

# General Terms and Conditions

## Terms and Definitions

- Customer** the person or company entering into an agreement with, receiving an offer or quotation from, or by other means having any legal agreement with Trianect or for whom Trianect performs any act;
- Agreement:** the agreement between Trianect and the customer.
- Product:** the product deliverable by Trianect under the agreement.

## Article 1. General

- 1.1 These general conditions apply to all offers, quotations and agreements of Trianect as well as to all (other) acts between Trianect and customers, also including negotiation and other pre-contractual situations.
- 1.2 Any exceptions to these general terms and conditions are only valid if expressly agreed in writing or by electronic mail.
- 1.3 The applicability of any purchase or other conditions of the customer is explicitly rejected.
- 1.4 If one or more of the provisions in these general terms and conditions is invalid or void, the remaining provisions of these terms and conditions shall remain fully applicable. The invalid or unenforceable provisions will be replaced by Trianect, with the purpose and intent to observe the original provision(s).
- 1.5 If at any time Trianect does not require strict compliance with these general terms and conditions, this does not mean that its provisions do not apply, or that Trianect in any degree would lose the right to the strict compliance with the provisions of these conditions in all other cases.
- 1.6 In case of explanation of the content and scope of these general terms and conditions, the original Dutch text will prevail.
- 1.7 Trianect has the right to change the General Terms and Conditions.

## Article 2. Offers and quotations

- 2.1 Offers and quotations are not binding.
- 2.2 Each offer is based on but not limited to information, data, documents, etc. provided by the customer. The customer is responsible for the accuracy and completeness of the by (or on behalf of) Trianect specified requirements and specifications and other data on which Trianect bases its offer.
- 2.3 If the acceptance differs from the terms included in the quotation, Trianect is not bound. The agreement will not be in accordance with said deviating acceptance.
- 2.4 Offers and quotations shall not automatically apply to future agreements.
- 2.5 Any apparent errors or mistakes in offers and quotations, marketing and sales materials, website, brochures, flyers, proposals, publications or e-mails from Trianect are not binding to Trianect.
- 2.6 Offers and quotations from Trianect to the customer, as well as other documents, may not be reproduced without permission from Trianect, nor be disclosed to third parties.
- 2.7 The content of offers and quotations from Trianect to the customer is confidential and may not be disclosed to third parties.

## Article 3. Images

- 3.1 All images of the products listed on offers and quotations, marketing and sales materials, smartphone applications, website, brochures, flyers, proposals, publications, contracts or e-mails from Trianect are only approximate reproductions of the products and cannot lead to compensation and/or dissolution.

## Article 4. Conclusion of the Agreement

- 4.1 The agreement is concluded at the time that the customer has signed the offer or contract and returned to Trianect or after the customer has accepted the offer from Trianect in writing or via electronic mail or after Trianect has confirmed the order from the customer.
- 4.2 If the customer has placed an order and this order is confirmed by Trianect, a sales contract is entered into by parties. This contract is binding and cannot be canceled by the customer.
- 4.3 Trianect has the right to reject an order from a customer. The customer will be duly notified.
- 4.4 After confirmation of the order by Trianect, the customer is allowed to change the order when the customer has agreed to compensate Trianect for any possible and/or additional costs it encounters for changing the agreement. If the customer does not agree with the extra cost, the original order, along with any and all associated costs, remains valid.

## Article 5. Prices

- 5.1 The prices quoted are exclusive of B.T.W. (V.A.T.) and based on delivery Ex Works Utrecht, the Netherlands.
- 5.2 Trianect has the right to adjust its prices from time to time.
- 5.3 Trianect's pricing structure is based on the euro (€). If invoicing occurs in other currencies and between the time of conclusion of the agreement and the delivery of the products a change has occurred in the exchange rate, Trianect

- 5.4 shall be entitled to revise the original price.
- 5.4 Trianect reserves the right to increase prices reasonably which is no ground for the customer to dissolve the agreement, if the increase in price is the result of a power or duty under any law or regulation or its cause in an increase in purchase prices, wages, etc. or for other reasons that were not reasonably foreseeable at the conclusion of the agreement.

