

General Terms and Conditions of Sale of BIOTRONIK Vertriebs GmbH & Co. KG (hereinafter: „BIOTRONIK“)

1. Scope

These General Terms and Conditions of Sale (“GTCS”) shall apply to all contractual relations between BIOTRONIK and customers, inasmuch as they are not consumers within the meaning of sec. 13, subsec. 1 BGB (German Civil Law Code) („Customer“) and shall be part of all contracts BIOTRONIK enters into with Customer with regard to the deliveries and services it offers. All deliveries, services and offers of BIOTRONIK shall be exclusively rendered on the basis of these GTCS which shall apply to any and all further contractual relations between BIOTRONIK and Customer irrespective of whether or not agreed upon expressly.

BIOTRONIK objects to the application of standard terms and conditions of Customer even if those are communicated in an order confirmation or in any other way. Even if BIOTRONIK refers to a letter of Customer that includes or refers to standard terms and conditions of Customer, this shall not constitute consent with those standard terms and conditions. Deviating, opposing or additional standard terms and conditions of the Customer shall only and insofar become an integral part of the contract, if BIOTRONIK expressly consents to their application in writing.

2. Conclusion of Contract

All offers of BIOTRONIK are subject to confirmation and non-binding, unless expressly identified as binding or stating a specific acceptance period. This shall also apply if BIOTRONIK provided Customer with catalogues, technical documentation, any other form of product information or documentation (also in electronic form).

The placement of an order represents Customer’s binding purchase offer. BIOTRONIK has the right to accept the purchase offer within 14 days after receipt of the order. This acceptance may either be communicated in writing or by delivering the goods to Customer.

The contractual relations between BIOTRONIK and Customer are exclusively governed by the written sales contract, including these GTCS which represents the entire agreement between the Parties regarding the subject matter. Verbal covenants of BIOTRONIK prior to the conclusion of the contract and verbal agreements between the Parties shall be replaced by the written contract unless the written contract expressly provides that these remain in force.

Any amendments or alterations to the contract concluded between the Parties, including these GTCS, must be agreed in writing to be effective. With the exception of managing directors and procurists, BIOTRONIK employees are not entitled to conclude deviant verbal agreements. The content of such agreements is dependent on a written contract or written confirmation by BIOTRONIK. The written form requirement within the meaning of this section 2 is satisfied by using telefax; however, any other form of telecommunication, especially email, is not sufficient.

BIOTRONIK reserves title and retains copyright to all of its offers and quotations as well as all drawings, presentations, catalogues, brochures, designs and other documentation made available to Customer. Customer is not allowed without the express consent of BIOTRONIK to make the aforesaid documents available to a third party, to disclose, to use on its own or through a third party or to reproduce. Upon BIOTRONIK’s request Customer shall return all such documents and destroy copies thereof if these documents are not needed anymore in the ordinary course of business.

3. Delivery and Shipment

BIOTRONIK delivery dates shall be binding only if they have been agreed upon explicitly as binding between the Parties. If shipment is agreed, delivery dates and delivery periods refer to the date of commissioning to the forwarding carrier, freight agent or any third party designated to carry out the shipment. Any confirmation of a delivery date or delivery period shall be subject to BIOTRONIK, for its part, receiving the deliveries and services of its respective suppliers in good time and good order.

BIOTRONIK is permitted to partial deliveries, if such partial deliveries are usable for the Customer with regard to the contractually agreed purpose, the supply of the remaining goods ordered is secured and Customer does not accrue any material additional expenditure within 14 days after placement of the order.

The risk of accidental destruction or accidental impairment of the goods shall pass to Customer at the latest upon handing over the goods to the forwarding carrier or freight agent or any third party designated to carry out the shipment. In the event delivery of the goods is delayed due to reasons caused by the Customer, the risk shall pass at the notification of BIOTRONIK’s readiness for dispatch to the Customer. Customer shall bear warehousing and storage costs after passing of risk. The preceding shall not apply if something else has been agreed upon by an individual contractual agreement.

All deliveries of the goods shall be insured by Customer up to the arrival at Customer’s premises against transport risk or risk of loss. If the insurance is concluded by or at cost of BIOTRONIK Customer must report damages and loss to BIOTRONIK (with appropriate documentation of the forwarding carrier) without undue delay upon receipt of the delivery in order to secure possible claims against the transport insurance carrier. The damaged or impaired goods have to be put at the disposal of BIOTRONIK.

