# GENERAL TERMS AND CONDITIONS UNDER THE CONTRACT BETWEEN TFD AND THE CUSTOMER

#### 1. INTERPRETATION

1.1 Definitions. In these Conditions, the following definitions apply:

<u>Conditions</u>: the terms and conditions set out in this document as amended from time to time in accordance with clause 12.13.

<u>Consumables</u>: any consumables and any ancillary services set out in the Order. <u>Contract</u>: the contract between TFD and the Customer for the sale and purchase of the Products in accordance with these Conditions.

<u>Customer</u>: the company or other entity who purchases the Products from TFD.

Force Majeure Event: has the meaning given in clause 11. Instrument: any instrument provided by TFD whether by sale, lease or rental.

<u>Order</u>: the Customer's order for the Products, as set out in the Customer's purchase order form or in the Customer's written acceptance of TFD's quotation as the case may be.

Product: Instruments and Consumables.

<u>Shelf-life of Consumables</u>: the duration of the life of the Consumables as specified on the Consumable label or the product documentation or package inserts.

<u>Specification</u>: any specification for the Products further to TFD's catalogue that is agreed in writing by the Customer and TFD.

<u>TFD</u>: Thermo Fisher Diagnostics, Sociedade Unipessoal Lda, Lagoas Park, Edificio 11, Piso 0, Lisoa, 2740 270 Port Salvo, Portugal.

2. BASIS OF CONTRACT

2.1 These Conditions apply to any contract entered into by TFD and its Customers for sale/purchase of Products, placement of Instruments and provision of any ancillary services. These Conditions apply to the exclusion of any other terms that the Customer seeks to impose or incorporate, or which are implied by trade, custom, practice or course of dealing, except if expressly agreed to in writing by TFD.

2.2 The Order constitutes an offer by the Customer to purchase Products in accordance with these Conditions. The Customer is responsible for ensuring that the terms of the Order and any applicable Specification are complete and accurate.

2.3 TFD does not have any obligation to accept any Order. The Order shall only be deemed to be accepted when TFD issues a written acceptance of the Order or when TFD carries out the Order delivering Products partially or wholly to the carrier, at which point the Contract shall come into existence. No Order which has been accepted by TFD may be amended or cancelled by the Customer except with the agreement in writing of TFD. The Customer shall indemnify TFD in full against all loss (including loss of profit), costs (including the cost of all labour and materials used), damages, charges and expenses incurred by TFD as a result of such amendment or cancellation.

2.4 TFD shall have a lead-time as set out in the written acceptance of the Order, as applicable, or a quotation for the Products to be supplied to the Customer. If any minimum purchase is set out in the quotation for the Products given by TFD, this minimum purchase amount must be reflected in the Order submitted by the Customer.

2.5 The Contract constitutes the entire agreement between the parties. The Customer acknowledges that it has not relied on any statement, promise, representation, assurance or warranty made or given by or on behalf of TFD which is not set out in the Contract.

2.6 Any samples, drawings, descriptive matter, or advertising produced by TFD and any descriptions or illustrations contained in TFD's catalogues or brochures are produced for the sole purpose of giving an approximate idea of the Products described in them. They shall not form part of the Contract or have any contractual force.

2.7 A quotation for the Products given by TFD shall not constitute an offer. Unless otherwise stated in writing, a quotation shall only be valid for a period of 30 days from its date of issue, provided that it has not been withdrawn by TFD. TFD may amend a quotation at any time to take account of any error or omission or any lack of information received from the Customer.

# 3. THE PRODUCTS

3.1 The Products are described in TFD's catalogue as modified by any applicable Specification (which may be set out in TFD's quotation or acceptance of an Order).

3.2 TFD reserves the right, without notice to the Customer, to amend the Specification if required by any applicable statutory or regulatory requirements or to make any changes in the Specification which are required to conform with any applicable safety or other statutory requirements or, where the Products are supplied in accordance with a Specification supplied by TFD, which do not materially affect their quality or performance, even if the Contract has already been concluded.

3.3 Some Consumables may be multi-packed, in which case the Customer must order the Consumables in multiples of the pack sizes, as directed by TFD.