## Article 6. Execution of the agreement

- 6.1 Trianect will execute the agreement to the best of its ability, in accordance with the requirements of good workmanship and on the basis of the currently known state of science and technology.
- 6.2 Trianect is always entitled to require the customer to provide sufficient security for the fulfillment of current or future payment(s). Trianect is entitled to suspend the execution or further execution of the agreement until the required security has been provided.

## Article 7. Customer obligations

- 7.1 The customer shall ensure that all data which Trianect indicates is necessary or which the customer reasonably understands to be necessary for the execution of the agreement, will be provided to Trianect. If the customer has not fulfilled this obligation, Trianect has the right to suspend and/or charge the customer any and all extra costs resulting from the delay for the implementation of the agreement.
- 7.2 If the data provided by the customer is incomplete and/or incorrect, this is entirely the responsibility and risk of the customer.
- 7.3 The customer is required to duly inform Trianect about facts and circumstances that may be related to the implementation of the agreement including but not limited to: changes in the market, defects or malfunctioning of the product and finding that a third party infringes the intellectual property rights of Trianect.
- 7.4 The customer indemnifies Trianect for claims and damages from third parties in connection with the execution of the agreement and attributable to the customer.
- 7.5 It is the responsibility of the customer to observe all legal and other regulations that are applicable in the country where the customer is located in relation to the retention, storage, use, transport and sale of the product, in any manner whatsoever.
- 7.6 The customer (or his subsequent customer(s)) is required to use the delivered product only as indicated in the instructions for use or in the technical specifications. General instructions for use are available in hardcopy form.
- 7.7 All data and information (relevant to the product) provided by Trianect is given without obligation and does not relieve the customer from his or her obligation to perform or implement their own inspections and tests.
- 7.8 If the customer does not, not fully or not timely comply with any and all obligations set forth, the customer can be held liable for all damages Trianect might suffer.
- 7.9 The products supplied by Trianect are designed and validated for use under the conditions specified in the Instructions for Use and technical specifications. The customer is solely responsible for: (a) ensuring that the product is appropriate and suitable for its specific clinical protocols, operational procedures, and patient population prior to deployment; (b) ensuring that the product is used exclusively within the intended use as defined by Trianect and as registered with the applicable regulatory authorities; (c) notifying Trianect in writing before deploying the product in any environment, application, or clinical context that deviates from the intended use as described in the Instructions for Use. Any use of the product outside the intended use, including but not limited to use in hospital settings, fixed clinical installations, or applications not validated by Trianect, is at the sole risk and responsibility of the customer. Trianect accepts no liability for any damage, injury, or regulatory consequence arising from use outside the intended use.
- 7.10 The customer is required to ensure all personnel who operate, handle, maintain, or supervise the use of the product have received adequate training in accordance with the training materials, programs, and requirements provided or specified by Trianect.
- The customer must not permit untrained personnel to operate the product in any clinical or operational setting.
  - The customer is required to maintain a training register for each individual operator, recording as a minimum: the name and role of the operator, the date and content of training received, and the name of the trainer or training organization.
  - Initial training may be provided by Trianect, a Trianect-authorized training partner, or by the customer's own qualified clinical or technical trainers, provided that such trainers themselves have been certified by Trianect. Training delivered by non-authorized parties does not fulfil the obligation under this article.
  - The customer is responsible for ensuring that training is repeated: (a) whenever a new operator is assigned to use the product; (b) following any significant software update or change in device functionality notified by Trianect; (c) following any serious incident or near-miss involving the product; (d) at intervals not exceeding 2 years for all active operators.
  - Trianect accepts no liability for any patient harm, device damage, regulatory consequence, or operational failure arising from the use of the product by personnel who have not received training in accordance with this article. The customer indemnifies Trianect against any claim by a third party, including patients, arising from use of the product by untrained personnel.
- 7.11 The customer must not remove, obscure, damage, or alter any UDI label, UDI-DI, UDI-PI, or any other identification marking affixed to the product, its packaging, or its accompanying documentation, in accordance with MDR Article 27 and Commission Regulation (EU) 2017/745 Annex VI.
- 7.12 The customer is required to record the UDI of each product unit received from Trianect in its asset management or inventory system within 5 business days of receipt. Upon request by Trianect, the customer must provide a full UDI record of all product units in its possession within 5 business days.
- 7.13 The customer must ensure that UDI data is passed on to any subsequent customer, user, or recipient of the product, and that the obligation to maintain UDI records is communicated and enforced throughout its supply chain.

