

## **1. Scope of Application**

**1.1** These General Terms and Conditions will not apply if and to the extent it is otherwise agreed with our respective customer in an individually negotiated agreement. In all other respects, these General Terms and Conditions apply as follows:

**1.2** These General Terms and Conditions apply to all our transactions with regard to work supplies, work performances and services with merchants, legal entities under public law or special funds under public law (in each case hereinafter, the "Customer").

**1.3** Within current business relationships these General Terms and Conditions will also be applicable to all follow-up transactions with the Customer, without any obligation on us to additionally refer to their application in each case.

**1.4** Our General Terms and Conditions are conclusive for all business transactions with the Customer with regard to the subject matter of the contract. Particularly general terms and conditions of the Customer, such as e.g. terms and conditions of purchase will not become part of the contract, irrespective of whether they contain, compared to these General Terms and Conditions, deviating or supplementary provisions.

**1.5** This applies even if the contracting parties have or had already been engaged in a business relationship in which the Customer's general terms and conditions have applied, or if the Customer's general terms and conditions are referred to during order processing and we do not expressly object their inclusion again.

## **2. Conclusion and Content of Contract, Quality- and Technical Regulations**

**2.1** Our offers are non-binding. A contract will be deemed concluded only if the Customer has received our written order confirmation in accordance with the order, or if he accepts our order confirmation deviating from his order, however at the latest if we, in express or implicit agreement with the Customer, have commenced with the performance of our contractual obligations.

**2.2** The scope and content of the contract will be determined by our written order confirmation, or if such is not furnished, by our offer.

**2.3** Subject matter of contract as to our manufacturing works (hereinafter "Manufacturing Works") may be, as agreed from time to time, the contract manufacturing of pharmaceutical products destined for the placing on the market or the use in clinical trials (in each case after being released by the Customer), medical devices and other products using our blow-fill-seal® technology, as well as packaging in secondary packaging materials. Our Manufacturing Works will be performed in the form of contracts for work and materials (Werklieferungsverträge).

**2.4** The Customer shall in case of Manufacturing Works be (in each case dependent on the type of the product to be manufactured) pharmaceutical entrepreneur in the sense of § 4 Nr. 18 AMG, or Sponsor, manufacturer of medical devices or manufacturer of technical products and shall in relation to third parties act as sole manufacturer of the product, to the extent legally permissible. The Customer is as to medicinal products solely responsible for the release of the product to the market and/or the release for use in clinical trials, as to medical devices and technical products for the conformity assessment and compliance with the essential requirements. We shall perform Manufacturing Works or Services agreed and authorized by Customer in accordance with Customer's requirements considering an agreed Quality Agreement (if any) and the quality and technical regulations as set forth in sect. 2.10.

**2.5** Subject matter of contract as to our services (hereinafter "Services") may be, as agreed from time to time, consulting services regarding process development, regarding adaptation and optimization of container designs, the performance of filtration and scale-up tests, the performance of microbiological and chemical tests, the consulting regarding the implementation of GMP-standards and in other GMP-relevant fields of the project work, the planning, qualification and validation of Customer's facilities and processes, the manufacturing of sample charges for preclinical studies and / or for technical or stability charges (not intended for placing on the market nor clinical studies). Our Services will be performed based on contracts to produce a work, contracts for work and materials and/or service contracts.

**2.6** Documents such as images, drawings, samples, indications of measurements or weight attached to our offers and order confirmations will only be binding if and insofar as we have unambiguously described them as being binding.

**2.7** Contractual stipulations of a particular quality ("Beschaffenheitsvereinbarungen") or the declaration of guarantees will only be effective if made by means of an unambiguous individual agreement.

**2.8** In case of obvious typographical or arithmetical errors in the offer or order confirmation, such will apply that for the addressee observably was meant without the error.

**2.9** We are entitled to rescind the contract if after conclusion of the contract the performance of our contractual obligations turns out to be impossible or unreasonably difficult due to no fault of our own. If the impossibility or unreasonable difficulty is not due to the Customer's fault either, we will inform the Customer promptly upon our knowledge of the impossibility or unreasonable difficulty and promptly reimburse him for any expenses paid, especially any down payments, plus 5% interest p.a. Any further claims of the Customer based on impossibility or unreasonable difficulty to perform our contractual obligations due to no fault of our own are excluded. The provisions of sect. 3 (including subsections) remain unaffected.