BIOTRONIK is not liable for failure to perform or delay in performance of its obligations if such failure to perform or delay in performance is a result of Acts of God BIOTRONIK is not responsible for (e.g. downtime of production, disruption of material and energy supply, shipment delays, labor dispute, strike, lockout, shortages of labor force, energy or raw materials, difficulties in obtaining approvals and concessions, faulty or late supply by BIOTRONIK). As long as Acts of God persist BIOTRONIK is free of its obligations. If Acts of God are

temporary, the delivery dates and delivery periods are prolonged by the time period of the impediment plus an adequate lead time.

If the acceptance of delivery is not reasonable for Customer due to the aforementioned delays, Customer has the right to rescind the contract by immediate written notice to BIOTRONIK.

In the event of a delay in performance BIOTRONIK's liability for damages shall be limited in accordance with section 7 of these GTCS.

4. Prices and Terms of Payment

The prices are effective for the scope of deliveries and contract performance as stated in the order confirmation and are net prices, plus value added tax as applicable at the time of delivery or service, but including packaging costs.

Unless prices are separately agreed in the sales contract, the prices listed in BIOTRONIK's price list at the time of the order placement shall apply.

Payments have to be made in advance unless agreed otherwise. Payments shall regularly be made by bank transfer. Payment shall be deemed made if and when the amount to be paid is irrevocably credited in full to BIOTRONIK's bank account. In case of Customer's default in payment, default interest at the statutory rate shall accrue starting at the payment date. The right to assert higher interest or damages incurred as a result of the default shall remain unaffected.

Only payments made to BIOTRONIK directly have the effect of discharging the payment obligation. In case of more than one outstanding debt, payments are made successively on default interest, costs incurred and then on the outstanding debt. Payments shall be allocated to the oldest outstanding debt.

Customer shall only be entitled to offset against claims which are undisputed by BIOTRONIK or which have been legally established.

5. Retention of Title

BIOTRONIK shall remain the sole owner of the delivered goods until all receivables, current and future of BIOTRONIK against the Customer have been fully paid.

Customer is entitled to sell the delivered goods within the ordinary course of business. Customer hereby assigns in advance to BIOTRONIK the receivables arising from the resale of goods against third parties. BIOTRONIK hereby accepts such assignment.

Customer must not sell the goods to third parties if he is insolvent, experiences payment difficulties and debt enforcement proceedings are executed against the Customer or if an application for the opening of insolvency proceedings over Customer's assets has been filed. In case of the resale of goods Customer is obliged to retain title to the goods sold until the full payment of the sales price or claim for reimbursement by the second purchaser.

Customer shall remain entitled to collect payments besides BIOTRONIK. BIOTRONIK refrains from collect-

ing payments as long as Customer meets its payment obligations, is not in arrears with payments to BIOTRONIK, no application for the opening of insolvency proceedings is filed and there is no other deficiency in Customer's ability to perform. If the last-mentioned cases exist, BIOTRONIK may demand from Customer the disclosure of the assigned claims and its debtors, the supply of all information required for collection, the handing over of all necessary documentation and the notification of the second purchasers of the assignment.

At the request of Customer BIOTRONIK undertakes to release at its sole discretion the securities insofar as the value of the securities exceeds the secured accounts receivable by more than 10 %. In case of current accounts the retention of title shall apply up to a maximum of 110 % of the value of the accounts receivable still unsettled as provision of security on a balance existing in favor of BIOTRONIK.

Customer shall not be entitled to pledge or assign by way of security to a third party any delivered goods subject to BIOTRONIK's retention of title until the secured claims are fully paid. Retention of title shall also extend to replaced goods.

If and insofar a third party has access to goods subject to BIOTRONIK's retention of title, Customer shall be required to inform the third party about the retention of title of BIOTRONIK and immediately notify BIOTRONIK. Customer shall bear any costs incurred in the defense against such access of third parties to the goods under ownership of BIOTRONIK.

If Customer infringes any of the aforementioned provisions, especially does not pay the purchase price, BIOTRONIK has the right to rescind the contract in accordance with statutory provisions or demand damages for non-performance and the return of the goods subject to retention of title and on the basis of rescission.

In case the retention of title is not legally effective due to applicable legal provisions, Customer agrees in advance to establish a lien or a comparable security on the transferred goods for the benefit of BIOTRONIK. Such lien on the goods or comparable security shall be recorded in a public register, if such a public register exists. Customer shall bear the costs of such registering procedure.