- 7.14 In the event of a product recall, FSCA, or regulatory inspection, the customer must be able to provide full UDI traceability for all product units in its possession or previously transferred to third parties. Failure to maintain UDI records as required by this article constitutes a material breach of the agreement.
- 7.15 Trianect accepts no liability for regulatory consequences, including fines or sanctions imposed on the customer, arising from the customer's failure to comply with UDI obligations under this article or under applicable medical device regulations.

## Article 8. Delivery

- 8.1 The delivery time is always approximate. When the delivery time is exceeded, the customer is not entitled to compensation, termination of the agreement or any other form of compensation.
- 8.2 The delivery period shall commence at the time the order has been confirmed and Trianect has received all customer data which is necessary to carry out the agreement.
- 8.3 In the event that an exceeded delivery time is the result of an event which is in fact beyond the power of Trianect, such as described in Article 18 of these general terms and conditions, this period is automatically extended by the period that they were exceeded as a result of such an event.
- 8.4 Delivery is Ex Works Utrecht, the Netherlands, according to the latest published incoterms.
- 8.5 Trianect has the right to deliver the order in parts.
- 8.6 The customer is obliged to accept the ordered products.

## Article 9. Invoicing and payment

- 9.1 Trianect requires a prepayment of 50% of the total order value upon order confirmation. Production or delivery will not commence until this prepayment has been received by Trianect.
- 9.2 The remaining 50% must be paid prior to collection / release of goods, unless parties have expressly agreed otherwise in writing. Trianect reserves the right to require full prepayment for first orders, high-value orders (at Trianect's discretion), or if the customer's creditworthiness gives Trianect reasonable cause for concern.
- 9.3 The customer must pay the invoice(s) to Trianect within the payment period indicated on the invoice.
- 9.4 Payment must be made without any discount, deduction or set-off, unless the parties have expressly agreed otherwise. Any applicable bank charges are to be paid for by the customer.
- 9.5 If the customer does not meet the payment arrangements and/or does not pay the invoice to Trianect on time, the customer is immediately in default and the statutory interest will be charged to the customer.
- 9.6 In case of foreclosure, liquidation, bankruptcy, seizure or suspension of payment of the customer, Trianect's claims on the customer become immediately payable.
- 9.7 Every payment by the customer will first go towards any possible interest(s) and the costs related to recovery. Only after payment of these amounts will any payment by the customer be applied toward the outstanding principal balance.

## Article 10. Retention of title

- 10.1 All deliverable and delivered products remain the exclusive property of Trianect, until all existing and upcoming claims on the customer by Trianect are paid in full.
- 10.2 Until such time that ownership of the product has been transferred to the customer, the product may not:
- be pledged;
  - be signed interest to third parties therein;
  - be sold outside its normal business scope.
- 10.3 With observance of retention of title the customer is obliged to store product with the necessary care. The customer must always do what can be reasonably expected to secure the property rights of Trianect. The customer is required to carry a reasonable insurance policy providing full coverage over the products and to keep them protected and insured against fire, explosion, water damage and theft. The customer must duly provide a copy of the insurance policy to Trianect upon its first request.
- 10.4 If the customer's obligations towards Trianect are not (or not fully) complied with and in case of termination of the agreement, for whatever reason, Trianect is entitled to reclaim the product without prior notice or judicial intervention and without prejudice to the right of full compensation. All costs incurred by Trianect to reclaim the product, including but not limited to transport, packaging, labelling, and storage costs, will be charged to the customer.
- 10.5 If Trianect wishes to exercise its right as described in this article, then the customer is obliged to grant, or the third party engaged by Trianect, unrestricted access to the location where the product is located.
- 10.6 In case of foreclosure, liquidation, bankruptcy or seizure, the customer will duly notify Trianect and will duly notify and explain the bailiff, the receiver or liquidator of the (property) rights of Trianect.
- 10.7 The provisions mentioned in this article leave any future rights of Trianect without prejudice.

