

General Purchase Terms and Conditions European Medical Contract Manufacturing B.V., v. January 2011

Article 1: Definitions

- EMCM : European Medical Contract Manufacturing B.V.
- Supplier : EMCM's counterparty.
- Agreement : the agreements laid down in writing between EMCM and supplier concerning the delivery of goods.
- Delivery : Putting one or more items in EMCM's possession, respectively under its control and any installation and assembly of these items, pursuant to whatever title.
- Order : EMCM's offer to reach an agreement.
- Parties : EMCM and supplier.
- On-demand contract : A minimum-terms contractual arrangement where the realistic estimated use has been determined beforehand based on historical turnover data at previously determined prices and orders are placed on demand by EMCM as needed. Therefore the anticipated use does not constitute a guarantee for the future. EMCM shall also endeavour to comply with this expectation in all reasonableness.

Article 2: Applicability

2.1 In the event of contradiction, the agreement prevails over these purchase terms and conditions.

2.2 These purchase terms and conditions apply to all requests, offers, orders and agreements, with regard to delivery of items by supplier to EMCM, whereby the supplier's general terms and conditions, however called, are explicitly rejected here. Derogation from these terms and conditions can only be agreed on by parties in writing.

Article 3: Conclusion of an agreement

3.1 Agreements can only be entered into on EMCM's side by the persons authorised to do so. An overview of authorised persons has been filed with the Registrar's Office at the District Court of Arnhem.

3.2 A request by EMCM will be followed by a fixed (irrevocable) offer by the supplier; this offer is free of charge, unless otherwise agreed in writing.

3.3 If a written order follows an offer from the supplier then the agreement shall be concluded at the time that EMCM sends the order.

3.4 If EMCM places a written order without a prior offer from the supplier then the agreement shall be concluded if and at the time that the items are delivered in accordance with the order within 14 days of the date of the order, or an order confirmation fully corresponding to the order is received by EMCM. In the event of deviations between the order and order confirmation supplier must consult with EMCM. If no response is received within 14 days of the date of the order, EMCM is entitled to place the order elsewhere and the original order shall then be deemed cancelled.

3.5 If in derogation from the provisions of article 1 there is a case of an oral agreement, the performance of the agreement shall be suspended until EMCM has sent a written confirmation of the agreement entered into orally. The performance of the oral agreement shall not be suspended however if an order number is provided when the oral agreement is entered into by EMCM and the supplier.

3.6 For on-demand contracts the agreement is concluded each time that the order for a (partial) delivery, within the scope of the on-demand contract, is sent by EMCM.

3.7 If drawings, models, specifications, instructions, inspection instructions made available or approved by EMCM are used for the performance of the agreement, these form part of the agreement.

Article 4: Amendments

4.1 EMCM is authorised at all times in consultation with supplier to amend and/or to supplement the scope and/or properties of the items to be delivered. Amendments are agreed in writing or must be confirmed in writing by EMCM if they have been agreed orally.

4.2 Supplier shall inform the Purchase Department immediately by fax or in writing and after approval by the Purchase Department of any (intended) amendment with regard to changes in the size, the composition and/or properties of the items to be delivered, price amendments, changes with regard to packaging, amended article numbers and articles which are no longer available and notify the Purchase Department immediately of any delivery problems and back orders.

4.3 Within reasonable limits EMCM is entitled at all times to order articles from third parties if it does not accept the amendment referred to under 4.2.

4.4 If EMCM wishes to make an amendment to this agreement, including the appendices, the supplier shall take the measures necessary, in reasonableness, to comply with the new change. Any such change and any price increase or reduction arising from it must be confirmed in writing by EMCM and shall thereafter form part of this agreement.

4.5 If in the opinion of the supplier an amendment has consequences for the agreed fixed price and/or delivery time, it is required, before effecting any such change, to inform EMCM of this in writing no later than 8 working days after notification of the desired change.

4.6 In the event that a change leads to extra work the supplier shall make a written offer with regard to the price and the period concerned, as well as stating the consequences on the other work to be carried out by the supplier. The supplier shall not carry out extra work until written order from EMCM to do so has been given. Extra work shall not include additional work which the supplier could have or should have foreseen in order to supply the agreed performance and functionality or which is the result of an imputable failing by the supplier.