3.4 The Customer shall, at its own expense, obtain any licence or consent of any government or other authority, permit or licence necessary for the acquisition, carriage, storage, use or sale of the Products by the Customer and if necessary shall produce evidence of same to TFD upon demand.

3.5 The Customer acknowledges that some Products may be dangerous if not properly stored or used and the appropriate precautions taken. The Customer accordingly agrees to use all reasonable endeavours to eliminate or reduce any risk to health and/or safety to which the Products may give rise and to adhere to, and comply with, any information provided by TFD in this regard, including information in the product safety data sheet

3.6 In case of Instrument(s) purchased by Customer, upon the expiration of the useful life time of the Instrument, Customer shall (a) provide for the proper storage, recycling or disposal of the Instrument consistent with (i) any written guidelines provided by TFD, and (ii) all applicable laws and regulations, including but not limited to those addressing disposal of medical waste and electronic equipment, and (b) indemnify, defend and hold TFD and its directors, officers, agents and employees harmless from any and all direct or indirect damage, loss, claim, cost, suit or proceeding relating to Customer's failure to comply with the obligations under (a).

# 4. PLACEMENT OF INSTRUMENTS

The terms and conditions set out in this Clause 4 shall apply to any placement of Instruments, whether by lease or rental.

4.1 The lease/rental fee of the Instrument and the delivery and placement charges will be defined in the Order accepted in writing by TFD or in the lease/rental contract, if any.

4.2. Unless otherwise agreed by the Customer and TFD, the lease/rental has duration of one year from the delivery of the Instrument and is automatically renewed year per year if it is not terminated by a party with prior notice of at least 3 months per registered mail with advice of receipt.

4.3 Unless otherwise agreed by the Customer and TFD, delivery of the Instrument shall be made in accordance with the Order and as set out in this Clause 4.2. TFD shall deliver the Instrument to the location set out in the Order (or such other location as the parties may agree). The Instrument will be delivered per the incoterms, and to the location, agreed between the parties.

4.4 If the Instrument is not delivered on the delivery date as agreed between the Parties, Customer's sole and exclusive remedy (and TFD's only obligation) shall be for TFD to repay to Customer the fees, if any, paid in advance by Customer for the lease/rental period. For the avoidance of doubt and to the largest extent admitted by applicable law, TFD shall not be liable to pay damages in respect of such delay and revocation.

4.5 The Customer shall store the Instrument properly and in accordance with TFD's instructions from time to time. Customer agrees to insure the Instrument, at Customer's cost, against loss, damage and theft. Customer shall notify TFD of any loss or damage to the Instrument without undue delay. The Customer assigns all claims against the insurance company arising out of the insurance contract to TFD in advance. TFD accepts said assignment.

4.6 During the lease/rental period set out in the Order, Customer is granted a limited, personal right to use the Instrument. The Instrument may be used by Customer and its employees only, and the Customer may not assign, sub-lease, sub-let or otherwise transfer the right to use the Instrument

4.7 Customer agrees that (i) the title to and ownership of the Instruments remains with TFD, (ii) the Instrument may not be removed from the site specified in the Order.

4.8 Customer shall mark the Instrument and at all times keep it marked in a way that clearly indicates to a third party that the Instrument is the property of TFD. The inventory list of Customer shall reflect TFD's ownership to the Instrument. Customer may not remove or alter any marks and/or labels applied by TFD on the Instrument.

4.9 Unless otherwise agreed between the Customer and TFD, TFD extends, to the largest extent admitted by applicable law, no representations or warranties of any kind, express or implied, with respect to the Instrument. TFD, however, will endeavour, at TFD's option, to see to it that the Instrument shall materially conform to its technical specifications during the term of the lease/rental. In the event that despite TFD's endeavours, the Instrument will not materially conform to its technical specification, Customer's sole and exclusive remedy (and TFD's only obligation) shall be to return the Instrument, at Customer's cost and risk, and to receive a refund of any fees paid in advance for the remainder of the lease/rental period. For the avoidance of doubt and to the largest extent permitted by applicable law, TFD shall not be liable to pay damages in respect of such return.

4.10 Customer, at its own cost, shall properly maintain and keep the Instrument in good order and promptly, and no later than 30 days, return it, at Customer's cost and risk, to TFD on the expiration of the lease/rental period set out in the Order in the same conditions in which it was delivered except for the normal wear.