## Article 11. Return policy

- 11.1 Product can only be returned upon Trianect's explicit prior written permission or via electronic mail. All returns are subject to Article 13.4 and will be accepted only when Article 13.4 applies.
- 11.2 In case the customer returns a product without having received prior authorization for the return by Trianect, then the return

will be refused and returned or stored at the customer expense and risk. Invoice(s) and payment(s) for products that are returned without prior consent remain due and will not be credited.

## Article 12. Maintenance and Servicing Obligations

- 12.1 The customer is required to maintain the product in accordance with the maintenance schedule and procedures specified in the Instructions for Use and any applicable maintenance manual provided by Trianect. Preventive maintenance must be performed at the intervals specified by Trianect, which shall be no less than once per calendar year unless otherwise stated in the Instructions for Use.
- 12.2 Preventive and corrective maintenance may only be performed by Trianect or a service partner explicitly authorized in writing by Trianect. Maintenance performed by unauthorized parties will immediately void the warranty as set forth in Article 13 and may invalidate the regulatory certification of the product, for which Trianect accepts no liability.
- 12.3 The customer is required to maintain a maintenance log for each individual product unit, recording the date, nature, and outcome of each maintenance activity, and the identity of the party performing the maintenance. This log must be made available to Trianect upon first request and must be retained for a minimum of 10 years from the date of last use of the product, in accordance with MDR Article 10(8).
- 12.4 If the customer identifies or suspects a defect, malfunction, or degradation in product performance, the customer must immediately: (a) cease use of the affected product unit; (b) notify Trianect in writing within 24 hours; (c) quarantine the product unit and make it available for inspection by Trianect. The customer must not attempt to repair or adjust the product without prior written authorization from Trianect.
- 12.5 Trianect will use reasonable efforts to provide corrective maintenance within the timeframe agreed in a separate Service Level Agreement (SLA) or, in the absence of an SLA, within a reasonable timeframe given the nature of the defect and operational circumstances. In a pre-hospital EMS environment, Trianect acknowledges the operational criticality of the product and will prioritize corrective maintenance requests accordingly.
- 12.6 Trianect does not supply spare or backup units. The customer is responsible for ensuring sufficient unit availability to maintain continuity of care during maintenance or repair periods.
- 12.7 All replacement parts used in maintenance or repair of the product must be genuine parts supplied or approved by Trianect. Use of non-approved parts will void the warranty and may invalidate the regulatory certification of the product.