Article 5: Prices

5.1 The agreed prices are fixed and can therefore not be subject to revision, unless the agreement reports circumstances which can lead to price amendment, as well as the manner in which the amendment takes place, which cannot take effect any earlier than 3 months after prior written notification of price increase. Price increases may only be made once per year and are subject to EMCM's approval. Supplier shall send Purchase an overview of the price amendments per EMCM article number, supplemented by any change of article numbers, descriptions and/or packaging units no longer used.

5.2 The agreed prices are in Euros, do not include VAT (unless explicitly stated otherwise) and are based on the delivery condition postage paid domicile.

5.3 Prices as listed on the order from EMCM are binding and cannot be considered for invoice correction unless the supplier, on receipt of the order, informs the EMCM Purchase Department of the price increase immediately in writing or by fax within 2 working days and for urgent orders within 1 working day of order date.

Article 6: Delivery

6.1 The "Incoterms" (most recent version), published by the International Chamber of Commerce apply for the interpretation of delivery conditions.

6.2 Delivery takes place at the agreed time or within the agreed period. The supplier is in default without further notification in the event of untimely delivery.

6.3 The items to be delivered must be accompanied by a packing list. The packing list must state EMCM's order number as well as the article numbers, quantities and descriptions. The supplier must use a separate packing list per order for deliveries.

6.4 If EMC M requests the supplier to delay the delivery the supplier shall properly pack and recognisably mark the items for EMC M and store, secure and insure them.

6.5 Delivery also includes delivery of all pertaining accessories as referred to in article 10.2, as well as the delivery of all pertaining documentation (including with regard to maintenance, operation, safety and sterilisation), drawings, quality certificates and guarantee certificates.

6.6 Supplier must report impending delivery delays immediately in writing to EMC M. This does not affect any consequences of this delay pursuant to these terms and conditions, the agreement or statutory provisions.

6.7 Inspection, control and/or testing of items in accordance with the provisions of article 10 does not constitute delivery or acceptance.

6.8 The orders are delivered in packaging to EMC M. Deliveries can be made on any work day between 8.30 a.m. and 4.00 p.m. The delivery location is:

Middenkampweg 17A
6545 CH Nijmegen

6.9 Deliveries of bulk stock will always be made exclusively on Euro pallets.

6.10 If Supplier is in default with regard to delivery, EMC M can claim compensation to the amount of at least all costs and possible consequential damage arising from endeavours by EMC M to safeguard the organisation's continuity (staff costs, costs of purchase of replacement products, logistic costs, etc.). In such a case EMC M is entitled to purchase products from another supplier and to recover any extra costs from supplier.

6.11 Each new delivery must have a shelf life which may not expire earlier than agreed and which is customary for the products delivered. The expiry date must be stated on the exterior of the immediate packaging.

6.12 All deliveries comply with the agreed product requirements and the applicable law and legislation.

Article 7: Packaging and dispatch

7.1 The items must be properly packaged and marked in accordance with EMC M's instructions so that by normal transport they reach the location of destination in good condition. The supplier is liable for damage caused by improper packaging and dispatch,

7.2 All packaging (except for loaned packaging becomes EMC M's property on delivery. Loaned packaging must be clearly marked as such by the supplier.

7.3 Loaned packaging will be returned at the supplier's account and risk to a location to be indicated by it.

7.4 If Supplier wishes to deliver its products to EMC M on pallets these must meet the quality requirements and be "Euro pallet" pallets.

7.5 Supplier guarantees that the pallets used: are clean, in new condition and undamaged. Products supplied on pallets which do not meet the requirements of the previous sentence will be returned to Supplier at its expense. Supplier must then immediately arrange for suitable replacement and without expense to EMC M.

7.6 Supplier guarantees that if different products/articles are delivered on one pallet, the articles of which there are the greatest quantity (standard outer packaging) will be on the bottom of the pallet and the products will be stacked upwards in declining quantity.

