

General Terms and Conditions Xilloc Medical BV

- 1 General**
 - 1.1 The present terms and conditions shall apply to each and every offer, sale and delivery by Xilloc Medical BV i.o., established in Maastricht, The Netherlands ("XM") of goods and services to Client.
 - 1.2 The present terms and conditions shall also apply to all agreements between XM and the Client, the execution of which calls for the services of third parties.
 - 1.3 Possible deviations from the present general terms and conditions shall only be valid provided they have been explicitly agreed upon in writing.
 - 1.4 The applicability of Client's possible purchase or other conditions is explicitly rejected.
- 2 Agreement, offers and confirmation**
 - 2.1 Offers shall be free of obligation. They shall be valid for a period of thirty (30) days.
 - 2.2 An agreement exists only after it has been signed by XM and Client. Further oral understandings are only binding to XM after they have been confirmed in writing by XM and Client.
 - 2.3 The agreement between XM and the Client shall be entered into for an indefinite period of time unless the nature of the agreement dictates otherwise or if XM and the Client have agreed otherwise.
- 3 Execution of the Agreement**
 - 3.1 XM shall execute the agreement to the best of its knowledge and ability and in accordance with the requirements of good craftsmanship.
 - 3.2 If and in so far required for the proper execution of the agreement, XM shall have the right to have certain work done by third parties.
 - 3.3 The Client shall see to it that XM shall be provided in due time with all data and materials which are reasonably necessary or desirable for the timely and appropriate execution of the agreement by XM.
 - 3.4 XM shall not be liable for damage of whatever nature caused by the fact that XM worked on the basis of incorrect and/or incomplete data provided by the Client, unless Client should have been aware of said incorrectness or incompleteness.
 - 3.5 If XM and the Client have agreed that the agreement will be executed in stages, XM can suspend the execution of the parts belonging to a following stage until the Client has approved in writing the results of the stage prior to it.
 - 3.6 Unless expressly stated otherwise in the agreement, all deliveries of goods shall be DDP XM's DPP shall have the meaning assigned to same in the latest version of INCOTERMS published by the International Chamber of Commerce at Paris, France, at the time of the conclusion of the agreement.
 - 3.7 Unless expressly stated otherwise in the agreement, any times or dates for delivery by XM are estimates and shall not be of the essence.
- 4 Changes to the agreement**
 - 4.1 If it is shown during the execution of the agreement that the work to be done needs to be changed and supplemented in order to ensure its proper execution, XM and the Client shall adapt the agreement accordingly in due time and in mutual consultation.
 - 4.2 If a fixed fee has been agreed upon then XM shall indicate the degree to which the change or supplement to the agreement will result in an increase of said fee.
- 5 Secrecy**
 - 5.1 XM and the Client shall be bound to secrecy of all confidential information they have received within the scope of the agreement from the other party. Information shall be considered to be confidential if the other party has indicated so or if the confidential character results from the nature of the information.
 - 5.2 If a statutory provision or a judicial decision compels XM to convey confidential information to third parties designated by law or by the court and XM cannot for that purpose invoke a legal right to refuse to give evidence or such a right acknowledged or allowed by the competent court, XM shall not be held to pay damages or compensation and the Client shall not be entitled to demand the dissolution of the agreement on the ground of any damage resulting from said circumstance.
- 6 Intellectual property and copyrights**
 - 6.1 Unless expressly stated otherwise in the agreement, all intellectual property rights resulting from the execution of the agreement –including the patent right, the design right and the copy right, shall belong to XM. To the extent such right can only be obtained by a filing, only XM is entitled to do so.
 - 6.2 Unless expressly stated otherwise in the agreement, XM has no obligation to implement an investigation to the existence of third party rights, as patent rights, trademark rights, design rights, copyrights or portrait rights or to implement an investigation to the possibility to develop such protection in favor of Client.
 - 6.3 XM is entitled to mention or to remove its name on or at goods.