**2.10** For the compatibility of the subject matter of our Manufacturing Works or Services with quality or technical regulations, e.g. such as GXP- and GMP- respectively; DIN/ISO-, VDE-; WHO-; PIC-; pharmacopoeia standards and/or accident prevention regulations, only such regulations or parts thereof will be applicable, which were expressly agreed for the respective products, or for the subject matter of the respective Manufacturing Works or Services, as the case may be, or are mandatorily applicable to our respective Manufacturing Works or Services and effective at a particular time in Germany by law. This will expressly also apply for export transactions.

**2.11** There will be no inclusion of Customer's affiliates or business partners in this contract in the sense of a "contract for the benefit of a third party (Vertrag zugunsten Dritter)" or in the scope of protection of this contract in the sense of a "contract with protective effect for the benefit of a third party (Vertrag mit Schutzwirkung zugunsten Dritter)". Our sole contract partner and the sole business entity our protective obligations according to this contract are addressed to, is the Customer himself.

## **3. Customer's Duties of Cooperation, Indemnification.**

**3.1** The Customer is obliged to provide us with all information about the Manufacturing Works or Services requested by him which are relevant for the performance of our contractual obligations, if necessary together with drawings, statistical calculations, samples, installation plans etc., and to describe us in detail and accurately all relevant conditions under which our Manufacturing Works or Services are intended to be utilized, in particular under which the deliverables are intended to be used.

**3.2** For Manufacturing Works and Services that refer to the manufacture of products, Customer shall provide us with a product dossier, for which Customer shall be solely responsible and which we may rely on in the course of the manufacture of the product.

**3.2.1** This shall include in particular, but not exclusively, all necessary specifications (for starting materials; primary packaging materials; semi-finished, bulk and finished products), the weighing-compounding instruction and manufacturing instruction, the secondary packaging instruction (if existent) and the quality control instruction. Furthermore, the product dossier shall contain all information, which is necessary or pertinent to ensure that we are at any time fully aware of any problems associated with the product and its manufacture, especially with regard to potential hazards to our production sites, equipment, personnel, materials, the contract products or other products, as well as a Material Safety Data Sheet for all substances and the filling liquid (for clarity, the latter including liquid and semi-liquid).

**3.2.2** The information contained in the product dossier shall, given the current state-of-the-art of science and technology, be as comprehensive as possible, suitable to carry out the contracted manufacturing steps correctly and at all times compliant with all applicable quality and technical regulations and the applicable laws and regulations.

**3.2.3** The product dossier shall be continuously re-assessed and updated as necessary by Customer. Each new version of the product dossier must take into account the latest data, the technology currently used and the regulatory requirements, in case of pharmaceutical articles the Good Manufacturing Practice and pharmacopoeia requirements, and must allow traceability to the previous version of the document. The Customer shall promptly inform us about any changes and their implications on the manufacturing records or product quality.

**3.3** The Customer is obliged to examine all logos, images, trademarks, product designs, texts, product instructions and product warnings which we are supposed to use at his request, for correctness, completeness and absence of third party rights, and only relinquish them to us for use, if he has ensured the compliance with those requirements.

**3.4** With respect to products designed, manufactured or placed on the market by the Customer and based on our Services, the Customer is solely responsible for any Product Specifications and product features, irrespective of the Customer's usage of the Services rendered by us or his reliance on its work results in this connection. This shall apply in particular for product stabilities, expiry dates and clinical features, determined on the basis of additional studies by the Customer. With respect to pharmaceutical products or medical devices the term „Product Specifications“ shall encompass in this context any and all information which is part of the “Product Specification File” according to Sect. 9 of Annex 13 (Investigational Medicinal Products) of the EU-GMP-Guideline. The Customer shall in connection with Manufacturing Works be solely responsible to ensure, that the respective primary packaging materials are, in due consideration of the usage intended under the contract, compatible with the filling liquid.

**3.5** If the Customer for the first time furnishes the information mentioned in sect. 3.1 and sect. 3.2 (including subsections) after conclusion of the contract and if, due to circumstances that become identifiable for us according to this information and were not otherwise positively known by us before, the performance of our contractual obligations is rendered impossible, significantly more difficult or, in our own reasonable discretion, economically no longer viable at the terms agreed in the contract, we have the right to rescind the contract.