## Article 13. Complaints and warranty

- 13.1 It is the sole responsibility of the customer to duly inspect the products upon delivery for, but not limited to the following:
  - a. if the correct products have been delivered;
  - b. if the correct quantity of products have been supplied;
  - c. if the products meet the quality requirement of the requirements that may apply for normal use of the products.
- 13.2 Complaints regarding the delivered order must in any case be disclosed to Trianect within 7 days after delivery. Complaints must be submitted in writing or via electronic mail to Trianect. Complaints that are submitted late will not be considered.
- 13.3 Electronic equipment has a warranty period of 2 years. This warranty is granted from and remains solely with the original equipment manufacturer. To the best of Trianect's ability, Trianect will facilitate the execution of this warranty. The warranty period starts at the time of collection / release of goods.
- 13.4 The customer is required to allow Trianect to verify any complaints regarding the product, the order, or a warranty claim. In that context, Trianect may require the customer to return the order (or part of the order) to Trianect. The fact that Trianect proceeds to investigate a complaint or a warranty claim does not imply that Trianect acknowledges that the delivered order is incorrect or that the product is defective.
- 13.5 As soon as a defect with the product is detected, the product shall not be used.
- 13.6 If the customer notifies Trianect that incorrect product or an incomplete order was delivered, then Trianect will correct the order.
- 13.7 If the product contains a defect within the warranty period and the warranty claim is accepted by Trianect, then Trianect will, at its sole discretion, exchange the product or issue a (partial) credit note. The liability of Trianect is always limited to what is set forth in Article 17.
- 13.8 A product defect does not entitle the customer to refuse or return the entire order of which the defective product is a part.
- 13.9 The warranty expires and complaints about the product are not (further) considered if:
  - a. defects are the result of improper use, poor maintenance or improper product cleaning;
  - b. the product is not used in accordance with the instructions for use or for the intended purpose;
  - c. any modifications and/or repairs are made to the product by the customer and/or any third party activities;
  - d. defects are the result of normal wear and tear;
  - e. defects are the result of external conditions such as: fire, natural disasters, explosions, terrorism, detergents, dirt accumulation, landslides, floods and weather conditions;
  - f. defects are the result of any government regulation regarding the nature or quality of the materials used;
  - g. the damage caused by the user of the product;
  - h. there is a minor and/or generally accepted and/or technically unavoidable deviation;
  - i. the product is not used in accordance with the technical specifications;
  - j. (preventive) maintenance is not performed in accordance with IFU guidelines;
  - k. defects are the result of components and/or products not supplied by Trianect.
- 13.10 Complaints or warranty claims will not affect or suspend the payment obligation of the customer.

## Article 14. Field Safety Corrective Actions (FSCA) and Recall Cooperation

- 14.1 The customer is required to maintain an up-to-date register of all product units in its possession or deployed in its operational fleet, recording as a minimum:
- (a) the unique device identifier (UDI) or serial number of each unit;
  - (b) the physical location of each unit;
  - (c) the date of receipt and date of first deployment;
  - (d) the current operational status of each unit. This register must be made available to Trianect immediately upon request.
- 14.2 In the event that Trianect issues a Field Safety Corrective Action (FSCA) notice or recall, the customer is required to: (a) acknowledge receipt of the FSCA notice in writing to Trianect within 2 business days; (b) implement the required corrective action in full within 5 business days of receipt of the FSCA notice, or within such shorter timeframe as Trianect specifies where patient safety requires urgent action; (c) confirm in writing to Trianect that the corrective action has been fully completed, including the serial numbers or UDI codes of all affected units.
- 14.3 Where a product unit cannot be located or accounted for within the timeframe specified in Article 14.2, the customer must notify Trianect immediately in writing, providing all available information regarding the last known location and status of the unit.
- 14.4 The customer must not continue to use any product unit subject to an FSCA notice or recall until Trianect has confirmed in writing that the corrective action has been completed and the unit is safe to return to service.

