

TERMS AND CONDITIONS FOR THE SALE OF REMANUFACTURED SINGLE-USE MEDICAL DEVICES AND ACCESSORIES - UK

Application

- A. These Terms and Conditions will apply to all contracts made with the customer whose object is the sale of remanufactured single-use medical devices and accessories ("**Customer**") from Vanguard Medical Devices Ltd., a corporation organised and existing under the laws of England with registered number 12215708 and VAT number 341391615, having its registered office at The Scalpel, 18th Floor, 52 Lime Street, London EC3M 7AF, UK ("**Vanguard**").
- B. These Terms and Conditions constitute the entire agreement between the Customer and Vanguard in respect of its subject matter. Any orders for remanufactured single-use medical devices and accessories shall be solely governed by these Terms and Conditions, and no other terms and conditions of either party referred to in purchase orders, order confirmations or elsewhere shall apply, unless expressly agreed in writing signed by the parties. Vanguard is not bound by terms and conditions of the Customer that deviate from these Terms and Conditions for the sale of remanufactured single-use medical devices and accessories, even if Vanguard does not expressly object to such Customer terms and conditions or performs services or accepts services of the Customer without reservation.

TERMS AGREED:

1. DEFINITIONS AND INTERPRETATION

1.1 In these terms and conditions:

"**Agreement**" means these terms and conditions and the accompanying Order Confirmation.

"**Applicable Laws**" means any applicable statute, regulation, legislative instrument having the force of law, guidance, directions, codes of practice, self-regulation, or determination, including without limitation, the Medical Device Directive (93/42/EEC), once applicable, the Medical Device Regulation ((EU) 2017/745), and those issued by the Medicines & Healthcare products Regulatory Agency (MHRA).

"**Business Day**" means a day, other than Saturday or Sunday or public holiday in England, when banks are open for business in London.

"**Confidential Information**" means information that one party discloses to the other party under this Agreement, and that is marked as confidential or ought reasonably to be considered confidential information under the circumstances. It does not include information that becomes public through no fault of the recipient, that was independently developed by the recipient, or that was lawfully given to the recipient by a third party.

"**Delivery**" means completion of delivery of an Order in accordance with Clause 5.3. "**Deliver**" shall be interpreted accordingly.

"**Delivery Date**" means the date specified for Delivery in the Order Confirmation.

"**Delivery Location**" means the location specified for Delivery in the Order Confirmation.

"**Force Majeure Event**" means any circumstance not in a party's reasonable control including, without limitation: acts of God, flood, drought, earthquake or other natural disaster; epidemic or pandemic; terrorist attack, civil war, civil commotion or riots, war, threat of or preparation for war, armed conflict; any law or any action taken by a government or public authority, including without limitation imposing an export or import restriction, quota or prohibition, or failing to grant a necessary licence or consent; collapse of buildings, fire, explosion or accident; any labour or trade dispute, strikes, industrial action or lockouts; or interruption or failure of utility service.

"**Intellectual Property Rights**" means rights, title and interest in patents, inventions, trade marks, service marks, trade and business names, rights in design, utility models, copyright, database rights, know-how (including trade secrets and Confidential Information) and any other similar right whether presently existing, applied for or in relation to which there is a right to apply for registration and any analogous rights to any of the preceding rights under any other jurisdiction.

"**Order**" means the Customer's order for the Products.

"**Order Confirmation**" means the confirmation of an Order issued by Vanguard.

"**Process Number**" means the number assigned to an Order Confirmation by Vanguard.

"**Products**" means the remanufactured single-use medical devices and respective accessories (where applicable) set out in the Order Confirmation).

"**Product Prices**" means the prices of the Products as set out in the Order Confirmation.

"**Regulator**" means any person or entity having regulatory or supervisory authority over any part of the Products or either party's business (including any competent authority or notified body), in whatever jurisdiction, and, in each case, any successor body or bodies.

"**Term**" means the term of this Agreement as set out in Clause Fehler! Verweisquelle konnte nicht gefunden werden..

1.2 References to "includes" or "including" shall be read as being immediately followed by the words "without limitation".

1.3 In the event of any inconsistency between the Order Confirmation and the Clauses of the main body of this Agreement, the Clauses shall prevail to the extent of the inconsistency.

1.4 A reference to a statute or a statutory provision or an Applicable Law is a reference to it as amended, extended, re-enacted or consolidated and includes all statutory instruments or orders from time to time made pursuant to it.

2. SUPPLY OF PRODUCTS

2.1 Vanguard shall supply and the Customer shall purchase, such quantities of Products as are set out in the Order Confirmation.

3. ORDER CONFIRMATION

3.1 An Order shall only be binding on the parties if Vanguard accepts the Order and issues an Order Confirmation in writing (including by email).