 - 6.4 All documents, such as reports, advice, agreements, designs, sketches, drawings, software and prototypes etc., provided by XM, shall not be reproduced, made public, or brought to the notice of third parties by Client, unless the nature of the documents and goods dictates otherwise.
- 7 Fee and price**
 - 7.1 XM and the Client can agree upon a fixed price or fee the moment the agreement is concluded.
 - 7.2 If no fixed price or fee has been agreed upon, the price or fee for services of XM shall be determined on the basis of the number of hours actually spent on the work, calculated in accordance with XM's usual hourly rates unless a deviating hourly rate has been agreed upon.
 - 7.3 The price or the fee and all other costs and expenses shall be exclusive VAT and other charges levied by the government.
- 8 Payment**
 - 8.1 XM is entitled to invoice on a monthly basis for work implemented and costs made in connection with the agreement.
 - 8.2 Payment must be made within fourteen (14) days from the date of invoice by transfer to a bank account designated on the invoice.
 - 8.3 Payments shall be made without discount or set-off excluding the settlement with pre-payments made to XM in accordance with the agreement.
 - 8.4 If after the elapse of the payment term XM has not received the (full) payment, then Client shall be in default by operation of law. In that event, Client shall owe an interest equal to the Dutch legal trade interest.
 - 8.5 All costs and expenses incurred by XM, as litigation costs and extrajudicial and judicial costs and expenses, including the costs for legal assistance, bailiff and debt-collection agencies shall be borne by the Client. The extrajudicial costs are deemed to be at least ten (10) % of the amount of the invoice.
 - 8.6 Claims with respect to an invoice shall be submitted within eight (8) days after the date of the invoice. Thereafter the Client shall be deemed to have approved the invoice.
- 9 Non-employment of personnel**
 - 9.1 Throughout the duration of the agreement and for one year following termination thereof, the Client shall not hire or employ in any other way, be it directly or indirectly, staff of XM or of enterprises that XM has engaged to execute the present agreement and who are or were involved in the execution of the agreement.
- 10 Retention of title**
 - 10.1 All goods delivered by XM, possibly also including designs, sketches, drawings, films, software, (electronic) files, etc., shall remain XM's property until Client has fulfilled all of his obligations under all agreements concluded with XM.
 - 10.2 Client shall not be authorised to pledge or encumber in any way the goods falling under the retention of title.
 - 10.3 If third parties seize goods delivered subject to retention of title or wish to establish or assert a right to them, Client shall be held to inform XM promptly thereof.
- 11 Guarantee**
 - 11.1 XM solely guarantees construction and functioning of the parts of the goods delivered. This guarantee is valid for a period of twelve (12) months from delivery, unless differently agreed in writing.
 - 11.2 The guarantee is only applicable if the fault is not attributable to the Client. The guarantee is at the option of XM limited to repairing by or on behalf of XM or replacement of the relevant part or good.
 - 11.3 The Client needs to send the goods which qualify for repair or replacement at his own risk and expense to the address designated by XM. XM is entitled to invoice Client for transport charges for sending repaired or replacing goods to him.
- 12 Complaints**
 - 12.1 The Client must notify XM in writing of complaints about the work done within eight (8) days following their detection, but no later than within fourteen (14) days following completion of the work concerned.
 - 12.2 If a complaint proves to be well-founded, XM shall do the work as agreed upon, unless such has become demonstrably useless in the meantime to the Client and such has been notified by Client to XM in writing.
- 13 Liability**
 - 13.1 XM cannot be held liable for results which are not reached, because pursuant to the agreement it will only have an obligation to use best endeavours.
 - 13.2 XM shall never be liable for damages caused by loss of profit or lost savings and indirect and consequential damage.
 - 13.3 If XM is liable for direct damage, then said liability shall be limited to a maximum of the invoiced amounts. XM's liability shall at all times be limited to a maximum equalling the amount of the payment to be made by XM's professional liability insurer in the occurring event.
 - 13.4 In the event of an assignment with a duration of more than 6 months, the liability shall, contrary to the stipulations under 3. of the present article, furthermore be limited to the part of the price or fee due for the last six months.