## Article 15. Adverse Event and Vigilance Reporting

- 15.1 The customer is required to report to Trianect any serious incident, adverse event, or near-miss involving the product without undue delay and in any event within 24 hours of the customer becoming aware of the event. A serious incident includes any malfunction, deterioration in performance, or inadequacy in labelling or instructions for use that has led to or could lead to:
- (a) the death of a patient, user, or third party;
  - (b) a serious deterioration in the state of health of a patient, user, or third party;
  - (c) a serious public health threat.
- 15.2 Near-miss events - defined as events which, but for fortunate circumstance, could have led to a serious incident - must be reported to Trianect in writing within 5 business days of the customer becoming aware of the event.
- 15.3 Reports under Articles 15.1 and 15.2 must include as a minimum:
- (a) the UDI or serial number of the product unit involved;
  - (b) the date, time, and location of the event;
  - (c) a factual description of the event and the circumstances in which it occurred;
  - (d) the clinical outcome for any patient involved;
  - (e) any immediate action taken by the customer.
- 15.4 The customer must not make any public statement, press release, or regulatory notification regarding a serious incident or FSCA involving the product without prior written consent from Trianect, except where the customer is legally obliged to report directly to a competent authority, in which case the customer must notify Trianect simultaneously.
- 15.5 The customer must cooperate fully with any investigation by Trianect, a notified body, or a competent authority into a serious incident or adverse event, including providing access to maintenance records, training records, UDI registers, and the product unit involved.
- 15.6 Failure to report a serious incident or adverse event within the timeframes specified in this article constitutes a material breach of the agreement. Trianect accepts no liability for regulatory consequences arising from delayed or absent reporting attributable to the customer.

## Article 16. Suspension and termination

- 16.1 Trianect is entitled to suspend the agreement if, after the conclusion of the agreement, Trianect became aware of circumstances, giving good ground to fear that the customer will not (be able to) fulfill its obligations. If there is good reason to fear that the customer will only partially or improperly fulfill his obligations, suspension shall only be allowed as far as the shortcoming justifies.
- 16.2 Trianect is entitled to terminate the agreement if the customer does not fully comply with the obligations under the agreement.
- 16.3 Trianect is entitled to terminate the agreement if circumstances arise of such a nature that reasonable and fair fulfillment of the contract becomes impossible, can no longer be expected or if other circumstances arise of such a nature that unaltered and intended fulfillment of the agreement cannot reasonably be expected.
- 16.4 Trianect is entitled to terminate the agreement if the customer requests suspension of payment or if the customer is declared bankrupt or an application for bankruptcy is submitted, in case the customer is unable to pay its debts, files for termination or liquidation of its business, are placed under guardianship, or if an administrator is appointed.
- 16.5 If Trianect proceeds to suspend or dissolve the agreement, Trianect is in no way liable for damages and costs it incurred in any manner.
- 16.6 If the agreement is terminated, any and all claims of Trianect towards the customer become immediately payable. If Trianect suspends the fulfillment of its obligations, it will retain its rights under the law and the agreement.
- 16.7 Trianect always retains the right to claim damages.

## Article 17. Liability and limitation

- 17.1 Trianect waives all liability for damage which is a direct or indirect result of:
- an event, which is in fact beyond its control, such as described in Article 18 of these general terms and conditions;
  - any act or omission of the customer, its employees, or other persons who are employed by or acting on behalf of the customer.
- 17.2 Trianect is not liable for damages of any kind, if it was provided with false and/or incomplete information by the customer.
- 17.3 Trianect is not liable for damages which are the result of improper storage, processing, packaging or transportation by or on behalf of the customer.
- 17.4 Trianect is not liable for any damage due to abuse, misuse or improper use of the products, by use of the products in violation with instructions for use, by improper maintenance or cleaning of products or by no (or lack of) normal and/or required scheduled inspection.
- 17.5 Trianect is not liable for damages if the customer or third parties have made any alterations, changes or modifications to the products.
- 17.6 Under no circumstance is Trianect liable for damages arising from or caused by the use of the product for a purpose other than for which it is intended.
- 17.7 If, to Trianect's sole discretion, it is taking action, or is cooperating with manufacturers to initiate recall actions, the customer is obliged to cooperate. Trianect cannot be held liable for the damages suffered by the customer from (initiated) recall actions.
- 17.8 Trianect waives all liability and damages resulting from consequential damages. Consequential damage is in any case: lost revenue, lost profits, lost savings, loss of production, loss of profits, business interruption, stagnation damage, delay damages, reputational damage, environmental damage, fines and indirect damage, regardless of their origin.
- 17.9 Should Trianect be found liable for any damage, then the liability of Trianect is limited to the amount of the payment made by the insurer of Trianect. If the insurer does not pay out or if the damage is not covered by insurance, the liability of Trianect is limited to the invoiced amount, at least that part of the agreement to which the liability relates.
- 17.10 The customer indemnifies Trianect for claims by third parties against Trianect for events, acts or omissions for which Trianect is not liable under the preceding. At the first request by Trianect, the customer is obliged to hold Trianect harmless for all costs, damages and interest that may arise as a direct or indirect result of a third party action brought against Trianect as referred to in this paragraph.
- 17.11 Claims and other rights from the customer irrespective of the account towards Trianect expire at one year from the time that an event occurs for which the customer may apply these rights and/or responsibilities towards Trianect.
- 17.12 If the customer does not timely or properly fulfill its contractual and/or its legal obligations, or performs any illegal act against Trianect, then the customer must compensate Trianect for all the damages it has suffered, suffers or will suffer.

