, if it furnishes incorrect results, interrupts its run in an uncontrolled manner, or otherwise fails to work according to its functions so that the use of the software is considerably impaired.
- 8.3** We do not warrant for defects of the software
- that have been caused by faulty application on the part of the customer or its purchasers and that could have been prevented in the event of careful consultation of the program documentation; this applies also in the event of non-existent or insufficient backup measures;
 - that are due to virus infestation or other external influences such as fire, accidents, power outage, etc. for which we are not responsible;
 - that are due to the software being used in a different operating system than approved by us or defects of the hardware, the operating system, or the software of other manufacturers; or
 - that are due to the software having been modified by the customer or a third party without authorization.

Clause 7.4 remain unaffected.

- 8.4** In the event that defects within the meaning of no. 8.2 above occur, the customer shall be obligated to furnish us with all information necessary for an error analysis and subsequent performance, and to grant us and/or the persons commissioned by us unrestricted access to the software and the system of the customer on which the software is installed. Notifications of defects must contain information as to the

type of defect, the application during which the defect has occurred, as well as the work that has been carried out for purposes of removing the defect. The defect must be described such that it can be reproduced. If we carry out an error analysis at the customer's request and the analysis shows that there is no defect that we are obligated to remove, we may invoice the customer for the corresponding expenditure on the basis of our hourly rates as applicable at that time.

- 8.5** In the event of software leasing (including Lease&Click) strict liability due to initial defects according to §536a para. 1 BGB shall be excluded.

9 Third-party Rights

- 9.1** We warrant within the limits of the following provisions that the goods delivered or works created by us are free of third-party rights that prevent the use of such goods or works as agreed by the customer or the customer's purchasers.

- 9.2** In the event that such rights are asserted by third parties, the customer must inform us without undue delay of the assertion of such third-party rights and shall grant us any and all powers and authority necessary for defending the customer against the asserted third-party rights.

- 9.3** In the event of an infringement of third party rights, we will be entitled, at our choice:

- to remove the third-party rights that affect the use of the goods or works as agreed by taking suitable measures; or
- to modify or replace the goods or works such that they no longer infringe third-party rights, if and to the extent that such modification or replacement does not affect the contractually agreed functions.

- 9.4** To the extent that we fail to take the measures also upon the second attempt according to no. 9.3 above within a reasonable period of time to be set by the customer, the customer may, at its choice and without prejudice to possible claims for damages or for reimbursement of expenses according to no. 10 below,

demand a reduction of the agreed remuneration or – if the agreed use of the goods or works is not only insignificantly impaired by such third-party rights – rescind the contract (for purchase of Software) or terminate the contract (for leasing of Software, including Lease&Click).

- 9.5** With regard to the limitation period for claims based on third-party rights related to the delivery of goods and the performance of work services, no. 7.5 above shall apply correspondingly.

10 Liability for Damages and for Reimbursement of Expenses

- 10.1** We shall be liable within the limits of the statutory provisions if the customer asserts claims for damages or for reimbursement of expenses which are based on intent or gross negligence or non-compliance with guarantees agreed in writing as well as in cases of culpable violation of life, body, or health.
- 10.2** In cases of slight negligence we are liable for breach of material contractual obligations only. Material contractual obligations are those arising from the nature of the contract and which are of particular importance for the purpose of the contract. In the event of breach of material contractual obligations by slight negligence our liability for damages shall be limited in its amount to the foreseeable, typically occurring damage. Claims for damages and reimbursement of expenses of the customer according to this no. 10.2 shall become time-barred after 12 months; § 199 paragraph 1 BGB shall apply for commencement of the limitation period.
- 10.3** In the event of data loss, we shall be liable at maximum for the effort required to reconstruct the data in the case of correct data storage by the customer or its purchaser.
- 10.4** Any liability for damages or reimbursement of expenses beyond the scope of liability provided for in these *General Terms and Conditions for the Supply of Goods and Services* is excluded, regardless of the legal nature of the asserted claim. The

imperative provisions of the Product Liability Act (*Produkthaftungsgesetz*) remain unaffected.

- 10.5** To the extent that our liability is excluded or limited under these *General Terms and Conditions for the Supply of Goods and Services*, this shall likewise apply to the personal liability of our corporate bodies as well as vicarious agents and persons employed by us in the fulfillment of our obligations (*Erfüllungs- und Verrichtungsgehilfen*), especially members of our staff.

11 Acceptance and Disposal of Returned Devices

- 11.1** The customer assumes the obligation to properly dispose, at its own cost and in accordance with the statutory provisions, of the supplied goods after discontinuing their use.
- 11.2** The customer shall hold us harmless and indemnify us, in our capacity as manufacturer, from the obligations under § 19 ElektroG (German Law on Electric and Electronic Appliances) as well as from related claims of third parties.
- 11.3** The customer must impose on third parties to whom it passes on such of the goods supplied by us as are subject to the aforementioned law (ElektroG) and who do not use the goods in the context of a private household the contractual obligation to properly dispose of these goods – at their own cost and in accordance with the statutory provisions – after discontinuing their use and to impose the same obligation on any person who may receive the goods from them in the event of a further transfer.
- 11.4** If, subject to violation of the foregoing no. 11.3, the customer fails to impose on third parties to whom it passes on the delivered goods a contractual duty to assume the disposal obligation and to impose a corresponding obligation on their own purchasers, the customer remains under obligation to accept, at its own expense, the supplied goods that are returned after the discontinuation of their use and to properly dispose thereof in accordance with the statutory provisions.

