

**GENERAL CONDITIONS OF SALE<sup>1</sup>**  
**OF**  
**EUROPEAN MEDICAL CONTRACT MANUFACTURING B.V. ('EMCM')**

**1 General**

1.1 In these terms and conditions, the following terms have the following meaning:

Agreement: any and all purchase and sale agreement for the Products entered into between EMCM and Customer, however named, all amendments thereto and/or supplements thereto, including specific orders for Products;

Article: an article to these general conditions of sale;

Customer: a party who places orders for Products, purchases Products and/or concludes an Agreement;

Incoterms: the latest version of the Incoterms issued by the International Chamber of Commerce as in force at the time of conclusion the Agreement;

Ex Works: the concept ex works as defined in the Incoterms;

Force Majeure: any occurrence beyond the reasonable control of one of the Parties in consequence of which a Party cannot reasonably be required to execute its obligations under the Agreement;

EMCM: European Medical Contract Manufacturing B.V., a private limited liability company, with its registered office in Nijmegen, and its office address in Nijmegen, at Middenkampweg 17, (6545 CH) in Nijmegen;

Offers: all sales offers for Products made by EMCM to Customer, all amendments thereto and/or supplements thereto;

Party: either EMCM or Customer;

Parties: EMCM and Customer;

Products: all products manufactured, marketed, sold and/or distributed by EMCM that are subject to an Agreement.

**HANDELSREGISTER ARNHEM  
GEDEPONEERD**



**KAMER VAN KOOPHANDEL  
CENTRAAL GELDERLAND**

**28 APR 2009**

**CONFORM ORIGINAL**

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<sup>1</sup> version 4 – April 7, 2009

- 1.2 These general conditions of sale, apply to all Offers and Agreements, unless explicitly agreed otherwise in writing.
- 1.3 The applicability of any other general terms used by Customer or referred to by Customer in any way is hereby explicitly excluded and declared not to be applicable.
- 1.4 Stipulations varying from these general terms must be expressly agreed upon in writing between Parties.
- 1.5 If any provision of these general conditions of sale in whole or in part is held to be illegal, void and/or unenforceable by a competent court or other competent authority, the other provisions of these general conditions of sale shall remain in full force and effect and the (remainder of the) affected provision(s) shall be deemed to be amended to the minimum extent necessary, so that it is no longer illegal, void and/or unenforceable and most nearly reflects the intention of both Parties.

## 2 **Offers and Pricing**

- 2.1 EMCM shall make its Offers without prejudice and subject to Agreement. If Customer has provided data, documents and/or other information to EMCM with respect to an Offer, EMCM may assume the correctness thereof and Offers shall be based thereon.
- 2.2 Prices of the Products are agreed between EMCM and Customer. Such price Agreement will be valid for one calendar year. However, EMCM is entitled to change prices at any time as a result of costs increases irrespective of their nature and reason, subject to one month's prior notice to Customer. Customer shall be entitled to dissolve Agreement, in the event EMCM increases prices with more than 10% (ten percent).
- 2.3 Unless otherwise agreed upon in writing between EMCM and Customer, the price of the Products shall be Ex Works EMCM's facility in Nijmegen, the Netherlands.
- 2.4 Unless otherwise agreed upon in writing between EMCM and Customer, all prices are exclusive of value-added, sales and/or any other taxes, fees or charges that may be levied by a competent authority against Customer or EMCM in connection with the sale and purchase of the Products.

## 3 **Invoices and payment**

- 3.1 If Customer disputes an invoice of EMCM, Customer shall explicitly notify in writing its substantiated objections to EMCM within the payment term. If no such objections have been made within such term, the invoice shall be deemed to be accepted by Customer.
- 3.2 Customer must pay the invoice without any deductions, discounts or debt settlement within thirty (30) days from the invoice date. Such ultimate payment date shall be considered as a firm date. All payments shall be made by Customer to EMCM in euro, and shall be made by means of wire transfer to a bank account to be designated by EMCM.