## Article 18. Force Majeure

- 18.1 Trianect is not obliged to fulfill any obligation if it is prevented from doing so by force majeure. Force majeure shall in any case include: weather; theft; electricity and internet outage; floods, landslides and other natural disasters; terrorism; barriers by third parties, including those of governments; barriers in transport; strikes; riots, wars or war threats; loss of or damage to goods during the transport thereof; the late or non-delivery of products to Trianect by its supplier(s); import and export restrictions; fires, breakdowns and accidents in the company of Trianect or its supplier(s); the burning of means of transportation of Trianect, its supplier(s) or on transport, getting involved in (traffic) accidents, the occurrence of transport service disruption; measures of any domestic, foreign or international government.
- 18.2 Force majeure is further defined as a non-attributable shortcoming of the supplier(s) of Trianect.
- 18.3 In case of force majeure, Trianect shall not be obliged to pay any damages as a direct or indirect result and will also be relieved of its obligation to deliver. It will depend on the circumstances of the case, whole or in part, if the case persists, or whether there is only a suspension of delivery. If an opportunity arises to yet deliver and/or to deliver otherwise, both Trianect and the customer are obliged to use the opportunity, if necessary by amending the amounts to be paid by the customer.

## Article 19. Confidentiality

- 19.1 Both parties are required to treat any and all information obtained in the course of their agreement from each other or from another source as confidential. Information is considered confidential if the one party has duly notified the other party or if this follows from the nature of the information. The party receiving the confidential information shall only use it for the purpose for which it was provided.
- 19.2 If on the basis of a statutory provision or a court order Trianect must disclose confidential information to by law or by the court appointed third parties, and Trianect itself is unable to invoke legal privilege recognized by the competent court or permitted otherwise, then Trianect is not liable for damages or compensation and the customer is not entitled to terminate the agreement pursuant to any resulting damage.
- 19.3 Any software, firmware, or digital components provided by Trianect, including but not limited to source code, object code, algorithms, software documentation, and updates, are and remain the exclusive intellectual property and confidential information of Trianect. The customer shall not reverse-engineer, decompile, modify, copy, or distribute such software in any form without prior written consent of Trianect. Unauthorized modification of software or firmware provided by Trianect will void any applicable warranty and may invalidate regulatory certifications, for which Trianect accepts no liability.
- 19.4 The customer shall: (a) not share, transfer, or disclose any login credentials, remote access rights, or network access granted by Trianect to unauthorized third parties; (b) notify Trianect without undue delay upon becoming aware of any actual or suspected cybersecurity incident, breach, or vulnerability affecting the product; (c) apply software updates and security patches provided by Trianect within a reasonable timeframe as indicated by Trianect; (d) not connect the product to networks or systems in a manner inconsistent with Trianect's technical specifications or instructions for use. Failure to

comply with these obligations releases Trianect from any liability arising from cybersecurity incidents attributable to the customer's environment or actions.