**3.6** In case the information provided by the Customer under sect. 3.1 or sect. 3.2 (including subsections) is defective, which means i.e. incorrect, incomplete, insufficient, contradictory or its implementation infringes applicable law or third party rights, we are entitled to rescind the contract, if not the Customer (i) promptly cures the respective defect of the information and (ii) undertakes to bear the reasonable additional costs incurred due to the defective information and grants a reasonable extension of the delivery period, (iii) the defect of the information has neither caused nor increased the risk of damage or third party claims, and (iv) the further execution of the contract is neither rendered impossible, unreasonably difficult nor, in our own reasonable discretion, economically unviable at the terms agreed in the contract, otherwise due to the defect of the information.

**3.7** If we suffer any damage or incur third party claims due to defective information or information furnished for the first time after conclusion of the contract according to sect. 3.1 and sect. 3.2 (including subsections) and/or the breach of duties mentioned in sect. 3.3 and/or sect. 3.4, the Customer has to compensate us for such damages and/or indemnify us from such third party claims, except to the extent they are not due to his fault.

#### **4. Pricing, Payment Terms, Default in Payment, Set-Off**

**4.1** All prices and compensation will be non-binding to future agreements.

**4.2** The Customer must pay the contractually agreed price for our Manufacturing Works and the contractually agreed compensation for our Services. Statutory value added tax is not included in our prices or compensation, and is additionally payable at the applicable rate.

**4.3** If the subject matter of our Manufacturing Works or Services is to be delivered to Customer, the prices and compensation are “ex works” (EXW Incoterms 2010) excluding packaging, loading, transport and insurance.

**4.4** If a Customer domiciled outside of Germany, or his agent, collects EU-customs cleared objects, or transports or dispatches them to a foreign location, the Customer has to provide us with such export certificate as required for tax purposes. If he fails to provide such

documentation, the Customer will pay the statutory value added tax imposed on the invoice amount of the respective shipment, even if this leads to a double taxation.

**4.5** If for our Services a total compensation or lump-sum payment is not expressly agreed, compensation is calculated on the accrued expenditure of time and cost of materials. To the extent an agreed price or compensation does not expressly include the following costs, additional travel expenses, subsistence expenses and other expenses pursuant to sect. 7 (Secondment of our Personnel to Customer) will be charged in connection with the assignment of our personnel at the Customer's business or his place of operation.

**4.6** We have the right to issue interim or partial invoices for parts of our Manufacturing Works or Services performed according to the contract, irrespective of possible immaterial defects in the performance of our obligation.

**4.7** On our request, for Manufacturing Works or Services to be provided, the Customer is obligated to make reasonable advance payments.

**4.8** Unless otherwise agreed, the Customer shall pay the amount invoiced within 14 days net without discount as of the invoice date. The Customer is not entitled to deduct a discount on early payment. Foreign and domestic bank charges for the payment will be borne by the Customer in addition to the price / the compensation.

**4.9** If the Customer fails to comply with the payment terms according to sect. 4.8, we have the right to recover default interest from the respective point on, without reminder, at the statutory rate.

**4.10** The Customer will only be entitled to set-off or withhold against claims that are of the same kind as our claim, and undisputed, due for decision by a court or have been determined by a court of law in a legally binding manner. For claims that are not equivalent, a right of retention of the Customer is limited to claims arising from the same contractual transaction.

**4.11** We are entitled to adjust our prices and / or compensation within the scope of the general increase in our prices and/or compensation rate, if (i) between placing of the order but before performance we incur cost increases which are not only insignificant, especially due to any changes of our labor or material costs, or (ii) if after the conclusion of the contract completion or acceptance is delayed not only insignificantly due to circumstances within the responsibility of the Customer.

**4.12** If the Customer's financial situation substantially deteriorates after the conclusion of the contract, or if we for the first time after conclusion of the contract become aware of such deterioration which has occurred previous to the conclusion of the contract, we are entitled to demand either prepayment or the provision of a security, at our discretion. If the Customer does not comply with our demand even after a reminder and within a reasonable grace period set by us, we are entitled to rescind the contract. Our right to claim damages remains unaffected.