4.11. Should the Customer fail to meet the minimum purchase quantity, as applicable, or delay in the payment of the Products, TFD shall be entitled to terminate immediately the contract of lease/rental, without prejudice of any other right.

# 5. DELIVERY OF PRODUCTS

5.1 If, and to the extent it is relevant and can be reasonably required,

#### TFD shall ensure that:

(a) each delivery of the Products is accompanied by a delivery note which shows all relevant Customer and TFD reference numbers, the type and quantity of the Products, lot number, expiry date and, if the full Order is not being delivered, the outstanding balance of Products remaining to be delivered; and

(b) if TFD requires the Customer to return any packaging materials to TFD, that fact is clearly stated on the delivery note. The Customer shall make any such packaging materials available for collection at such times as TFD shall reasonably request. Returns of packaging materials shall be at TFD's expense.

5.2 Unless otherwise agreed by the Customer and TFD, the Products will be delivered to the destination specified by the Customer (Delivery Location) FCA (Incoterms 2010) TFD's premises, at any time after the date agreed between the Customer and TFD or the date when TFD notifies the Customer that the Products are ready. TFD reserves the right to stop delivery of Products in transit and to withhold shipments in whole or in part if the Customer fails to make any payment to TFD when due or otherwise fails to perform its obligations hereunder.

5.3 Delivery of the Products shall be completed on the completion of loading of the Products to the carrier.

5.4 Any dates quoted for delivery are approximate only, and the time of delivery is not of the essence. TFD shall not be liable for any delay in delivery of the Products that is caused by a Force Majeure Event or the Customer's failure to provide TFD with adequate delivery instructions or any other instructions that are relevant to the supply of the Products.

5.5 If TFD fails to deliver the Products, its liability shall be limited to the costs and expenses incurred by the Customer in obtaining replacement products of similar description and quality in the cheapest market available, less the price of the Products. TFD shall have no liability for any failure to deliver the Products to the extent that such failure is caused by a Force Majeure Event or the Customer's failure to provide TFD with adequate delivery instructions or any other instructions that are relevant to the supply of the Products.

5.6 TFD may deliver the Products by instalments, which shall be invoiced and paid for separately. Each instalment shall constitute a separate Contract. Any delay in delivery or defect in an instalment shall not entitle the Customer to cancel any other instalment.

5.7.a For Orders with an order value below 100 Euros, TFD reserves the right to charge a handling fee of 15 Euros.

6. WARRANTIES

A) Warranty for the Consumables

6.1 TFD warrants that, for the Shelf-life of Consumables or if the Shelf-life cannot be assessed, for a period of ninety (90) days from the date of delivery, the Consumables shall:

(a) conform in all material respects with the Specification;

(b) be free from material defects in material and workmanship,

in both cases subject to normal, proper and intended usage by properly trained personnel.

6.2 The Customer has the duty to inspect the Consumables at delivery and declare on the transport document any visible fault and damage to the Consumables and or packaging and any further occurrence that may have damaged the Consumables or their conformity to the Specification. Failure to comply with the above declaration duty will cause forfeiture of the warranty for any non-declared fault.

6.3. Subject to clause 6.2. and 6.4, the warranty under clause 6.1. will perform if:

(a) the Customer gives notice in writing to TFD within 2 working days from the reception of the Consumables. As to any deviation from the technical specification that couldn't reasonably be identified during inspection at delivery or any hidden defect shall be promptly reported in writing to TFD upon appearance.;

(b) TFD is given a reasonable opportunity of examining such Consumables; and

(c) the Customer (if asked to do so by TFD) returns such Consumables to TFD's place of business.

In performance of the warranty, TFD shall, at its sole option replace the defective Consumables, or refund the price of the defective Consumables in full.

6.4 TFD shall not be liable for the warranty set out in clause 6.1 in any of the following events:

(a) the Customer makes any further use of such Consumables after giving notice in accordance with clause 6.3;

(b) the defect arises because the Customer failed to follow TFD's instructions as to the storage, commissioning, installation, use and maintenance of the Consumables or (if there are none) good trade practice regarding the same;

(c) the defect arises as a result of TFD following any drawing, design or Specification supplied by the Customer;

(d) the Customer alters or repairs such Consumables without the written consent of TFD;  $% \left( {{{\rm{TFD}}} \right)_{\rm{TFD}}} \right)$ 

(e) the defect arises as a result of fair wear and tear, wilful damage, negligence, or abnormal storage or working conditions; or

(f) the Consumables differ from the Specification as a result of changes

made to ensure they comply with applicable statutory or regulatory requirements.

