1. The Parties and the Product

1.1 In these general terms and conditions (the “General Terms and Conditions”), the term “the Seller” shall be taken to signify Breas Medical AB or any of its affiliates. The term “the Buyer” shall be taken to signify any private, public or state owned company with whom a framework agreement on sale of the Seller’s product has been reached or to whom a tender has been submitted or any buyer listed on any purchase order for the purchase of Products from the Seller. The Seller and the Buyer are separately referred to as a “Party” and collectively referred to as the “Parties”.

1.2. As used herein, “Product” shall mean any medical equipment and other products manufactured or sold (including accessories, consumables and spare parts) by the Seller. The term Product shall include all applicable manuals and other written instructions about any Product given by the Seller. The term “Product Related Services” shall be taken to signify services rendered or advice given by the Seller or its representatives in relation to the sale of the Product.

1.3 The Seller reserves the right to change, without prior notice, the design, construction, and type of materials used in the manufacture of any of its Products. The Seller further reserves the right to discontinue, without prior notice, any of its Products and/or replacement parts therefor. However, the Seller undertakes to abide by any regulations outlining any support periods needed for such discontinued Products.

1.4 These General Terms and Conditions have been drawn up in the English language, but may be translated into other languages. In case of discrepancies between the different language versions the English version shall prevail.

2. Applicability

2.1 These General Terms and Conditions shall be applicable to all purchases and deliveries of the Product to the Buyer and to any and all Product Related Services offered by the Seller within the Territory unless they have been altered explicitly by the Parties in writing. These General Terms and Conditions constitute an integral part of the agreement between Seller and the Buyer (collectively, together with any other applicable agreement or purchase order that incorporates these terms by reference, the “Agreement”).

3. Conclusion of individual Agreements

3.1 The Buyer shall place a purchase order (the “Purchase Order”) by written communication to the Seller, identifying the Products, or parts by number, quantity, purchase price, address for delivery, requested date of shipment and any special shipping instructions.

3.2 A legally binding agreement in respect of individual deliveries of Products or Product Related Services shall be deemed to have been concluded when the Seller has confirmed the Buyer’s Purchase Order in writing (the “Order Confirmation”).

3.3 If the Buyer, in connection with the Purchase Order, has dictated conditions which are contrary to those set out in the Seller’s Order Confirmation or these General Terms and Conditions, failure on the part of the Seller to object to such conditions does not imply that they have been approved by the Seller, but the delivery shall be considered to be done according to the Seller’s Order Confirmation and these General Terms and Conditions.

4. Prices and Payment

4.1 The price of the Product or Product Related Services shall be according to the current price list of the Seller at the time of the Seller’s receipt of the applicable Purchase Order unless otherwise has been agreed upon in writing between the Parties. The Seller’s prices for the Products are always exclusive of any freight cost, unless otherwise agreed. Please note that other local charges may occur, depending on the Buyer’s region and local customs. Any and all discounts shall be separately agreed upon in writing by the Parties. Any amendment of the basis of calculation shall be agreed upon in writing by the Parties. The Seller shall have the right to change the prices for the Products at any time. Any price adjustments shall be made with at least 30 days’ notice prior to the new prices coming into effect.

4.2 Payment shall be made in accordance with the Purchase Order or as agreed between the Parties. Unless otherwise agreed, payment shall be made in EURO, USD or SEK. Payment shall be made at latest thirty (30) days after the date of the invoice, which shall be issued upon shipment of the applicable Products or performance of the applicable Product Related Services by Seller, unless otherwise has been agreed upon in writing between the Parties.

4.3 At payment after due date the Seller has the right to interest on overdue payment at currently 2% per month and to recover any costs or expenses (including attorney’s fees) incurred by Seller to recover amounts due hereunder. The Seller shall furthermore have the right to withhold deliveries of Products to the Buyer, demand that acceptable securities be provided, amend the terms of payment and any possible credit limit and cancel the Agreement and all open Purchase Orders, whether or not they have been accepted by Seller, upon delayed payment.

5. Reservation of Title

5.1 Any and all delivered Products shall remain the property of the Seller until paid for in full to the extent that such retention of property is permitted by applicable law. If the Buyer fails to timely pay all amounts due to Seller, the Seller shall have the right to reclaim the applicable Products for which payment has not been received by Seller in full. Until the title of the Product has been transferred to the Buyer, Buyer shall be obligated to take good care of the Product.