3.2 Vanguard shall assign an Order Confirmation with a Process Number to each Order it accepts and notify those Process Numbers to the Customer together. Each party shall use the relevant Process Number in all subsequent correspondence relating to the Order.

4. CUSTOMER OBLIGATIONS

4.1 The Customer may only use each individual Product on an individual patient during a single procedure.

4.2 The Customer shall notify Vanguard's Customer Service Centre (using the email address Service.uk@Vanguard-healthcare.com) immediately in writing:

(a) of all enquiries, contact, investigations or notices from a Regulator relating to the Products and / or Vanguard, and shall, if requested to do so by Vanguard, provide Vanguard with full details of all correspondence with and from the Regulator in relation to any such enquiry, contact or notice; and

(b) of any incidents, or suspected incidents (including any serious incidents or suspected serious incident) related to any Product, as such terms are defined in Applicable Laws, including without limitation any malfunction or deterioration in the characteristics or performance of the Product, any use-error due to ergonomic features, any inadequacy in the information supplied with the Product, any undesirable side-effects, or any safety issues.

4.3 The Customer shall ensure the personnel responsible for use, or preparation of the Products for use, are properly educated, trained and qualified in connection with such activities. The Customer shall provide regular and sufficient instructions and training to such personnel in respect of the handling and preparation of the Products in accordance with this Agreement.

4.4 The Customer shall ensure that the Products are used only in properly equipped electrophysiological laboratories (for electrophysiological products and accessories) or in properly equipped operating theatres (for surgical products).

4.5 If Vanguard institutes a recall or withdrawal of any Product, the Customer shall provide all reasonable support to Vanguard in carrying out any such recall or withdrawal in full compliance with the instructions of Vanguard.

4.6 In performing its obligations under the Agreement, the Customer shall comply with all Applicable Laws.

4.7 The Customer shall not use the Products outside the UK or deliver the Products to outside the UK.

5. DELIVERY

5.1 The title and risk in the Products shall pass to the Customer on Delivery.

5.2 Vanguard shall use its reasonable endeavours to deliver the Order to the Delivery Location. The parties acknowledge that the Delivery Dates are estimates only.

5.3 Delivery of the Order shall be complete when Vanguard places the Order at the Customer's disposal at the Delivery Location ("Delivery").

5.4 Vanguard may deliver Orders by instalments, which may be invoiced and paid for separately. References in this agreement to Orders shall, where applicable, be read as references to instalments. For the avoidance of doubt, there is no obligation on Vanguard to deliver any Order by instalment, although Vanguard may elect to do so in its sole discretion.

5.5 Delays in the delivery of an Order shall not entitle the Customer to refuse to take delivery of the Order or claim damages. Vanguard shall have no liability for any failure or delay in delivering an Order to the extent that any failure or delay is caused by the Customer's failure to comply with its obligations under this Agreement.

5.6 If the Customer fails to accept Delivery of an Order on or around the specified Delivery Date, then, except where such failure or delay is caused by Vanguard's failure to comply with its obligations under this Agreement:

- (a) the Order shall be deemed to have been Delivered at 9.00 am on the Delivery Date; and
- (b) Vanguard shall store the Order until Delivery takes place, and charge the Customer for all related costs and expenses (including insurance).

5.7 The delivery of Products shall be accompanied by a delivery note from Vanguard showing the Process Number, the Customer's order number (where relevant), the type and quantity of Products included in the Order, including the code numbers of the Products, and, in the case of Products being delivered by instalments, the outstanding balance of Products specified in an Order remaining to be delivered.

6. WARRANTIES

6.1 Vanguard warrants that:

- (a) the Products shall: (i) materially conform to the agreed type and condition of the Products as set out in Schedule 1; and (ii) be materially suitable for the use specified in Schedule 1, or in the absence of such specification, for the customary use of the Products in the UK; and
- (b) the remanufacturing, supply and Delivery of the Products complies with Applicable Laws, including in respect of remanufactured single-use medical devices.

6.2 Vanguard warrants that the supply of the Products shall not infringe the Intellectual Property Rights of any third party. In the event of such infringement, Vanguard shall, at its own expense and in its discretion:

- (a) procure for the Customer the right to use the infringing Product;
- (b) replace the infringing Product with a non-infringing, functionally equivalent one, or (c) suitably modify the infringing Product so that it is non-infringing. In the event that Vanguard is unable to provide any of the remedies set out in this Clause 6.2 above within a reasonable period of time, Vanguard shall refund to the Customer the full amount of any fees paid by the Customer to Vanguard with respect to such infringing Product. This Clause sets out the Customer's sole and exclusive remedies for any breach of the warranty set out in this Clause 6.2.