- 3.3 A right of revocation invoked by or a claim of Customer, shall not entitle Customer to suspend, set-off or deduct payments.
- 3.4 If Customer fails to pay within the payment term, EMCM has the right to charge Customer the statutory (trade) interest on the outstanding amount, from the due date until the date on which payment is made in full. All judicial and extra-judicial costs incurred within reason by EMCM as a result of Customer's failure to fulfill its payment obligations, are for the account of Customer.
- 3.5 The value day indicated on the bank statements will be leading and will be deemed to be the day on which the payment from Customer has been received.
- 3.6 EMCM is entitled to demand that Customer furnishes security in a form to be determined by EMCM, and/or that Customer makes an advance payment. If Customer fails to furnish the requested security or to make the advance payment, EMCM has the right, without prejudice to any other rights it may have, to immediately suspend its obligations towards Customer until the latter has furnished the desired security or made the advance payment.
- 3.7 Payments made by Customer always serve to settle all costs due primarily, then (accrued) interest and subsequently collectible invoices outstanding for the longest period.

#### 4 **Packing and Shipping**

- 4.1 EMCM shall ensure that all packages and labeling comply with the regulatory requirements.
- 4.2 Customer shall not re-package or re-label any Products or in any other manner alter the packaging or labeling of the Products without prior written approval of EMCM. EMCM, in its turn, shall not change its packaging format or in any other manner alter specifications with respect to the labeling of the Products EMCM without prior written approval of Customer.
- 4.3 All Products must be shipped in accordance with the shipping instructions agreed between EMCM and Customer. Customer shall only use reliable freight forwarders and reliable local transportation to minimize the risk of damage to the Products. Freight charges will be paid by Customer, unless EMCM and Customer have agreed otherwise in writing. Customer shall promptly make all claims for damage to the Products to its insurance carrier and provide a copy of such claims to EMCM.

#### 5 **Materials and Information of Customer**

- 5.1 Customer warrants that the supplied data, documents, information and/or (raw)materials, if any, meet all quantity and quality requirements in order for EMCM to manufacture the Products in accordance with the applicable quality and quantity requirements.
- 5.2 EMCM shall notify Customer immediately if it becomes aware of any shortcoming of Customer to (timely) deliver the agreed materials and/or to deliver such in the agreed quantity and/or quality.

Three handwritten signatures in black ink, located at the bottom right of the page. The signatures are stylized and appear to be initials or names.

5.3 EMCM shall not assume any liability with respect to unsound Products directly or indirectly caused by data, documents, information and/or (raw)materials provided by Customer nor for suitability and/or quality of the data, documents, information and/or (raw)materials provided by Customer. Any non-attainment of EMCM in connection herewith shall not constitute a breach of EMCM. Customer shall fully indemnify EMCM for any third party claim in this respect.

## 6 **Delivery, Store and Warehousing**

6.1 Without prejudice to article 7 hereunder, the delivery of the Products shall be Ex Works, unless another delivery clause is included in the Agreement. In case another delivery clause is agreed upon in the Agreement, the agreed delivery clause shall, in the absence of rules in the Incoterms, be interpreted in accordance with the general accepted terms in trade in the Netherlands.

6.2 Customer shall check accurately the quantity and quality of the delivered Products immediately upon delivery. Claims with respect to the quantity and/or the quality of the Products delivered have to be notified in writing within 5 (five) business days after delivery. In the event a defect in the quality of the Products could not reasonably be observed by Customer within the aforesaid term, Customer shall notify such defect in writing forthwith after Customer observed or could have observed such defect. If no claim is filed within the aforementioned term, EMCM shall be deemed to have duly and correctly performed its obligations resulting or arising from the Agreement with regard to inter alia the quantity and quality.

6.3 If Customer has filed a claim pursuant to article 6.2 and EMCM deems one or more Products to be defect, EMCM shall, at its own discretion either (i) replace the defective Products or (ii) repair the defect Products. Only at the request of EMCM, Customer shall return the defective Products to EMCM, for which Products it shall send a credit-invoice and whereby transport shall be at the expense of EMCM. EMCM shall accept such returned Products, provided that the Products are in the original packaging and condition.

6.4 The delivery period shall always be based on the assumption that EMCM will be able to perform its obligations under the circumstances as known to EMCM at the time of determination of the delivery period and shall always be a delivery period by approximation only. Exceeding the agreed delivery period shall not entitle Customer to any damage compensation whatsoever, unless explicitly agreed otherwise in writing.