6. Warranty

Regardless of the guarantee conditions of BIOTRONIK, warranty shall only be assumed according to the statutory provisions unless otherwise agreed upon herein.

The warranty obligations are primarily based on the agreed composition and quality of the goods. The product description identified as such and handed over to the Customer prior to its order or integrated within the contract in the same way as these GTCS shall be considered such agreement on the composition and quality of the goods.

The warranty period shall be one year from delivery or insofar as an acceptance inspection is required from such acceptance inspection.

The delivered goods shall be inspected immediately upon delivery to the Customer or to a third party designated by the Customer. The goods are deemed accepted unless BIOTRONIK receives a complaint relating to apparent defects or other defects that would be recognized in an immediate, thorough inspection in writing and within three working days after delivery of the goods, or otherwise within three working days after discovery of the defect or from the time in which the defect could be recognized by the Customer in normal usage without closer inspection.

In case of defects BIOTRONIK shall be obliged (upon its own choice to be exercised within reasonable time) either to rectify the defects or provide supplemental performance. If supplemental performance is unsuccessful or fails within an appropriate deadline stipulated in writing by the Customer or such deadline is unnecessary according to statutory provisions, Customer is entitled to rescind the contract or to reduce the purchase price. No right of rescission exists in case of insignificant defects.

Customer must allow BIOTRONIK the requisite time and opportunity to perform any repairs or replacements. In the event of the substitute delivery the Customer must return the defective product according to statutory regulations. The expenses necessary for the purpose of inspection and supplementary performance, in particular transport, work and material costs shall be on the account of BIOTRONIK insofar as the product is actually defective.

The warranty under this section 6 shall be inapplicable if the Customer makes defect detection by BIOTRONIK impossible or difficult, for example in the case of implantable devices, by not providing

- ▶ after implantation the surgical report of the implantation (if permissible under applicable law)
- and / or
- ▶ after explantation of the device the explanted device

as well as not providing a written explanatory statement for the explantation. The same applies if the product has been manipulated by Customer or a third party.

7. Liability

BIOTRONIK's liability for damages for whatever reason, especially due to impossibility, default, defective or incorrect supply, breach of contract, breach of obligations with contract negotiations and tort, insofar as such liability is dependent on fault by BIOTRONIK, shall be restricted in accordance with this section 7.

BIOTRONIK shall not be liable for simple negligence of any of its organs, statutory representatives, employees or other vicarious agents unless such claims are based on a breach of material contractual duties. Material contractual duties are the obligations for prompt sup-

ply, free of defects and duties of consultation, protection and care, which will make the use of the delivered goods in accordance with the contract possible for the Customer or which serve the purpose of protecting the life and limb of personnel of the Customer or third parties or Customer's property against considerable damage. To the extent BIOTRONIK is accordingly in principle liable for damages, such liability shall be limited to damages which are reasonably foreseeable by BIOTRONIK at the execution date of the contract or which, taking into consideration the circumstances that BIOTRONIK knew or reasonably should have known, BIOTRONIK would have foreseen had BIOTRONIK exercised reasonable care. Furthermore, indirect damage and consequential damage resulting from defects in the delivered goods are only subject to compensation in so far as such damage is typically to be expected when using the goods supplied as stipulated.

Insofar as BIOTRONIK provides technical information or acts as an adviser and this information or advice is not part of the contractually agreed scope of duties owed by it, this is done free of charge and under the exclusion of any liability.

The limitations of this section 7 do not apply to BIOTRONIK's liability on account of intent or gross negligence, for guaranteed characteristics, on account of injury to life, limb or health or according to the German Product Liability Act. The aforementioned limitations of liability also apply to the liability of the organs, legal representatives, employees or other vicarious agents of BIOTRONIK.

8. Traceability of Implants

BIOTRONIK as manufacturer of implantable medical devices (i.e. cardiac pacemakers, defibrillators, hereinafter "Implants") has to ensure the traceability of such Implants (sec. 5 German Medical Devices Act, sec. 14 subsec. 1 German Medical Devices Security Plan Regulation).

Observing the pertinent data protection law provisions, the Customer shall guarantee the traceability of the delivered products by keeping a data overview that contains information on:

- ▶ Product type and Serial number
- ▶ Date of delivery
- ▶ Date of a possible subsequent delivery including name and address of the recipient (i.e. physician / clinic)
- ▶ Name of patient implanted with the device
- ▶ Date of implantation
- ▶ Date of explantation

The Customer shall ensure that in an emergency the relevant data can be conveyed to BIOTRONIK within five days. The applicable data protection law provisions have to be observed. Emergencies are for example recalls, product liability cases and possible violations of applicable laws.