6.3 No conditions, warranties or other terms apply to any Products or to any other goods or services supplied by Vanguard under this Agreement unless expressly set out in this Agreement. Subject to Clause 10.3, all implied conditions, warranties or other terms (including any implied terms as to satisfactory quality, fitness for purpose or conformance with description) are excluded. For the avoidance of doubt, Vanguard shall have no liability in respect of the suitability of the Products for uses other than their agreed customary use or any expectation of Customer deviating from the expressly agreed quality or condition of the Products.

7. ACCEPTANCE AND DEFECTIVE PRODUCTS

7.1 The Customer shall inspect all Products immediately on Delivery. The Customer may reject any Products delivered to it that do not comply with Clause 6.1, provided that:

- (a) notice of rejection is given to Vanguard in writing (including by email) using the relevant complaint form provided in respect of such Product by Vanguard from time to time:
 - (i) in the case of a defect that is apparent on normal visual inspection, within three (3) Business Days of Delivery;
 - (ii) in the case of a latent defect, within a reasonable time of the latent defect having become apparent; and
- (b) none of the events listed in Clause 7.3 apply.

7.2 If the Customer fails to give notice of rejection in accordance with Clause 7.1, it shall be deemed to have accepted these Products.

7.3 Vanguard shall not be liable for a Products' failure to comply with the warranty set out in Clause 6.1 in any of the following events:

- (a) the Customer makes any further use of those Products after giving notice in accordance with Clause 7.1;
- (b) the defect arises because the Customer failed to follow Vanguard's oral or written instructions for the storage, commissioning, installation, use and maintenance of the Products or (if there are none) good trade practice regarding the same;
- (c) the defect arises as a result of Vanguard following any drawing, design or specification supplied by the Customer;
- (d) the Customer alters, repairs or reprocesses /remanufactures those Products without the written consent of Vanguard;
- (e) the defect arises as a result of fair wear and tear, wilful damage, negligence, or abnormal storage or working conditions; or
- (f) the Products differ from their specification as a result of changes made to ensure they comply with Applicable Laws.

7.4 If the Customer rejects Products under Clause 7.1 then Vanguard may either (in its discretion):

- (a) repair or replace the rejected Products; or
- (b) repay the price of the rejected Products in full.

7.5 Once Vanguard has complied with the Customer's request, it shall have no further liability to the Customer for the rejected Products' failure to comply with Clause 6.1. This Clause sets out Vanguard's sole and exclusive liability to the Customer (and the Customer's sole and exclusive remedy) in respect of any breach of Clause 6.1.

7.6 The terms of this Agreement shall apply to any repaired or replacement Products supplied by Vanguard.

8. PAYMENT

8.1 In consideration of the supply of Products as set out in this Agreement, the Customer shall pay to Vanguard the Product Prices in accordance with the Order Confirmation.

8.2 The Product Prices shall be inclusive of the costs of packaging, insurance, storage and standard delivery of the Products. If the Customer requires non-standard delivery, Vanguard may charge for such non-standard delivery separately.

8.3 Vanguard shall be entitled to invoice the Customer for the Products on or at any time after Delivery. Each invoice shall quote the relevant Process Numbers.

8.4 The Customer shall pay invoices in full and in cleared funds within thirty (30) days of receipt. Payment shall be made to the bank account nominated in writing (including by email) by Vanguard.

8.5 All Product Prices shall be exclusive of any Value Added Tax, which shall be payable in addition at the applicable legal rate upon provision of an appropriate VAT invoice.

8.6 In the event of non-payment in whole or part of any sum due by either party to the other under this Agreement within thirty (30) days of the due date for payment thereof, the party to whom the payment is due shall be entitled to charge interest on the outstanding sum unpaid from the due date until the actual date of payment (as well after as before decree or judgment) at a rate equal to 4% per annum above the base rate of Barclays Bank plc.

8.7 Except as otherwise expressly provided in this Agreement, each party shall be responsible for its own costs incurred in preparing and performing its obligations under this Agreement.