6.5 In the event EMCM is not able to deliver the Products within the agreed time frame as a result of an act or omission attributable to Customer, the non-attainment of the delivery date shall not constitute a breach of EMCM, nor shall it result in any liability of EMCM whatsoever. Customer shall fully indemnify EMCM for any third party claim in this respect. The delivery date of the Products shall be extended for a period at least equal to the period of suspension.

6.6 Customer shall, at its own expense, store its stock and deliver the Products to a third party in accordance with good industry practices in order to preserve and protect the Products.

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7 **Transfer of Title and Risk**

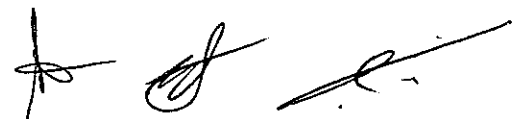
- 7.1 EMCM shall remain the owner of all Products sold to Customer, and the legal title to these Products shall as a result be retained, as long as Customer has not duly and adequately fulfilled all obligations resulting or arising from the Agreement (including but not limited to full payment). Delivery as referred to in Article 6.1 above shall therefore only imply that Customer shall become the detentor of the Products. Legal transfer of title shall be effected by and after full payment is made and all other obligations resulting or arising from the Agreement have been adequately and duly fulfilled. The foregoing also applies to partial deliveries. Such condition for transfer of title shall not apply to those purchased Products that have been sold by Customer in its normal course of business.
- 7.2 Other than in its normal course of business, Customer is not entitled to sell, rent, pledge, give third parties the use of, transfer title of such Products or otherwise alienate or encumber such Products until the ownership shall be transferred to Customer.
- 7.3 In the event Customer does not take possession of the Products upon delivery, EMCM shall keep the Products at Customer's disposal to the extent reasonable. EMCM shall in this respect store such Products at the expense and risk of Customer.

8 **Recalls**

- 8.1 At first request of EMCM, Customer shall destroy, return to EMCM or in any other way dispose, as instructed by EMCM, any and all Products that EMCM determined to be unsaleable or otherwise require such disposition. In the event of such return, destruction or other disposition for any reason, including but not limited to any government-ordered recall, EMCM shall either replace the Products at its expenses or reimburse Customer for the cost of Products and for any transport and/or shipping costs incurred as a result of the recall, at EMCM's sole discretion.
- 8.2 Customer shall maintain complete and accurate records of all Products sold for such period as may be required by applicable law.

9 **Warranty and Liability**

- 9.1 EMCM ensures that the Products to be delivered to Customer meet the applicable EU quality standards to the extent necessary and are free from defects in materials, workmanship and fabrication. EMCM shall guarantee the sound performance of the Agreement for a period of 12 months after delivery in accordance with Article 6.1. Customer may only invoke such guarantee if Customer has fulfilled all its obligations towards EMCM.
- 9.2 Customer is acquainted with the purpose of the Products. Customer shall not use the Products for other purposes than as explicitly indicated on the label. If Customer uses the Products for other purposes, Customer declares and undertakes vis-à-vis EMCM that such use is at his own risk and in full compliance and in accordance with all applicable regulations. Customer assumes full liability for such use of the Products and Customer indemnifies and holds EMCM harmless against any and all liability resulting from such other use of the Products.



- 9.3 The warranties set forth herein are the only warranties granted by EMCM in connection with the Product.
- 9.4 EMCM shall only be liable for damages suffered by Customer if such damages are a sole and direct result of a failure attributable to EMCM. Eligible for compensation in this respect are direct damages for which EMCM is - or reasonably should have been - insured. If for whatever reason no payment is made under EMCM's liability insurance, the liability of EMCM shall not exceed the total sum of the Agreement.
- 9.5 EMCM shall not be liable for consequential damages, including but not limited to damages as a result of standstill, loss of turnover and/or profits sustained by Customer, storage and advisory costs, or damages caused by auxiliary persons as a result of a willful misconduct or gross negligence.
- 9.6 Customer shall indemnify EMCM, its officers, directors, employees and successors and hold them harmless from and against, any and all claims, demands and actions of every kind arising out of or attributed, directly or indirectly, to the conduct, acts, omissions, operation or performance of Customer or any of Customer's officers, directors, employees, affiliates, sub-distributors or agents, including but not limited to any damages, costs and expenses incurred by EMCM in connection with such claim, demand or action.
- 9.7 EMCM shall not rely upon any limitation of liability as set out in [9.4] or [9.5] above or the indemnity set out in [9.6] above, if and to the extent that the damage concerned is a result of a willful misconduct or gross negligence on the part of EMCM or the employees of EMCM who are part of the management (board), or to the extent that EMCM's liability is a result of mandatory applicable product liability law in the meaning of section 6.3.3 of the Dutch Civil Code.