6. The Quality

6.1 The Product shall in all material respects comply with the specifications given in the official product information that the Seller supplies for the Product unless otherwise has been agreed upon in writing between the Parties.

7. Delivery

7.1 Delivery shall be made Ex Works the Seller’s premises Mölnlycke, unless otherwise agreed in writing between the Parties. Trade terms shall be interpreted in accordance with the INCOTERMS in force at the formation of the Agreement.
7.2 If the price disclosed in the Agreement entails that the Seller shall wholly or partly be responsible for freighting costs, the Seller shall be entitled to choose the mode of transportation.

7.3 Any time of delivery stated by the Seller is the Seller’s best estimate of a calculated delivery date. If the Seller finds that it will not be able to deliver the Products at the agreed time for delivery or if delay on its part seems likely, it shall forthwith notify the Buyer thereof in writing, stating the reason for the delay and if possible the time when delivery can be expected. Seller may make partial shipments at Seller’s sole discretion.

7.4 If delay in delivery is caused by transport delays beyond the Seller’s control, or because of any circumstance encompassed by Article 15, or by an act or omission on the part of the Buyer, the delivery time shall be extended by a period, given all of the circumstances in the case that may be deemed reasonable. This applies regardless of whether the reason for the delay occurs before or after the expiry of the agreed delivery time.

7.5 The Seller’s liability in the event of delay is limited to verified material direct losses (all kind of indirect and consequential losses and damages excluded) and shall not, in any event, exceed 5 % of the invoiced value of the delayed delivery.

7.6 If the delivery of Products is subject to the granting of an export or import license by a government and/or any governmental authority under any applicable law or regulation, or otherwise restricted or prohibited due to export or import control laws or regulations, the Seller may suspend its obligations and the Buyer’s rights regarding such delivery until such license is granted or for the duration of such restriction and/or prohibition, respectively, and the Seller may rescind the transaction without incurring any liability towards the Buyer.

8. The Buyer’s obligation to take delivery
8.1 Should the Buyer fail to take delivery of the Product at the appointed time, it is nevertheless obliged to make each payment as if delivery of the Product in question had been taken. If the Buyer, regardless of grounds, fails to take delivery of the Product at the appointed time, the Seller shall be entitled, by written notification to the Buyer, to cancel the Agreement in respect of such outstanding part of the Product that, due to the Buyer’s failure has not been received, and receive compensation from the Buyer for any and all damage incurred due to the Buyer’s failure to fulfil his obligations.

9. Inspection and complaints
9.1 The Buyer shall as soon as possible after receipt of the Product examine the Product for visible defects, ensure that the number of pallets and boxes correspond with the number given in the delivery notes and that the quantities delivered correspond with the quantities given on the boxes and that the Product overall complies with the Seller’s Order Confirmation and with what is stated in the Agreement.

9.2 Complaint regarding lack of conformity of delivered Products that the Buyer has noticed or should have noticed upon the required receipt inspection, shall be lodged at the latest 20 days from the date at which the Products were delivered. Such written complaint shall contain a description of how the lack of conformity manifests itself. If there is reason to believe that the lack of conformity may cause damage, such complaint shall be given immediately. Complaint regarding such a fault as could not have been discovered at such a receipt inspection shall be made directly after the fault is noticed or should have been noticed by the Buyer, however, at the latest within 12 months after delivery. Failing to do so causes the Buyer to lose the rights that belong to it due to lack of conformity of the Products.

10. Buyer’s handling of the Product
10.1 The Buyer undertakes to transport, handle, store and repair the Product with proper care and always in accordance with professional standards and the instructions of the Seller. The Buyer undertakes not to change the Products, remove or change any trademarks, names or any other markings concerning the Products or alter the Product’s packaging or repack the Products in non-approved non-Seller packaging.

10.2 The Buyer undertakes to comply with all the instructions and information about the Product given by the Seller when marketing and selling the Product, educating its personnel and instructing and educating its customers about the handling and use of the Product.

10.3 The Buyer undertakes to, when marketing and selling the Product, not to give any information about the Product or make any warranties or representations as to the Product, its nature or use that is contrary to or goes further or beyond the instructions, information, warranties or representations given by Seller. The same applies when the Seller is educating its customers about the use of the Product. The Buyer undertakes to indemnify and hold the Seller harmless from any and all damages in the event the Seller suffers damage as a result of breach of these undertakings.