In order to ensure the traceability in case of resale by Customer to medical institutions (i.e. physicians, clinics) or business owners (hereinafter "Subsequent De-

livery") and in order to prevent a loss of data in the course of Subsequent Deliveries (i.e. after insolvency), Customer agrees to give to BIOTRONIK the date plus name and address of the subsequent purchasers at first request within five working days, irrespective of a case of emergency.

Customer is responsible that any of its subsequent purchasers and all sub-distributors observe the aforesaid obligations to

- ▶ Keep a data overview containing the above mentioned content
- ▶ Hand over the above described data overview to BIOTRONIK in case of emergency
- ▶ Hand over, irrespective of a case of emergency, to BIOTRONIK at first request within five working days the date of a Subsequent Delivery and name and address of the subsequent purchaser and to further oblige subsequent purchasers to observe these obligations

In the event of product complaint, Customer shall inform BIOTRONIK in writing or in text form (letter, fax, e-mail) without delay of the cause of the complaint, on no account later than three working days after it becoming known. In case of an explanation, the Customer will send the explanted device to BIOTRONIK without delay, on no account later than ten working days. Customer shall ensure that any subsequent purchaser of its own observes these obligations and that the applicable provisions of the German Medical Products Operator Ordinance in its respectively current version are observed.

9. Export

The Customer undertakes to adhere to all applicable export/import provisions, as well as any associated embargo provisions, trade embargos and sanctions. The Customer undertakes particularly, in the absence of a relevant official authorization or order, to export technical data and software (including products that arise from such data or software) neither directly nor indirectly to a proscribed destination or a country of concern as may arise from the pertinent provisions cited above, and not to export or re-export (including passing on to nationals of one of these countries, irrespective of their location). Customer guarantees to implement adequate organizational measures to ensure adherence to EU regulations and insofar as applicable the according U.S. regulations. In case of a Subsequent Delivery according to section 8 Customer shall be responsible for ensuring that the second purchaser and any further purchasers adhere to the obligations set out in this section 9 and that such second purchaser imposes these obligations on their respective customers.

10. Secrecy

The Parties undertake to treat as confidential – even beyond the term of this contract – all information gained from the respective other Party before or on performance of the contract, irrespective of whether marked as confidential or not, and irrespective of the form of its conveyance (concrete or electronic), and to

make it available only to such staff and consultants who need access to the relevant information for the purpose of fulfilling their duties and have submitted to an appropriate obligation of confidentiality.

The aforesaid obligation of confidentiality shall not apply to such information already known to the public on conclusion of this agreement or subsequently becomes rightfully known or is relinquished to third parties after consent of the conveying party or must be disclosed due to binding official or court order.

11. Place of Performance and Place of Jurisdiction

The place of performance for all obligations arising from contractual relations subject to the inclusion of these GTCS is Berlin, Germany.

The place of jurisdiction for all disputes regarding a contractual relationship subject to the inclusion of these GTCS – also in the summary procedure based on documents – is Berlin, Germany.

Contractual relationships between BIOTRONIK and Customer are exclusively governed by the laws of Germany to the exclusion of its conflict of laws and the United Nations Convention on the International Sale of Goods.

12. Additional provisions for „HOME MONITORING®“ equipment

“HOME MONITORING®” describes a technology developed and manufactured by BIOTRONIK SE & Co. KG that transmits medicinal and technical data of a patient’s active implant via a receiving and emitting unit, the “CardioMessenger®”, through either the GSM mobile telecommunication network or the fixed telecommunication network to a service center (“Service Center”) run by BIOTRONIK.

The Service Center compiles such data for inspection by the treating medical facility [physician, clinic etc. (“treating medical facility”)] via a secured internet access. A medical diagnosis and reporting does not take place.

HOME MONITORING® is not an emergency system and does not replace an appointment with the physician.

Insofar as the delivered product is equipped with the HOME MONITORING® technology such technology and the according services are rendered by BIOTRONIK SE & Co. KG for BIOTRONIK and the following applies in addition to the contractual provisions and these General Terms and Conditions of Sale of BIOTRONIK:

12.1 Obligations of BIOTRONIK

BIOTRONIK operates the Service Center for the purpose of collecting, processing and transferring the data transmitted via the CardioMessenger®.