## 10 **Intellectual Property**

Customer acknowledges that all intellectual property rights and proprietary rights of EMCM, including but not limited to patents, royalties, trademarks, models, know how and all industrial rights and licenses related to the intellectual property rights, are owned and remain the exclusive property of EMCM or its licensors, and that nothing under the Agreement shall be construed to give Customer either during or after the duration of the Agreement any right, title or interest in the intellectual property rights of EMCM other than the right to use the intellectual property rights of EMCM in connection with the import, marketing, sale and distribution and/or export of the Products under the terms of the Agreement.

## 11 **Force Majeure**

- 11.1 Any delay or failure in the performance of any obligation by either EMCM or Customer shall be excused if and to the extent caused, directly or indirectly, by Force Majeure. If as a result of Force Majeure, any party hereto is precluded from receiving any benefit to which it is entitled hereunder, EMCM and Customer shall review the term hereof so as to restore them to the same relative positions as those previously obtained hereunder.
- 11.2 The party affected by Force Majeure shall promptly inform the other party of the occurrence of such Force Majeure.



11.3 Upon the occurrence of an event constituting Force Majeure, the party affected by this event shall take all measures which may reasonably be required to perform its obligations as quickly as possible. EMCM and Customer shall, if necessary, jointly examine the measures to be taken to limit the effect of Force Majeure.

12 **Compliance with Laws**

Customer shall comply with, and shall notify EMCM of all local laws and regulations in this respect, applicable to the sale of Products, including without limitation, import or export control, income tax laws and regulations and local price restrictions, if any. Customer shall notify EMCM immediately if any of the Products is in violation with such applicable laws.

13 **Assignment**

Neither EMCM nor Customer is allowed to transfer or assign any rights or obligations under this Agreement without the prior written approval of the other Party. Customer hereby approves that EMCM is entitled to assign this Agreement in whole or in part to an affiliate of EMCM.

14 **Relationship**

The relation between the Parties shall be solely that of EMCM and Customer. Nothing in this Agreement shall be construed (i) to give either Party the power to direct or control the daily activities of the other Party, or (ii) to constitute the Parties as employer and employee, principal and agent, franchiser and franchisee, partners, co-owners, representatives or otherwise participants in a joint undertaking. Neither Party shall have the right or authority to create or to assume any obligation on behalf of the other Party or to bind the other Party in any manner.

15 **No Waiver**

No omission or delay on the part of each Party in requiring due and punctual fulfillment by the other Party of the obligations of such other Party as set forth in the Agreement shall be deemed to constitute a waiver by the omitting or delaying Party of any of its rights to require due and punctual fulfillment of any other obligation hereunder, or a waiver of any remedy it might have hereunder.

16 **Surviving Conditions**

All terms and conditions of this Agreement which are destined - whether expressed or not - to survive the duration or termination of this Agreement shall so survive.

17 **Applicable Law and Jurisdiction**

17.1 These general conditions of sale and agreements or obligations ensuing there from, shall be governed by and construed in accordance with the laws of the Netherlands.


17.2 The United Nations Convention on Contracts for the International Sale of Goods is not applicable.

17.3 All disputes relating to or ensuing from the Agreements to which these general terms apply, shall exclusively be settled by the competent court in Arnhem, the Netherlands.

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For the purpose of filing these general terms with the Chamber of Commerce Centraal Gelderland signed by:

 20/4/09  
**European Medical Contract Manufacturing B.V.**  
By: aap bio implants Netherlands B.V.  
Name: B.S. Alemu, director  
Signature:

 27.04.2009  
M. Ligtenberg, Fin. Controller