6.5 If TFD determines that Consumables for which the Customer has requested warranty services are not covered by the warranty hereunder, the Customer shall pay or reimburse TFD for all costs of investigating and responding to such request at TFD's including the costs for labor, materials and further expenses implied by the investigation on the request. Such costs will be paid by the Customer also if TFD provides repair or maintenance services or replacement parts that are not covered by the warranty provided in clause 6.1.

6.6 Except for intended use explicitly stated on Consumables label, TFD does not warrant that the Consumables are fit for any particular purpose or intended use by the Customer and it is for the Customer to satisfy itself that the Consumables are so fit.

6.7 Except as provided in this clause 6, TFD shall have no liability to the Customer in respect of the Consumables failure to comply with the warranty set out in clause 6.1.

6.8 These Conditions shall apply to any repaired or replacement Consumables supplied by TFD.

6.9 Notwithstanding the foregoing, Consumables supplied by TFD that are obtained by TFD from an original manufacturer or third party supplier are not warranted by TFD, but TFD agrees to assign to Customer any warranty rights in such Consumables that TFD may have from the original manufacturer or third party supplier, to the extent such assignment is allowed by such original manufacturer or third party supplier.

B) Warranty for the Instruments

6.10 TFD warrants that the Instrument will operate or perform substantially in conformance with TFD's published specifications during a period of twelve (12) months from the date of delivery, provided that the warranty does not extend to defects in the Instrument which are caused by (i) the failure to observe TFD's installation and operating instruction, system requirements and recommendations for the use or maintenance of the Instrument, or (ii) the use of the Instrument with any reagents or other hardware or software products not furnished or recommended by TFD. The foregoing warranty shall not apply to (a) normal wear and tear, (b) consumable parts, and (c) minor or trivial deviations which in all material respects do not prevent the Instrument from being used in accordance with the technical specifications.

6.11. Any deviation from the technical specifications shall be promptly reported in writing to TFD upon appearance. Unless so reported, the above warranty shall be void.

6.12. In the event of breach of the above warranty, TFD is entitled and obligated, at the sole option of TFD, to repair or replace the Instrument. TFD shall be entitled to at least three (3) attempts to rectify the deviation. If TFD elects to repair defective Instruments, TFD may, in its sole discretion, provide a replacement loaner instrument to Customer as necessary for use while the instruments are being repaired.

6.13 If TFD is unable to repair or replace as set out in Clause 6.12 within a period of time which is reasonable taking all the circumstances into account, Customer may revoke the purchase of the Instrument (and of the Consumables and services ordered and intended for such Instrument) and TFD shall then repay to Customer the purchase price paid by Customer in respect of such Instrument, less an amount reasonably reflecting Customer's use and depreciation of the Instrument. For the avoidance of doubt, TFD shall not be liable to pay damages in respect of such termination except for fraud or gross negligence.

6,14. The obligation created by the warranty statement in clause 6.10 to repair or replace a defective Instrument shall be the sole remedy of Customer in the event of a defective Instrument. Except as expressly provided in Clauses 6.10 to 6.14 and in case of fraud and gross negligence, TFD disclaims all other warranties, whether express, implied, oral or written, with respect to the Instruments, including without limitation all implied warranties of merchantability or fitness for any particular purpose. TFD does not warrant that the Instruments will accomplish any particular result.

#### 7. <u>TITLE TO AND RISK OF LOSS OF THE PRODUCTS</u>

7.1 Subject to Instruments being places as set out in Clause 4 above and subject to TFD's right to stop delivery of Products in transit according to clause 5.2., title to and risk of loss of the Products will pass to the Customer upon loading of the Products to the carrier.

7.2. If the shipping is delayed on the Customer's request, the risk of the Products will pass to the Customer from the day in which the Products were ready for shipping. Unless subject to warranty liability under section 6 above, if the Customer sends back for any reason the supplied Products to TFD, all costs and risk of said shipping including risks for breakages, transport, theft, fire and robbery, will be borne by the Customer.