From time to time the Service Center may be temporarily offline for short periods for purposes of maintenance. The offline periods and their duration will be announced with sufficient prior notice on the Service Center’s website. During such offline-periods generally incoming data will only be stored but no data pro-

cessing will take place. Access to these data during the offline-period is not possible.

BIOTRONIK is free to change the volume of information or to adapt such information to the current state of the art. BIOTRONIK informs about such changes on the Service Center's website.

Generally data is stored at the Service Center so that it can be accessed online for a period of two years by the treating physician respectively and the medical facility employing the treating physician.

Regarding the usage and the technical specifications, the respective user manuals of the CardioMessenger® and the operating instructions of the Service Center's website have to be observed.

12.2 Obligations of Customer / Medical Facility

Provided that the customer and the medical facility responsible for the treatment of the patient are not identical, customer imposes on its customers, the medical facility or the distributor, ("Second Purchaser") the following obligations prior to delivery of the implant:

- a) Second Purchaser shall inform patients of the HOME MONITORING® system and advise them on the usage of the CardioMessenger®. Sec. 10 of the German Ordinance on the Operation of Medical Devices applies accordingly. Second Purchaser will provide to patients the product information authorized by BIOTRONIK for this purpose. Second Purchaser will advise patients that the HOME MONITORING® system properly functions only if it is adequately commissioned and if the user manual is observed.
- b) Second Purchaser shall inform patients on the processing of patient's health data and patient's option to stop the participation in HOME MONITORING® at any time without consequences for the patient's therapy or other adverse consequences for them. The patient's consent has to be documented in writing and the according records have to be kept.
- c) Furthermore Second Purchaser shall inform the patient about the fact that the HOME MONITORING® system is not an emergency system.
- d) Second Purchaser shall take all necessary steps to register patients with the Service Center after implantation. Second Purchaser knows that only after such registration the medical facility can access the patient's health data and that a registration may only take place if the patient's consent is given.
- e) Second Purchaser will not alter, manipulate or misuse the CardioMessenger®. Patients have to be instructed accordingly.

- f) Second Purchaser will inform patients that BIOTRONIK is entitled to end the HOME MONITORING® in case of a sale, rental or any other form of use of the CardioMessenger®, if this means that the patient registered with the HOME MONITORING® is not treated anymore by the medical facility. In this event the CardioMessenger® will be switched off and no patient health data will be transmitted anymore.

12.3 Duration

BIOTRONIK provides the HOME MONITORING® service for a consideration, however, BIOTRONIK is entitled to cancel the services. In this event BIOTRONIK will inform patients, customers and medical facilities with sufficient prior notice. Already made payments of customer will be refunded pro rata. Furthermore, BIOTRONIK is entitled to end the services for specific equipment for good cause. Inter alia such good cause exists if customer uses the CardioMessenger® not for the purpose of HOME MONITORING® or if Customer manipulates the CardioMessenger® or if the use of the implant in the patient ends (i.e. due to explantation or death).

The end of utilization is refutably presumed and entitles BIOTRONIK to end the HOME MONITORING® services for specific equipment if over a period of twelve month no medical data from the implant respectively the CardioMessenger® are transmitted to the Service Center and if the medical facility is informed accordingly. In this case BIOTRONIK will cease the data transfer.

12.4 Liability for HOME MONITORING®

In addition to the provisions on liability in these General Terms and Conditions of Sale the following is applicable with regard to the usage of HOME MONITORING® equipment:

BIOTRONIK is reliant on communication capabilities in order to ensure the proper and timely transfer of data from the CardioMessenger® to the Service Center and from the Service Center to the treating medical facility. The availability and proper functioning of such communication capabilities is outside BIOTRONIK's control. Any liability of BIOTRONIK for the conduct of operators of those communication capabilities, especially GSM mobile transmission, shall be excluded.

Moreover, BIOTRONIK shall not assume liability for the availability and functioning of the technical prerequisites needed for the HOME MONITORING® services at customer, patient or the respective medical facility [i.e. internet access, fixed network connection and mobile phone connection, availability of telefax transmission (sending and receiving)].

12.5 Consent of Customer

Upon acceptance of these terms and conditions and until revoked customer declares its consent with the storage and processing of its data in electronic form, inasmuch as this is necessary for the due and proper performance of the contract.

Berlin, March 2014
BIOTRONIK Vertriebs GmbH & Co. KG