#### **5. Delivery Terms, Passing of Risk, Procurement**

**5.1** If the contracting parties have not met a particular agreement on a place of delivery, the delivery and the transfer of risk will occur “ex works” (EXW Incoterms 2010). The transfer of risk to the Customer will occur even if partial deliveries are performed or if we have promised to perform additional services.

**5.2** We are not obligated to effect a transport insurance. However, at Customer's request, we may effect a transport insurance for the delivery at Customer's costs and on behalf of Customer.

**5.3** If the products are air-freighted, and if the Customer is fully or in part responsible for the transportation of the products from the place of delivery to the carrier at the European forwarding airport, he will warrant the status “Safe Supply Chain” for the entire route, and in particular, effect dispatch exclusively by forwarders who are registered in the EU as “Regulated Agent” at the time they take over the products. If the status of “Safe Supply Chain” is disrupted due to the Customer's fault, the Customer will be liable for all resulting damage and expenses incurred by us.

**5.4** If, in the course of the performance of the contract, the Customer provides machinery, equipment, tools, materials or other objects at his expense, we shall not be liable for any accidental loss or accidental deterioration to the provided machinery, equipment, tools, materials or other objects, and we and shall not be obligated to insure such risks. The sole responsibility for, and the insurance of, such risks will be with the Customer.

**5.5** For the running-in and for test operations of such equipment at our site and at the Customer's site, the Customer shall provide us free of charge with the necessary amounts of plastic material and original filling liquid.

**5.6** If we send measuring instruments and / or other equipment to the place of operation for the customer order's use, the delivery shall occur "ex works" (EXW Incoterms 2010). We are not obligated to effect a transport insurance for the transport to the place of operation and back to us. At Customer's request, we may effect a transport insurance for the delivery to the place of operation and back to us at Customer's costs and on behalf of Customer. We shall not be liable for any accidental loss or accidental deterioration to the measuring instruments or other equipment and we shall not be obligated to insure such risks. The risk of any accidental loss or accidental deterioration shall be with the Customer, who shall also bear the sole responsibility for the insurance of such risks.

## **6. Dates and Delivery Times**

**6.1** The agreement on fixed dates for our Services or fixed delivery times for the subject matter of our Manufacturing Works or Services requires an express written confirmation by us. Information about the start or the duration of our Manufacturing Works or Services in our order confirmation or offer is in cases of doubt not a firm agreement on dates or delivery times, but only a non-binding forecast. As soon as we notice that a firmly agreed date may not be met, we will promptly inform the Customer indicating the reasons therefore.

**6.2** Agreed delivery times will not commence unless the Customer has fulfilled all his relevant duties of cooperation, and in particular, has provided us with all documents, approvals, and releases, has furnished all information and performed all investigations, in accordance with the contract and which are necessary for the performance of our obligations, and has made an agreed down payment. Commencement of the delivery terms will not be postponed insofar, as the non-compliance of Customer with its cooperation duties is solely caused by our fault.

**6.3** We will not be deemed to be in default, if our performance is delayed or does not take place due to circumstances which (i) are also within the scope of responsibility of the Customer; or (ii) render the performance of our obligations unreasonably difficult and were not observable to us given the current state-of-the-art of technology at the time of the order confirmation.

**6.4** If we are hindered from the performance of our works due to events of force majeure, the delivery time will automatically be extended by the duration of the hindrance plus a reasonable start-up period. This will apply even if such events occur during our default of delivery. Events of force majeure will be deemed to include measures based on monetary and trade policy and other acts of authorities, disruptions in operations (such as fire, breakdown of machinery, shortage of raw materials or energy), disruptions in transport, delays during import/customs clearance, and all events, which are neither due to our own fault nor to a risk inherent in our business and which render impossible or unreasonably difficult the performance of our obligations. This will also apply if such events occur to our affiliates, subcontractors or suppliers. We will promptly inform the Customer of the beginning and the end of such circumstances. If the performance of our contractual obligations is rendered impossible or unreasonably difficult for us due to the aforementioned events, if performance of material parts of the contract is delayed by more than four months, or if the performance of our obligations becomes worthless to the Customer because of the delay, we will be entitled to rescind the contract. At the request of the Customer we have to inform the Customer if we rescind the contract or deliver within a reasonable time determined by us. Damage claims of the Customer based on non- or late delivery due to force majeure are excluded. Rights of the Customer to rescind the contract provided by law shall remain unaffected.