## Article 20. Data Protection and Patient Data

- 20.1 To the extent that the product processes, stores, or transmits personal data, including but not limited to patient vital signs, ECG data, location data, or operator identifiers, the parties agree that: (a) the customer acts as data controller within the meaning of GDPR Article 4(7), being responsible for determining the purposes and means of processing; (b) Trianect acts as data processor within the meaning of GDPR Article 4(8), processing personal data only on behalf of and on the documented instructions of the customer.
- 20.2 Trianect will process personal data only for the purposes of:  
(a) providing and maintaining the product and associated services;  
(b) performing its post-market surveillance obligations under MDR Article 83;  
(c) complying with applicable legal obligations.  
Trianect will not process personal data for any other purpose without the prior written consent of the customer.
- 20.3 Trianect will implement and maintain appropriate technical and organisational measures to ensure a level of security appropriate to the risk, in accordance with GDPR Article 32, including as a minimum:  
(a) encryption of personal data in transit and at rest;  
(b) access controls limiting processing to authorised personnel;  
(c) measures to ensure ongoing confidentiality, integrity, and availability of processing systems.
- 20.4 In the event of a personal data breach within the meaning of GDPR Article 4(12), Trianect will notify the customer without undue delay and in any event within 24 hours of becoming aware of the breach, providing sufficient information to enable the customer to meet its own notification obligations to the supervisory authority within the 72-hour deadline imposed by GDPR Article 33.
- 20.5 The customer is responsible for ensuring that a valid legal basis exists for the processing of patient data by the product, and that patients have been informed of such processing in accordance with GDPR Articles 13 and 14. The customer indemnifies Trianect against any claim, fine, or sanction arising from the customer's failure to establish a valid legal basis or to provide adequate information to data subjects.
- 20.6 Upon termination of the agreement, Trianect will, at the customer's choice, delete or return all personal data processed on behalf of the customer, and delete existing copies, unless applicable law requires continued storage.
- 20.7 The parties agree to enter into a separate Data Processing Agreement (DPA) in accordance with GDPR Article 28(3) prior to the commencement of any processing of personal data. In the event of any conflict between this article and the DPA, the DPA shall prevail.

## Article 21. Decommissioning

- 21.1 The customer must notify Trianect in writing within 10 business days of decommissioning any product unit, providing the UDI or serial number of the decommissioned unit and the reason for decommissioning.
- 21.2 Decommissioned product units must be handled, returned, or disposed of in accordance with applicable waste regulations, including but not limited to the WEEE Directive (2012/19/EU) and any applicable national implementing legislation. The customer bears sole responsibility for ensuring compliant disposal.
- 21.3 The customer must not resell, donate, loan, or otherwise transfer any decommissioned product unit to a third party without prior written consent from Trianect. This obligation applies regardless of the reason for decommissioning and regardless of whether the product unit is functional.
- 21.4 Where Trianect has issued an FSCA or recall affecting a product unit, the customer must not decommission or dispose of the affected unit without first receiving written instructions from Trianect, as the unit may be required for regulatory investigation or corrective action verification.
- 21.5 Upon request by Trianect, the customer must return decommissioned product units to Trianect at Trianect's cost, for the purpose of post-market surveillance, failure analysis, or regulatory compliance. Trianect will not reimburse the customer for the residual value of returned units unless expressly agreed in writing.
- 21.6 Trianect accepts no liability for any harm, regulatory sanction, or third party claim arising from the customer's unauthorised resale, donation, or disposal of a decommissioned product unit.

## Article 22. Intellectual Property

- 22.1 Trianect always retains all intellectual property rights to documents, quotes, pictures, designs and drawings provided by Trianect.
- 22.2 The customer must fully and unconditionally respect all intellectual property rights attached to and/or printed on product(s) and packaging delivered by Trianect.

## Article 23. Applicable law and jurisdiction

- 23.1 Any agreement between Trianect and the customer is governed by Dutch law. The applicability of the CISG is excluded.
- 23.2 All disputes related to agreements between the customer and Trianect must be submitted to the competent court in the district where Trianect is located.