- 8.8 If the Customer reasonably disputes any item(s) appearing on an invoice, the Customer may withhold payment of the disputed amount pending resolution of the dispute. In this case, Vanguard shall issue the Customer with an invoice for the undisputed amount, which the Customer shall pay in accordance with the provisions of this Clause 8. Upon resolution of the dispute and where the resolution determines that the Customer owes to Vanguard some or all of the disputed amount, Vanguard shall issue another invoice in respect of that amount, which the Customer shall pay in accordance with the provisions of this Clause 8.
- 8.9 All payments payable to Vanguard by the Customer under this Agreement shall become immediately due and payable on termination of this Agreement for any reason. This Clause 8.9 is without prejudice to any right to claim for interest under the law or under this Agreement.
- 8.10 Vanguard may amend the Product Prices on thirty (30) days' written notice to the Customer. Such updated prices shall take effect from the expiration of such notice.
- 9. CONFIDENTIALITY**
- 9.1 The recipient of any Confidential Information will not disclose that Confidential Information, except to affiliates, personnel, employees and/or professional advisors who need to know it and who have agreed in writing (or in the case of professional advisors are otherwise bound) to keep it confidential. The recipient will ensure that those people and entities: (a) use such Confidential Information only to exercise rights and fulfil obligations under this Agreement, and (b) keep such Confidential Information confidential. The recipient may also disclose Confidential Information when required by law after giving reasonable notice to the discloser, if permitted by law.
- 9.2 Vanguard may state on its website that its customers include NHS hospitals (without specific reference to Customer).
- 10. LIMITATION OF LIABILITY**
- 10.1 Subject to Clause 10.3, the total liability of Vanguard to the Customer arising under or in connection with this Agreement shall not in any circumstances exceed the total amounts paid or payable by the Customer to Vanguard in this Agreement, irrespective of the nature of the claim which results in such liability and whether based on contract, tort (including negligence), statutory duty, or otherwise.
- 10.2 Subject to Clause 10.3, neither party shall be liable to the other for any loss of profits, special, indirect, consequential or incidental damages, even if it has been advised of the possibility of such damages. The parties must in all circumstances take all reasonable steps for mitigation of any loss.
- 10.3 Nothing in this Clause or otherwise in this Agreement shall exclude or in any way limit a party's liability to the other party: (i) for fraud or fraudulent misrepresentation; (ii) for death or personal injury caused by its negligence; (iii) breach of the terms implied by section 12 of the Sales of Goods Act 1979; or (iii) to the extent the same may not be excluded or limited as a matter of law.
- 11. GENERAL**
- 11.1 This Agreement contains all the terms agreed between the parties regarding its subject matter and supersedes and replaces any prior agreement, understanding or arrangement between the parties, whether oral or in writing. No representation, undertaking or promise shall be taken to have been given or be implied from anything said or written in negotiations between the parties prior to this Agreement except as expressly stated in this Agreement. Neither party shall have any remedy in respect of any untrue statement made by the other upon which that party relied in entering into this Agreement (unless such untrue statement was made fraudulently) and that party's only remedies shall be for breach of contract as provided in this Agreement.
- 11.2 No amendment or variation of this Agreement shall be binding unless made in writing signed by the parties.
- 11.3 All notices of termination or breach must be in English, in writing and shall be validly given: (a) if delivered personally, or sent by pre-paid first class post or recorded delivery or by commercial courier to the party required to receive the notice at its address set out above or as otherwise specified by the relevant party by notice in writing to each other party; and (b) if provided by Customer to Vanguard, if sent by email to service.uk@vanguard-healthcare.com, and marked as being for the attention of the Vanguard Legal Department (in addition to being sent as set out in (a)).
- 11.4 All other notices can be by email. Vanguard's email address for these purposes is service.uk@vanguard-healthcare.com. Notice by email will be treated as given on receipt, as verified by written or automated receipt (as applicable). Notices delivered personally are deemed to have been received on the Business Day of delivery if received before 5pm. Notices sent by first class post shall be deemed to have been received two (2) Business Days from posting.
- 11.5 Should any provision or any part of a provision of this Agreement become invalid, illegal or unenforceable, the remaining provisions shall remain in effect. Neither party will be treated as having waived any rights by not exercising (or delaying the exercise of) any rights under this Agreement.
- 11.6 Neither party may assign, novate, otherwise transfer in whole or in part its rights or obligations under this Agreement without obtaining the other party's prior written consent, except that Vanguard may freely assign its rights and / or obligations to its affiliates.
- 11.7 If a party is prevented, hindered or delayed in or from performing any of its obligations under this agreement by a Force Majeure Event ("**Affected Party**"), the Affected Party shall not be in breach of this Agreement or otherwise liable for any such failure or delay in the performance of such obligations (and the time for performance of such obligations shall be extended accordingly); provided that the Affected Party shall:
- as soon as reasonably practical notify the other party in writing; and
 - take all reasonable steps to mitigate the effect of the Force Majeure Event.
- If either party is affected by a Force Majeure Event for a period longer than thirty (30) days, it may terminate this Agreement with immediate effect by providing the other party with notice in writing.
12. This Agreement does not create any agency, partnership or joint venture between the parties. This Agreement does not confer any benefits on any third party unless it expressly states that it does.
13. This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall constitute an original of this Agreement, but all the counterparts shall together constitute the same Agreement. No counterpart shall be effective until each party has executed at least one counterpart.
- 14. GOVERNING LAW AND JURISDICTION**
- 14.1 This Agreement and any non-contractual obligations arising out of or in connection with it or its subject matter shall be governed by and construed in accordance with English laws.
- 14.2 The parties irrevocably agree that the courts of England shall have exclusive jurisdiction to settle any dispute or claim that arises out of or in connection with this Agreement or its subject matter.