7.7 With regard to the packing materials the Dutch Packaging Agreement II 1997 ("*Convenant Verpakking II, 1997*") and the relevant law and legislation must be adhered to as departure point. During the agreement's duration the most recent version of this regulation shall apply.

7.8 The transport for returned items is at Supplier's expense and account.

Article 8: Transfer of Risk and Title

8.1 The title and the risk of the items transfers to EMCM after they have been delivered, ready to use, by the supplier and approved by EMCM in accordance with article 11 of these terms and conditions.

8.2 In the event that EMCM provides supplier with materials such as raw materials, expedients, tools, drawings, specifications and software in order to observe its obligations, these items remain EMCM's property.

Supplier shall keep them separate from items which belong to it or to third parties.

Supplier shall mark them as property of EMCM for its risk and account, keep them in good condition and insure them against all risks as long as the supplier acts as holder with regard to the ancillary means.

8.3 Amendments to or derogation from the ancillary means referred to in section 2, as well as the use of these means for or in relation to any other purpose than delivery to EMCM is only permitted after prior written consent from EMCM; approval does not affect the supplier's guarantee obligations.

8.4 At the time that materials, such as raw materials, ancillary means and software of EMCM have been processed in items of supplier which are to be transferred to EMCM there is a case of a new item, the title of which accrues to EMCM.

8.5 EMCM is authorised to request that the transfer of the property of the items and/or the material and parts intended for it shall take place at an earlier point in time. The supplier shall then mark the items and/or materials and parts intended for them as recognisable property of EMCM and indemnify EMCM for loss, damage and enforcement of rights by third parties.

Article 9: Invoicing and payment

9.1 The supplier must send an invoice or credit note respectively for each order/return (per order number). The order number must be clearly stated on the invoice. Debiting and crediting may not be set-off against each other on one invoice. Invoices must be sent in single copy.

9.2 Payment of the invoice, including VAT, shall be remitted within 60 days of receipt of the invoice provided the delivery and receipt of all pertaining documentation (including with regard to maintenance, service, safety and sterilisation), drawings, quality and guarantee certificates and the invoiced amount have been approved.

9.3 Payment by EMCM in no way constitutes renunciation of rights and is not equivalent to unconditional acceptance of the supplier's performance.

9.4 EMCM is entitled to suspend payment (partially) if EMCM establishes a defect in the items and any installation/assembly thereof, insofar as the defect justifies this.

9.5 The invoice shall be amended in accordance with the order if the supplier, after receipt of order from EMCM, fails to inform the Purchase Department at EMCM of any price increases in a timely manner.

9.6 Without prejudice to the provision in article 4.2 in the event of failure by the Supplier as determined in article 4.2, EMCM is not required to accept any invoice deviations with regard to the order and the invoice shall be adjusted in accordance with the order.

Article 10: Quality, guarantee and inspection

10.1 The supplier guarantees that the delivered items and any installation/assembly of them correspond with what was agreed, are free of defects, have the properties which were promised, are suitable for the purpose for which they are intended and meet the highest statutory requirements and other government provisions as well as the highest requirements of the safety, quality and environmental standards employed in the sector, all as these applied at the time of delivery. The supplier also guarantees that the delivered items are unencumbered and free of attachments.

10.2 The supplier guarantees that the delivered items are ready for use. It will ensure that all parts, accessories, fittings, tools, spare parts, technical documentation, user

instructions and instruction books which are necessary for realising the purpose indicated in writing by EMC M are supplied, even if they are not specifically referred to.

10.3 Inspection, control and/or testing by EMC M or persons or bodies appointed to do so by EMC M can take place both prior to delivery as well as during or after delivery.

10.4 The supplier shall grant access to the locations where the items are produced or stored and the supplier shall afford cooperation with the desired inspections, controls and tests and provide the required documentation and information at its expense.

10.5 If necessary the supplier shall inform EMC M in advance of the time when inspection, control and/or tests can take place, whereby supplier is expected to be present.

10.6 If the items are partially or fully rejected at inspection, control and/or testing EMC M shall report this in writing to the supplier.