- 14 Indemnification and guarantee Client**
 - 14.1 The Client shall indemnify and hold XM harmless for claims of third parties with respect to the use of the results of the services of XM and the use of the goods delivered.
 - 14.2 The Client shall indemnify and hold XM harmless against claims filed by third parties concerning intellectual property rights on material or data provided by the Client, which shall be used for and during the execution of the agreement.
 - 14.3 If the Client provides XM with information carriers, electronic files or software etc., the former shall guarantee that said information carriers, electronic files or software are free of viruses and defects.
- 15 Force Majeure**
 - 15.1 XM and the Client shall not be held to fulfil any of their obligations if they are hindered to do so by force majeure.
 - 15.2 In addition to the provisions of the law and the judge-made law in this respect, force majeure shall in the present general terms and conditions furthermore be understood to be an external circumstance, be it envisaged or not, on which XM cannot have any influence but which prevents XM from fulfilling his obligations. Strikes at XM's company shall also be understood to be a circumstance of force majeure.
- 16 Cancellation**
 - 16.1 XM and the Client shall be entitled to cancel the agreement at all times.
 - 16.2 If the agreement is terminated prematurely by Client, XM shall be entitled to compensation of the loss of capacity utilisation to be demonstrated caused by said premature termination and committed external costs, unless the termination is based on facts and circumstances which can be attributed to MI. Client shall furthermore be held in that event to pay the invoices for the work done up till that moment and related costs and expenses.
 - 16.3 If the agreement is terminated prematurely by MI, it shall see to it in conjunction with Client that the work still to be done be transferred to third parties, unless the termination is based on facts and circumstances which can be attributed to Client. If the transfer of the work still to be done entails extra costs for MI, said costs shall be charged to Client.
- 17 Suspension and dissolution**
 - 17.1 XM shall be authorized to suspend the fulfilment of the obligations under the agreement or to dissolve the agreement, in the event that:
 - Client does not fulfil or does not fully fulfil his obligations resulting from the agreement;
 - After the agreement has been concluded, XM learns of circumstances giving good ground to fear that the Client will not fulfil his obligations and the shortcoming justifies suspension or dissolution;
 - Other circumstances arise of such a nature that the unaltered maintenance of the agreement can no longer be demanded in all reasonableness.
 - 17.2 If the agreement is dissolved, MI's claims against the Client shall be forthwith due and payable.
 - 17.3 XM shall always retain the right to claim damages.
- 18 Limitation of action**
 - 18.1 No action by Client shall be brought unless Client first provides written notice to XM of any claim alleged to exist against XM within thirty (30) days after the event complained of first becomes known to Client and an action is commenced by Client within twelve (12) months after such notice.
- 19 Applicable law and jurisdiction**
 - 19.1 The laws of The Netherlands apply to this agreement excluding principles of conflict of laws. The applicability of the United Nations Convention on Contracts for the International Sale of Goods (CISG) is excluded.
 - 19.2 The court in Maastricht, The Netherlands shall have exclusive jurisdiction to hear actions. Nevertheless XM shall be entitled to submit the dispute to the court deemed competent by the law.
- 20 Patient data regulation**
 - 20.1 Patient data delivered by the Client. Privacy: all efforts are undertaken to guarantee privacy of the patient's information in the framework of the ISO 13485 quality system and other NEN which apply.
 - 20.2 Personal information will be identified by assigning a unique case number.
 - 20.3 By providing the patient data, Client confirms that the disclosure of any information is done in accordance with applicable privacy regulations and legislation and written acceptance of the patient for charging patients data with a third party.
- 21 Support devices**
 - 21.1 The supplied (electronic) devices are intended to support the design and validation process of XM's products. Support devices will be delivered after the first patient-specific implant order, if necessary. The devices remain the property of XM at all time. XM reserves the right to recall these devices at any time. XM cannot be held responsible for possible damage caused to or by these devices.