7.3 If the Customer fails to pay for the Products within the time limit set out in clause 8.6 below, TFD may at any time require the Customer to, at Customer's cost, deliver up all Products in its possession which have not been used, or irrevocably incorporated into another product.

8. PRICE AND PAYMENT

8.1 Unless agreed otherwise between the parties, the price of the

Products shall be the price set out in the TFD quotation, or, if no price is quoted, the price set out in TFD's published price list in force as at the date of delivery.

8.2 If the duration of the Contract exceeds one year, TFD may increase the prices for the Products no more than once in any calendar year, usually on the first day of January, by giving notice to the Customer at least 30 days prior to the effective date of such change. Notwithstanding the foregoing, TFD may, by giving notice to the Customer at any time before delivery, increase the price of the Products to reflect any increase in the cost of the Products that is due to:

(a) any factor beyond TFD's control (including but not limited to foreign exchange fluctuations, increases in taxes and duties, and increases in labour, materials and other manufacturing costs);

(b) any request by the Customer accepted by TFD to change the delivery date(s), quantities or types of Products ordered, or the Specification; or

(c) any delay caused by any instructions of the Customer or failure of the Customer to give TFD adequate or accurate information or instructions.

8.3 Unless otherwise agreed between the parties, the price of the Products is exclusive of amounts in respect of value added tax (VAT) at the rate applicable by law from time to time, customs and excise duties and all other surcharges, taxes and duties imposed (directly or indirectly) with respect to the sale, delivery and use of the Products, all of which must be paid by the Customer in addition to the price of the Products.

8.4 Subject to any applicable mandatory law, TFD may invoice the Customer for the Products on or at any time after loading of the Products to the carrier (or when the Products shall be deemed to be delivered in accordance with Clause 5.6 above).

8.5 Unless otherwise agreed between the Parties, the Customer shall pay the invoice in full and in cleared funds within 30 days of the date of the invoice. Payment shall be made to the bank account nominated in writing by TFD. Time of payment is of the essence.

8.6 If the Customer fails to make any payment due to TFD under the Contract by the due date for payment, without prejudice of any further right of TFD, then the Customer shall pay interest on the overdue amount according to applicable law. In addition, TFD shall have the right to stop delivery of Products in transit and to withhold shipments in whole or in part as set out in Clause 5.2 above for all and any contract between the Customer and TFD.

8.7 The Customer shall pay all amounts due under the Contract in full without any set-off, counterclaim, deduction or withholding (except for any deduction or withholding required by law). TFD may at any time, without limiting any other rights or remedies it may have, set off any amount owing to it by the Customer against any amount payable by TFD to the Customer.

#### 9. TERMINATION AND SUSPENSION

9.1 TFD can terminate the Contract with immediate effect and without obligation to observe any term, by registered mail with advice of receipt, if even only one of the following conditions occurs:

(a) non-payment, partial payment or late payment of any and all sums due to TFD by Customer related to contractual obligations of the Customer toward TFD.

(b) Customer's non-compliance with even only one of the obligations contained in Clauses 3.4, 3.5, 4.5., 4.6, 4.7, 4.8, 4.10, 4.11, 4.12, 4.13, 12.1, 12.2., 12.3, 12.4, 12.5, 12.6 b), 12.10, 12.11 and 13.

(c) the Customer becomes insolvent or bankrupt or subject to insolvency proceeding, has a Court-appointed administrator, receiver or manager appointed, or even only if a petition is filed or a proceeding started to these purposes.

(d) the Customer commences negotiations with all or any class of its creditors with a view to rescheduling any of its debts, or makes a proposal for or enters into any compromise or arrangement with its creditors;

(e) the Customer enters into winding up, or a petition is filed, a notice is given, a resolution is passed, or an order is made, for or in connection with the winding up of the Customer;

(f) a creditor or holder of guarantees of the Customer submits to enforcement or seizure the whole or any part of the Customer's assets or any petition is filed or any proceeding started to obtain such measures;

(g) any event occurs, or proceeding is taken, with respect to the Customer in any jurisdiction to which it is subject that has an effect equivalent or similar to any of the events above mentioned in clause 9.1(a) to clause 9.1(f) (inclusive);

(h) the Customer suspends, threatens to suspend, ceases or threatens to cease to carry on all or a substantial part of its business; and

(i) the Customer's financial position deteriorates to such an extent that the Customer's capability to adequately fulfil its obligations under the Contract has been placed in jeopardy.