10.4 The Buyer shall comply with all applicable national and/or international laws, rules and regulations concerning medical devices, including but not limited to the Medical Devices Directive (MDD 93/42/EEC) and respective guidelines of the European Commission. Notwithstanding all other provisions in the Medical Devices Directive, the Buyer is obliged to inform the Seller immediately in case of an incident with one of the Products or if it has indications that a Product is not safe.

10.5 According to the requirements of Annex II of The Medical Device Directive the Buyer shall maintain adequate records concerning product traceability. The Buyer’s traceability records shall be complete and accurate and trace the Seller’s Products to final point of use by product code, lot number and/or serial number. The Buyer agrees to comply with the rules of these directives and accepts them as legally binding conditions for all deliveries of Products.

10.6 The Buyer may not remove references to the capacity of the Seller as manufacturer or other references or instructions for use or serial numbers or distribute Products without such references and instructions for use.

10.7 The Buyer agrees to indemnify, defend and hold the Seller and its parent, subsidiary, or affiliated companies ("Affiliates") harmless from and against any expenses incurred by or claims made against the Seller arising out of any negligent actions of the Buyer including but not limited to the maintenance, repair or alteration of any
Product, or the improper assembly or incorporation of the Product into any other device.

11. Limited Warranty (Liability for defects)

11.1 Seller warrants, pursuant to Articles 11.2-11.4 below, that the Products will be free from defects in material, construction and design and that the Products will in all material aspects comply with the Seller’s specifications for the warranty period applicable to such Product as stated in the table at the end of these General Terms and Conditions. In case of non-conformity, the Seller undertakes to repair or replace any defective Products and to render necessary Product Related Services at no charge excluding the return freight cost to the Seller.

11.2 The Seller’s warranty according to Article 11.1 above is conditioned by that the Product has been transported and handled with proper care and stored and used in accordance with the Seller’s instruction for Products, that the Product has been subject to regular maintenance and service, that replacement and repair has been performed according to Seller’s instructions and that the Product is returned in the Seller’s packaging in case return to Seller is necessary.

11.3 The Seller’s warranty does not apply to any Products that have been specifically manufactured or modified at the request of the Buyer or altered by the Buyer or a third party, nor does it apply to defects caused by abnormal use of the Product or circumstances that have arisen after the risk for the Product has been transferred to the Buyer.

11.4 Seller will not be obligated beyond the replacement of Products or Product Related Services as are determined by Seller to be defective. Whether the Products are manufactured by Seller or by another, such replacement shall be Buyer’s sole and exclusive remedy for breach of this limited warranty and neither Seller nor the manufacturer (if other than Seller) shall be subject to any other or further liability and no claim for consequential or incidental damages will be allowed. No other warranties or representations, whether expressed or implied, shall apply to the Products or Product Related Services. The warranties are the Seller’s exclusive warranties and in lieu of any other warranties, whether expressed or implied.

12. Recalls

12.1 The Buyer shall cooperate with the Seller in effecting field corrections of systematic defects, removals, or upgrades (“Recall”) of the Product at the direction of Seller. The Seller is responsible for Recalls and shall determine when the defect is systematic and when a Recall shall be performed. In the event that a Recall is deemed to be necessary the Seller shall provide all written instructions to the Buyer as to the correct management of the affected Products.

12.2 Defects, removals or upgrades that have been specifically defined as Recalls by the Seller shall be remedied by the Buyer at its business location according to the instructions given by the Seller. If necessary and at the choice of the Seller, the Product or parts of the Product may instead be transported from the Buyer to the Seller for remedy. In case of remedy at Buyers location, the Seller shall without any costs for the Buyer deliver necessary new components, software etc. that replaces the item. The Seller shall further at cost price compensate the Buyer for the necessary repair or replacement work performed by it at its location. If the Seller instructs the Buyer to return the Products to the Seller, the Seller shall be liable for the costs for repair performed by the Seller as well as the cost of transportation of the Products from the Buyer to the Seller and back to the Buyer. The Buyer shall, if required, comply with the country’s regulations regarding such actions and assist the Seller in notifying the appropriate regulatory authorities.

12.3 The Seller’s liability in the event of a Product Recall is limited to the above explicitly stated costs and the Seller has no liability for any costs or damage incurred by the Buyer or its customers that go beyond the costs specified above.