**6.5** If we are in default of delivery due to our fault, the Customer will only be entitled to claim damages in lieu of performance insofar as our performance has become worthless to him due to our default. In all other respects, sect. 12.1 through sect. 12.5 will apply.

**6.6** We are entitled to perform partial deliveries as far as they are reasonably acceptable to the Customer (in particular taking into account the scope of delivery and the specific kind and use of the products). We are entitled to issue partial invoices for such partial deliveries. The payment terms will run separately for each partial delivery.

**6.7** Excess or short delivery is permitted up to 10% of the ordered total quantity per agreed delivery. Such permitted short deliveries are no partial deliveries in the sense of sect. 6.6. The price shall accordingly increase with excess deliveries and shall decrease with short deliveries.

## **7. Secondment of our Personnel to Customer**

**7.1** In case of the secondment of our service personnel to the Customer, the Customer must, at his own expense, take all necessary measures to ensure the safety of our personnel and their work equipment, and, in particular, provide lockable rooms which are suitable for the storage of work equipment, wardrobe etc. free of charge. The Customer will notify our personnel in good time of any applicable safety regulations. The Customer will notify us promptly of any breaches of such safety regulations by our personnel.

**7.2** In the event of any risk to health or life of our service personnel in connection with the performance of the Services, we are entitled to refuse or interrupt the secondment of our service personnel. This will in particular be the case, if an official body (e.g. the Office of Foreign Affairs of the Federal Republic of Germany) should issue a travel alert for or a recommendation against the stay at the place of operation at Customers.

**7.3** We will charge personnel costs, travel expenses and expenses on the basis of the price agreement met in the individual case. In case no specific hourly rate is agreed for individual works, the generally agreed hourly rate shall apply. Additional expenses that incur during the works in agreement with the Customer will be charged on the basis of the respective applicable hourly rate. In case of modifications made during the performance, such will be charged with the respective applicable hourly rate as well. The same shall apply for traveling time. Services on-site at the Customer require that the specific place of operation where we have to perform our works is accessible at any time. Work downtimes the Customer is responsible for will be charged separately on the basis of the respective applicable hourly rate. Work that needs to be repeated due to the fault of Customer will be charged in addition.

**7.4** Our personnel will provide the Customer with time sheets as work evidence. These time sheets are decisive for the calculation. They are submitted after completion of the Services or, in the case of long-term work assignments, on a daily basis.

**7.5** Rail journeys abroad or at night may be taken first class and with a sleeping car. Plane travel will generally be booked with business class tickets accepted by the IATA on scheduled aircraft, whereby the tickets will not be bound to a specific flight.

**7.6** In the event of a lengthy assignment our personnel has the right to travel home each weekend if the place of operation is located within Germany and less than 250 km from the employee's main working site; every second weekend if the place of operation is located within Germany but more than 250 km away; every four weeks if the place of operation is located outside of Germany within continental Europe; and every eight weeks if the place of operation is outside of continental Europe. Our personnel have the right to additionally travel home at Christmas, Easter and Pentecost. The costs for travelling home and back in accordance with the preceding provisions will be borne by the Customer.

**7.7** If our personnel is to be displaced or replaced due to reasons for which we are not responsible, the Customer will bear the extra costs incurred thereby.

**7.8** Customer will only be entitled to reduce the per diem rate because of a catering provided by him, if he has met a respective agreement with us prior to the commencement of our Services. If, in individual cases, it should become evident that the per diem rate is not sufficient for reasonable living expenses, we will be entitled to charge reasonably higher rates. If an overnight stay is required, the Customer must pay for a single-room accommodation in a three-star hotel according to Central European standard. We are not obligated to accept a hotel proposal of the Customer. If, however, we do so, we will be entitled to change hotels for good cause, whereas the Customer will bear any resulting additional costs.

## **8. Order-related Documents, Intellectual Property Rights and Know-How**

**8.1** Ownership and any rights under copyright or ancillary copyright, rights in patents, trademarks, design rights and utility models relating to the documents or information (hereinafter collectively: "IP Rights") to any kinds of documents or information (also including electronic or electronically transmitted) provided to Customer by us or our affiliates



in respect of the subject matter of our Manufacturing Works or Services, such as for example drafts, sketches, drawings, prototypes and samples, are reserved.