(i) for any change in the ownership of the Customer.

9.2. The termination of the Contract pursuant to clause 9.1. above will imply the automatic simultaneous termination of any and all contracts existing between TFD and the Customer. The termination for reason or cause of the Customer of any contract will likewise cause the automatic simultaneous termination of the Contract and any and all contracts existing between TFD and the

Customer.. TFD will be entitled to avoid the termination of specific contracts by exempting them in the written notice of termination to the Customer.

9.3 Without limiting its other rights or remedies, TFD may suspend provision of the Products under the Contract or any other contract between TFD and the Customer, if the Customer is in default of any of its obligations.

9.4 On termination of the Contract for any reason the Customer shall immediately pay to TFD all of TFD's outstanding unpaid invoices and interest.

9.5 Clauses which expressly or by implication survive termination of the Contract shall continue in full force and effect.

10. LIMITATION OF LIABILITY AND INDEMNITY

10.1 Nothing in these Conditions shall limit or exclude TFD's liability

(a) death or personal injury caused by its negligence, or the negligence of its employees, agents or subcontractors (as applicable);

(b) fraud or gross negligence;

for:

(c) any matter in respect of which it would be unlawful for TFD to exclude or restrict liability.

10.2 Subject to clause 10.1:

(a) TFD shall under no circumstances whatsoever be liable to the Customer, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, for any loss of profit, loss of goodwill or any indirect or consequential loss arising under or in connection with the Contract; and

(b) TFD's total liability to the Customer in respect of all other losses arising under or in connection with the Contract, whether in contract, tort (including negligence), breach of statutory duty, or otherwise, shall in no circumstances exceed the lesser of (A) the total purchase price theretofore paid by Customer to TFD with respect to the Products giving rise to such liability, or (B) one million (1,000,000) Euro.

10.3 TFD agrees to indemnify, defend and save Customer, its officer, directors, and employees from and against any and all damages, liabilities, actions, causes of action, claims, demands, losses, costs and expenses ("Indemnified Items") for (i) injury to or death of persons or damage to property to the extent caused by the negligence or wilful misconduct of TFD, its employees, agents or representatives or contractors in connection with the performance of services at Customer's premises under this Contract and (ii) claims that the Products infringe any valid third party intellectual property; provided, however, TFD shall have no liability under this clause to the extent any such Indemnified Items are caused by either (i) the negligence or wilful misconduct of Customer, its employees, agents or representatives or contractors, (ii) by any third party, (iii) use of Products in combination with equipment or software not supplied by TFD where the Products would not themselves be infringing, (iv) compliance with Customer's designs, specifications or instructions, (v) use of the Products in an application or environment for which it was not designed or (vi) modifications of the Products by anyone other than TFD without TFD's prior written approval. Customer shall provide TFD prompt written notice of any third party claim covered by TFD's indemnification obligations hereunder. TFD shall have the right to assume exclusive control of the defence of such claim or, at the option of the TFD, to settle the same. Customer agrees to cooperate reasonably with TFD in connection with the performance by TFD of its obligations in this Clause.

10.4 Notwithstanding the above, TFD's infringement related indemnification obligations shall be extinguished and relieved if TFD, at its discretion and at its own expense (a) procures for Customer the right, at no additional expense to Customer, to continue using the Products; (b) replaces or modifies the Products so that they become non-infringing, provided the modification or replacement does not adversely affect the Specification of the Products; or (c) in the event (a) and (b) are not practical, refund to Customer the amortised amounts paid by Customer with respect thereto, based on a five (5) year amortisation schedule. The foregoing indemnification provision states TFD's entire liability to Customer for the claims described herein.