13. Liability Limitation

13.1 In no event shall the Seller be liable to the Buyer or any of its customers or end users for any indirect or consequential damages, including but not limited to, loss of profits or revenue, goodwill even if the Buyer has been advised of the possibility of such damages, resulting from this Agreement, the Products, the Product Related Services, marketing material or any other items furnished by Seller under this Agreement. In no event shall the Seller’s aggregate liability resulting from or arising out of or in connection with this Agreement exceed the amount paid by the Buyer to the Seller for the applicable Products or Product Related Services giving rise to such liability.

14. Intellectual property rights

14.1 Buyer agrees that it does not have any property interest in Seller’s intellectual property, including, but not limited to, its trademarks, trade names, copyrights, trade secrets, patents, know how or other proprietary rights of any nature whatsoever, whether or not incorporated in the Products described in the Purchase Order, and Buyer will not attempt to reverse engineer any such Products or disclose or use any such intellectual property without Seller’s prior written consent. Any technical or other information the Seller provides to the Buyer in connection with the Agreement shall remain the property of the Seller and shall be kept confidential by the Buyer and used only to perform the Buyer’s obligations under the Agreement. Such information may include cost and pricing information, know-how and service manuals.

15. Force majeure

15.1 If one of the Parties is prevented from fulfilling its obligations due to circumstances outside its control, such as labour dispute, stroke of lightning, fire, storm, flood, earthquake, war, terrorist actions, mobilisation or extensive call-ups, requisition, confiscation, currency restrictions, directions from the authorities, insurrections and riots, restrictions concerning motive force, general scarcities in transportation, goods and energy, measures taken by state or government authorities or errors or delayed deliveries from contractors or subcontractors, this shall constitute reason for exemption, which entails the right to postpone meeting the obligations for as long as the hindrance exists, and relief from fines and other penalties of law. The Party shall as soon as possible inform the opposite Party if such circumstances arise. If the hindrance endures at least 3 months, the Party has the right
to terminate the Agreement in writing without liability to pay compensation.

16. Survival of obligations
16.1 All provisions of this Agreement which are expressly or by implication intended to survive and apply following expiry or termination of this Agreement, including but not limited to Clause 11.4 (Limited Warranty), Clause 13 (Liability Limitation), Clause 14 (Intellectual property rights) Clause 18 (Confidentiality) and Clause 19 (Applicable Law and Disputes), shall survive and shall continue in full force and effect notwithstanding such expiry or termination.

17. Subcontractors
17.1 The Seller shall have the right to engage a subcontractor to fulfil its obligations under the Agreement. Should the Seller engage a subcontractor the Seller shall be liable for such sub-contractors as for its own obligations.

18. Confidentiality
18.1 Each Party pledges himself for the duration of the Agreement and thereafter not to, without the other Party’s written consent, disclose any information to a third party (whether oral or written or in visual, electronic or tangible form) regarding or otherwise relating to the other Party’s affairs or other business matters if it may be deemed as business or trade secrets or otherwise be used as such information for any other purpose than the Party’s performance of its obligations according to the Agreement. Any information which the Party has stated is confidential shall be considered as business or trade secrets.

18.2 Such confidentiality shall not apply to information which the Party can show became known to it otherwise than through the Parties’ business relation or which is publicly known. Nor shall such confidentiality apply with respect to any required disclosure of such information by law or any governmental or other regulatory authority.

18.3 A Party shall return any confidential information upon request by the other Party.

19. Applicable law and disputes
19.1 All disputes regarding the interpretation or application of these General Terms and Conditions as well as individual sale contracts or contracts regarding Products or Product Related Services shall be subject to Swedish Law.

19.2 Any dispute, controversy or claim arising out of or in connection with this contract, or the breach, termination or invalidity thereof, shall be finally settled by arbitration administered by the Arbitration Institute of the Stockholm Chamber of Commerce (the SCC Institute). The Rules for Expedited arbitrations of the Arbitration Institute of the Stockholm Chamber of Commerce shall apply, unless the SCC Institute, taking into account the complexity of the case, the amount in dispute and other circumstances, determines, in its discretion, that the Rules of the Arbitration Institute of the Stockholm Chamber of Commerce shall apply. In the latter case, the SCC Institute shall also decide whether the arbitral tribunal shall be composed of one or three arbitrators. The English language shall be used throughout the arbitral proceedings. The place of arbitration shall be Gothenburg, Sweden.

19.3 The Seller, however, shall have the right to apply to a general court to obtain payment for an undisputed and matured claim.