10.7 Irrespective of the results of any inspection, control and/or test, if the items do not appear to meet the provisions of section 1 of this article the supplier shall repair or replace the items at EMC M's discretion at first notification unless EMC M prefers to terminate the agreement.

10.8 In urgent cases and additionally if after consultation with the supplier it can reasonably be assumed that the supplier cannot, or not in a timely or proper fashion, arrange for repair or replacement, EMC M is entitled to carry out or have repairs or replacement carried out by third parties at the supplier's expense and risk.

10.9 If supplier does not collect the rejected delivered items within 10 working days of the date of the written notification, EMC M is entitled to return the items to supplier at supplier's expense and entitled to crediting of any items already invoiced within 14 days.

10.10 Supplier and its employees as well as third parties it engages are required to observe the statutory safety, health and environmental provisions.

Article 11: Confidentiality, prohibition to publish and security

11.1 The supplier shall provide EMC M with all information concerning the delivery which could be of interest to EMC M. The Supplier shall not provide its own employees or third parties involved in the delivery with confidential information concerning the delivery unless EMC M has given prior written consent to do so. Without prior written consent from EMC M the supplier is not allowed to use the name EMC M in advertisements or other commercial expressions.

Article 12: Intellectual and industrial property rights

12.1 The supplier guarantees that the use, including selling on, of the items and/or accessories it delivered shall not infringe any patent rights, trademark rights, model rights, copyrights or other rights of third parties.

12.2 Supplier remains entitled party to any intellectual property right that supplier has to the delivered item. The supplier indemnifies EMC M for claims which arise from any infringement on the rights referred to in the previous section and it shall reimburse EMC M all damage which is the consequence of any infringement.

12.3 In the event that it is established at law or extrajudicially that the claim of the third party is legitimate, the supplier is authorised to take measures to honour this claim, unless these measures harm EMC M's interest.

12.4 The supplier is entitled to use the information provided by EMC M, however only in relation to the agreement. This information is and remains EMC M's property.

Article 13: Transfer of obligations

13.1 The supplier shall not transfer the rights and obligations which arise for him from the agreement either fully or partially to third parties without EMC M's prior written consent.

Article 14: Liability

14.1 The supplier is liable for all damage which is suffered by EMCM or third parties as the result of a defect in its product whereby it does not provide the safeness which one is entitled to expect.

14.2 The supplier guarantees the quality of the delivered products.

14.3 The supplier is liable for all damages which are the result of incorrect or otherwise incomplete data provided by the supplier.

14.4 The supplier is liable for damage suffered by EMCM as the result of delay in the delivery.

14.5 The supplier is liable for all damage which is suffered by EMCM or by third parties as the result of acts or negligence by it, its staff or those whom it has engaged in the performance of the agreement.

14.6 The supplier indemnifies EMCM for claims by third parties for reimbursement of damage pursuant to liability as referred to in the first two sections and at EMCM's first request shall reach an agreement with those third parties, or defend itself in legal proceedings instead of or together with EMCM, all this at EMCM's discretion, against claims as referred to here above.

14.7 For the application of this article, staff and employees of EMCM are deemed third parties.

14.8 The supplier shall take out adequate insurance against the liability as referred to in this article.

Article 15: Dissolution

15.1 Without prejudice to the rights further accruing to EMCM, EMCM is entitled to terminate the agreement fully or partially without further notification of default by way of written statement if:

- the supplier defaults on the observance of one or more obligations of the agreement;
- the supplier is declared bankrupt, has applied for moratorium of payments, has ceased or liquidated its business, attachment is levied on a considerable part of its assets or it transfers its business to third parties;
- rejection takes place after inspection or reinspection.

15.2 In the event of dissolution the risk of items already delivered remains with the supplier. The items are then at the supplier's disposal and must be collected. The supplier shall immediately reimburse anything already paid by EMCM with regard to the dissolved agreement.

Article 16 Applicable law, disputes.

16.1 Agreements between Supplier and EMCM are governed by Dutch law and exclude the Vienna Sales Convention (CISG). All disputes between EMCM and the supplier shall only be heard by the court having jurisdiction in the district of Arnhem.