11.5 Our claims to assumption of the obligation and/or indemnification by the customer pursuant to nos. 11.1 and 11.2 above and to the imposition of a corresponding obligation on the parties acquiring the device from the customer as well as to the disposal and acceptance of the returned device by the customer at its own cost pursuant to nos. 11.3 and 11.4 above shall not become time-barred before the expiration of two years following the final discontinuation of actual use of the device. The two-year limitation period (*Verjährungsfrist*) begins to run no earlier than upon receipt by us of a written notification of the discontinuation of use from the customer.

12 Protection of confidential information; Data protection (GDPR)

12.1 The contractual parties shall treat important information of the other respective party that are essential and not in the public affairs, which become known to them in the context of performance of contract, with the care usual in business dealings. Any further protection of particularly sensitive information and the associated establishment of terms and conditions of use of such information each require the conclusion of a separate written agreement (non-disclosure agreement).

12.2 Furthermore, ideas, concepts, methods or techniques that are not protected by copyright or other intellectual property, nor subject to any confidentiality agreement may be used freely by the contractual parties.

12.3 Precondition for performing technical support of any kind of cause or any other kind of assistance by our organization with potential access to systems, respectively possible access to personal data is the obligatory application of our data protection agreement. Lack of signed agreement leads to compulsory refusal of support.

13 Duties under Foreign Trade Law and Requirements according to Medical Device Legislation

13.1 In case of export of goods (including software) supplied by us, the customer is under obligation to comply with the provisions of applicable foreign trade law, as amended from time to time, in particular with the German Law on Foreign Trade and Payments (*Außenwirtschaftsgesetz, AWG*), the German Foreign Trade Regulation (*Außenwirtschaftsverordnung, AWW*), and the applicable EU Regulations and foreign statutory provisions concerning export and delivery. Upon our request, the customer must present an end-use certificate which meets the requirements of the aforementioned laws, regulations and provisions.

13.2 In the event of the supply of medical devices, the customer is obliged to establish records complying with applicable statutory requirements

- for the traceability of medical devices supplied by us through to the end customer,
- regarding installations and verification (acceptance tests) of medical devices supplied by us at the end customer,
- regarding maintenance (for example, service and repair) and periodic testing of the medical devices supplied by us at the end customer,

and to keep these over a period corresponding to at least the period specified by us as appropriate for each medical device and to provide access to such records to us and / or the competent authorities at any time.

13.3 The customer is obliged to attend the training which we offer for the acquisition and maintenance of the required expertise for Protec medical devices and to prove its expertise to us and / or the relevant authorities upon request. This applies to all employees of the customer, who provide the end users with technical information concerning Protec medical devices or who advise them on the proper handling of Protec medical devices.

13.4 Activities for the installation and verification (acceptance test) and maintenance (e.g. service and repairs) and periodic inspections of Protec medical devices may only be performed by persons who have attended a technical training for the relevant product group with us and have a valid certificate, whereby the validity of

temporary certificates is to be observed. When carrying out these activities, the customer and his employees are obliged to follow the PROTEC specifications. PROTEC will provide the customer with installation, maintenance and repair instructions as well as other information required for customer service in German and English language.

13.5 The customer is obliged to inform our person responsible for regulatory compliance (PRRC) for medical devices immediately in writing of all their own observations and of all communications from end users concerning side effects, interference, malfunctions, technical defects, contraindications, adulterations or any other risks experienced with Protec medical devices; and to provide adequate support in case of complaints, incidents, the exercising of any obligation to notify the competent authority including corrective measures and in particular recalls. This includes in particular enabling the immediate inspection of the records referred to in clause 13.2.

13.6 If the customer carries out an activity that falls under § 6 of the German X-ray Regulation (*Röntgenverordnung*) or equivalent foreign legislation, particularly in the case of examination, testing, maintenance and repair of X-ray equipment for commercial purposes, the customer must inform the competent authority immediately in writing before the start of such activity and provide evidence therefor to us upon request.

14 Applicable Law, Place of Performance and Jurisdiction

14.1 Legal relations with our customers are governed solely by the laws of the Federal Republic of Germany to the exclusion of the conflict of laws provisions, the United Nations Convention on Contracts for the International Sale of Goods, or any other international conventions concerning the sale of goods.

14.2 The statutory seat of our company is the exclusive place of performance for both parties to the contract. The exclusive place of jurisdiction is Stuttgart. We are, however, also entitled to sue the customer at its general place of jurisdiction.

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