**8.2** As between us and the Customer, we are exclusively entitled to any and all IP Rights and Know-How relating to our documents or information set forth in sect. 8.1, which are pre-existing, or newly created by us alone or together with the Customer, or by use of the documents or information of the Customer. As between the contracting parties, we therefore have the exclusive right to any use, reproduction and exploitation.

**8.3** To the extent the Customer's use of our IP Rights or Know-How is mandatorily required for the offering, placing on the market and the further contractual use of the subject matter of our Manufacturing Works or Services, the Customer is granted a non-exclusive right for the license-free-use of our IP Rights and our Know-How (in the sense of a "Negativlizenz", i.e. we will insofar not enforce our IP Rights against the Customer), which is transferable to third parties only as a whole and together with the subject matter of our Manufacturing Works or Services.

**8.4** As to Manufacturing Works or Services in which connection we create or work on tools, which are necessary for us for the performance of the order but whose sale is not the express subject matter of the contract, or in case of the absorption or reimbursement of costs associated herewith by us, the Customer shall, even if they were custom-built for the performance of the customer order, not be entitled to the ownership of these tools. Such tools will remain our property in any case, namely including any IP Rights therein, irrespective of whether they are registered or not, and including any Know-How therein.

**8.5** Beyond the scope stated in sect. 8.1 through sect. 8.3, the Customer shall neither through the performance of our Manufacturing Works or Services nor otherwise acquire any rights, whether directly nor indirectly, to our IP Rights or Know-How.

**8.6** The Customer warrants and guarantees that (i) he is entitled to use, and to allow us to use and exploit any and all IP Rights and right to Know How in documents or information originated from him we need for the performance of the Services or the fulfillment of any other obligation in connection with the customer contract; and that (ii) there are no IP Rights of third parties or third party rights related to Know-How that might prevent him to use or have used by us the IP Rights described under (i) for the performance of the Services or the fulfillment of any other obligation in connection with the customer contract. We are not liable for any violation of third party rights due to a breach of this sect. 8.6 by Customer.

**8.7** Moreover, we are not liable for any claims based on an actual or alleged breach of IP Rights or Know-How in countries outside Germany.

**8.8** If the subject matter of our Manufacturing Work or Services or their respective contractual use infringe IP Rights of third parties within Germany, because of a circumstance which is due to our fault, we will provide the Customer at our own expense, if possible, with the right for further use, or modify the products or subject matters in a way reasonably acceptable to the Customer so that the infringement of the IP Rights of third parties is no longer present. If this cannot be achieved at economically reasonable terms or within a reasonable period of time, or if a reworking is not reasonably acceptable to the Customer, we and/or the Customer will be entitled to rescind the contract.

**8.9** Unless otherwise specified above, sect. 12.1 through sect. 12.5 shall apply with respect to our liability for infringement of IP Rights of third parties or rights related to Know-How.

**8.10** Rights of the Customer to rescind the contract provided by law shall not be affected by sect. 8.7 through sect. 8.9.

### **9. Inspection and Notification of Defects. Warranty**

**9.1** The legal requirement of a commercial inspection and objection by the Customer will not be affected by any agreed on quality assurance measure, outgoing inspection, incoming inspections, acceptance inspections or training measures.

**9.2** The Customer has to notify us of any defects in our Manufacturing Works or Services which are observable to him during a respective measure specified in sect. 9.1 promptly upon the completion of the respective measure. Additionally, the statutory provision on the commercial inspection and objection duties apply.

**9.3** In the event of non-compliance of the Customer with the statutory commercial inspection and objection duties, the assumption of

absence of defects will also apply to claims arising from tort or from breach of a secondary contractual obligations which are concurrent with the contractual rights arising from a defect not notified due to such non-compliance.

**9.4** The limitation period for claims arising from defects of quality or title under a purchase contract will be one year, beginning with delivery, or in case of Customer's default of acceptance, with our actual offer for delivery, unless the purchased item is typically used for a building. This one-year limitation period for defects of quality or title will apply accordingly, if a contract for work and materials ("Werklieferungsvertrag") is agreed.

**9.5** With regard to claims for damages, sect. 9.3 and sect. 9.4 will not apply insofar, as our limitation of liability is not applicable due to sect. 12.2 et seq..

**9.6** In case of a defect in the subject matter of our Manufacturing Works or Services we will be entitled to choose between reworking and replacement. Our right to refuse subsequent performance in the case of unreasonable costs or unreasonable efforts will remain unaffected. If after expiry of a reasonable term set by the Customer, the reworking or replacement is unsuccessful, the Customer is entitled to either reduce the price or rescind the contract at his discretion. The Customer has no right to rescind the contract due to an insignificant defect.

**9.7** Our warranty is excluded for damage due to ordinary wear and tear, or inappropriate use, inappropriate or careless handling, inappropriate maintenance, operation with unsuitable operating materials, chemical, electrochemical or electrical influences, storage under unsuitable conditions, operation by use of non-original parts or changes made to the products without our consent, either through the Customer or by third parties which are not our vicarious agents.

**9.8** For Manufacturing Works and Services whose subject matter are feasibility studies, research or development performances, the planning and the performance of technical or stability tests, in particular trial fillings, we assume no warranty for the economic useability of the results.

**9.9** Furthermore, our warranty is excluded for any defects which are a consequence of a default of the Customer on any other violation of his obligations.

**9.10** For divisible deliveries, which the Customer can use separately, our warranty will be limited to the affected part.

**9.11** There is no warranty for the freedom of any IP Rights of third parties not applicable in Germany; we are not liable for the infringement of any such right.

**9.12** In all other respects, sect. 12.1 through sect. 12.5 will apply with respect to our liability for defects of quality or title.

**9.13** Rights of the Customer to rescind the contract provided by law shall not be affected by sect. 9.11 and sect. 9.12.

### **10. Acceptance**

**10.1** If Customer has to declare acceptance of the subject matter of our Manufacturing Works or Services due to legal or contractual regulations, we may set an acceptance period to Customer if the acceptance criteria are met. If we only declare the readiness for acceptance and do not set any period, a 14-days-term shall apply.

**10.2** If Customer does not declare acceptance within the applicable abovementioned term although he is obliged to do so, the acceptance shall be deemed declared upon the expiry of the term.

**10.3** Notwithstanding the aforementioned, the performance shall in any case be deemed accepted, if Customer takes the subject matter of the Manufacturing Works or Services in use or places it on the market.

### **11. Confidentiality**

**11.1** Our confidential information shall include any information of economic, commercial, technical or other nature, in particular all specifications, descriptions, sketches, drawings, designs, patterns, samples, data, inventions, formulae, procedures, schedules, programs, models as well as findings, experiences and Know-How, disclosed or made accessible to the Customer by us or our affiliates, or derived, created or developed in performance of the contract using our confidential information, namely regardless of the nature of the recording, storage, disclosure or making accessible and regardless of whether it has been explicitly or tacitly identified as being "confidential".

**11.2** Information shall not be deemed Confidential Information to the extent that the Customer can prove that such information: (i) at the time of disclosure or making accessible was known to the Customer,

generally known or freely accessible to the public; (ii) after the time of disclosure or making accessible was disclosed or made accessible to the Customer by an authorized third party outside the scope of a confidentiality obligation towards us or our affiliates; (iii) after the time of disclosure or making accessible became generally known or freely accessible to the public, except directly or indirectly by breach of confidentiality obligation towards us or our affiliates; (iv) was created or developed by the Customer without use of our or our affiliates' confidential information or IP Rights; or (v) was expressly in written form marked or described by us as non-confidential. Irrespective of the applicability of any such exceptions for the information communicated under the contract, Customer shall not be entitled to inform third parties of the fact, that it received such information from us or that we use such information in our business or our production, except the respective circumstance also falls within the scope of one of the aforementioned exceptions.

**11.3** Our confidential information shall be kept strictly secret by the Customer and shall only be used for the contractually intended purposes. A disclosure to employees or third parties shall only be permissible to the extent such disclosure is mandatorily necessary for the contractually intended purposes. In such cases the Customer is obligated to ensure that all persons who encounter such confidential information abide by the terms of the confidentiality obligation set forth in these sect. 11.1 through sect. 11.5 or an at least equally restrictive confidentiality obligation and he has to ensure such abidance even after the termination of the contractual relationship between the Customer and such persons. Within the scope of any judicial order or regulatory action, a disclosure is only permitted to the mandatorily ordered extent and only provided that (i) the Customer shall promptly inform us of any such order; and (ii) the Customer shall appropriately cooperate with us to prevent or limit the scope of the disclosure or to obtain an appropriate protective order. Irrespective of a permitted disclosure in accordance with the foregoing, the recipient shall not be released from his other obligations pursuant to sect. 11.1 through sect. 11.5.

**11.4** The Customer shall through our disclosure, making available or other provision of confidential information not acquire any further rights to use, adapt or reproduce. Insofar we reserve all rights, in particular any rights to register IP Rights. To the extent Customer no longer needs our confidential information for the contractually intended purposes, he shall return or destroy or, in case of an electronic storage, delete any and all confidential information, including all copies thereof, upon our request and at our discretion.

**11.5** The confidentiality obligation shall continue to be valid and effective for unlimited time; in particular, it shall not end with termination of the respective individual contract.

## **12. Liability**

**12.1** Subject to the provisions of sect. 12.2, the Customer will not be entitled to damages for whatever legal reason, among others including claims based on tort. Insofar, we will not be liable for any damage not incurred in the products delivered by us; in particular, we are not liable for lost profit or other financial loss incurred by the Customer.

**12.2** The exclusion of liability according to sect. 12.1 will not be applicable to wilfull and gross negligent conduct, fraudulent misrepresentation, to the extent a guarantee is applicable, claims based on a breach of pre-contractual obligations, claims pursuant to §§ 1, 4 German Product Liability Law (*Produkthaftungsgesetz*), culpable damage to life, body or health, and our slightly negligent infringement of material contractual obligations, namely such obligations the fulfilment of which is a substantial requirement to the due performance of the overall contract, and on the observance of which the Customer may rely on. These sect. 12.1 and sect. 12.2 will not constitute a change in the burden of proof, in particular will the legal presumption of negligence according to § 280 par.1, 2<sup>nd</sup> sentence BGB remain unaffected. Rights of the Customer to rescind the contract provided by law shall not be affected.

**12.3** In the event of our slightly negligent infringement of any material contract obligations, our liability for financial loss is, per incident limited to not more than the higher amount of (i) € 1 Mio. or (ii) the quadruple of our turnover under the respective (single) contract. The same will apply in the event of gross negligence by our vicarious agents.

**12.4** As far as our liability to compensate damage is excluded or limited, this will apply accordingly to the personal liability of our legal

representatives, employees, vicarious agents, subcontractors and suppliers.

**12.5** The limitation according to sect. 12.1 through sect. 12.4 will apply accordingly, if and insofar the Customer claims frustrated expenses instead of damages in lieu of performance.

## **13. Suspension of the Limitation Period During Negotiations**

If the Customer, who is entitled to a claim, in the course of negotiations about such claim or the constitutive circumstances of such claim which are suspending the expiry of the limitation period, fails to respond to a statement made by us within a reasonable notice period, or in the absence of such notice period within a time period of six weeks, the previous negotiations will be deemed failed from this moment on.

## **14. Subcontracting**

For performances, such as e.g. quality checks, which we do not perform ourselves (i.e. which we have performed by a third party in our name and on our behalf), we may entrust qualified subcontractors. To the extent required by law or the quality regulations possibly applicable pursuant to sect. 2.10 (e.g. the GMP-Guideline, the European Medical Devices Directives), subcontractors shall only be entrusted upon the Customer's express prior written consent.

## **15. Partial Invalidity**

In the event that individual provisions of these Terms and Conditions are or become void or inapplicable, entirely or in part, the validity of the remaining provisions will thereby not be affected.

## **16. Place of Performance, Jurisdiction**

**16.1** The place of fulfillment for all deliveries and payments is 74429 Sulzbach-Laufen, Germany.

**16.2** The exclusive jurisdiction for any disputes is with the courts competent for 74429 Sulzbach-Laufen, Germany, without prejudice to the jurisdiction of any competent court for measures of interlocutory legal protection or in the course of enforcement of judgements. We are entitled to also sue the Customer alternatively at his place of general jurisdiction.

## **17. Choice of Law**

All our legal relations with the Customer are governed by the laws of Germany, without giving effect, unless legally mandatory, to the conflicts of laws provisions thereof. The United Nations Convention on Contracts for the International Sale of Goods (CISG) will not apply.

\* \* \* \*

**Date:** February 2015