10.5 Customer shall indemnify, defend with competent and experienced counsel and hold harmless TFD, its parent, subsidiaries, affiliates and divisions, and their respective officers, directors, shareholders and employees, from and against any and all damages, liabilities, actions, causes of action, suits, claims, demands, losses, costs and expenses to the extent arising from or in connection with (i) the negligence or wilful misconduct of Customer, its agents, employees, representatives or contractors; (ii) use of the Products in combination with equipment or software not supplied by TFD where the Products themselves would not be infringing; (iii) TFD's compliance with designs, specifications or instructions supplied to TFD by Customer; (iv) use of the Products in an application or environment for which they were not designed; or (v) modifications of the Products by anyone other than TFD without TFD's prior written approval.

# 11. FORCE MAJEURE

Neither party shall be liable for any failure or delay in performing its obligations under the Contract to the extent that such failure or delay is caused by a Force Majeure Event. A Force Majeure Event means any event beyond a party's reasonable control, which by its nature could not have been foreseen, or, if it could have been foreseen, was unavoidable, including strikes, lock-outs or other industrial disputes (whether involving its own workforce or a third party's), failure of energy sources or transport network, acts of God, war, terrorism, riot, civil commotion, interference by civil or military authorities, national or international calamity, armed conflict, malicious damage, breakdown of plant or machinery, nuclear, chemical or biological contamination, sonic boom, explosions, collapse of building structures, fires, floods, storms, earthquakes, loss at sea, epidemics or similar events, natural disasters or extreme adverse weather conditions, or default of suppliers or subcontractors.

#### 12. GENERAL

12.1 It is the obligation of the Customer to obtain and maintain, at its own expense, any governmental consents, authorisations, approvals, filings, permits or licenses required for it to export the Products and for each of the Customer and TFD to exercise its rights and to discharge its obligations under the Contract including, without limitation, all consents and filings with any governmental body.

12.2 The Customer acknowledges that the Products and all related technical information, documents and materials may be subject to export controls under the U.S. Export Administration Act of 1969, as amended, and the rules and regulations promulgated from time to time thereunder and under the laws of other countries including, but not limited to, the United Kingdom (collectively, the "Export Act"), restricting exports and re-exports of software media, technical data and direct products of technical data. The Customer (i) shall comply strictly with all legal requirements established under the Export Act, (ii) shall cooperate fully with TFD in any official or unofficial audit or inspection related to the Export Act, and (iii) shall not distribute or supply the Products to any person if there is reason to believe that such person intends to export, re-export or otherwise take such Products to, or use such Products in, any country in violation of the Export Act. Without limitation to the foregoing, the Customer agrees to commit no act that, directly or indirectly, would violate any United States law, regulations, treaty or agreements, to which the United States adheres or complies or those of any other country including all European Union member states, relating to the export or re-export of any Products.

12.3 The Customer agrees not knowingly to export or re-export Products or any part thereof, directly or indirectly, without first obtaining permission to do so from the United States Office of Export Administration and other appropriate governmental (including the Governments of other countries including all European Union member states) agencies, into any of those countries listed from time to time at the time of any shipment of the Products in Title 15 of the code of Federal Regulations of the United States of America (or any successor or additional provision) as "prohibited or restricted" countries or any other country to which such exports of re-exports may be restricted (collectively, the "Prohibited Countries"). The Customer agrees not to distribute any Products or any part thereof to any person if the Customer has reason to believe that such person intends to export, re-export or otherwise take the same to, or to use the same in, any of the Prohibited Countries and the Customer agrees to seek reasonable written assurances in the form of binding covenants from customers as may from time to time be requested by TFD. The Customer agrees to indemnify and to hold TFD harmless from, or in connection with, any violation of the provisions of this clause by the Customer or its customers.

12.4 Training.

(a) If the Customer is a legal entity located outside of France, TFD may, in its sole discretion, provide (1) applicable Products training to the Customer or its employees, or (2) samples of Products to Customer for distribution to patients of the Customer, as applicable. The Customer agrees that any such samples shall be distributed to patients for patient use or, if not so distributed, returned to TFD. The Customer shall not use such samples to provide care to patient and shall not bill patients or third party payers for the provision of such samples.

(b) If the Customer is a legal entity located in France, TFD may, in its sole discretion, provide samples of the Products to the Customer for distribution to patients of the Customer. The Customer agrees that any such samples shall be distributed to patients for patient use or, if not so distributed, returned to TFD. The Customer shall not use such samples to provide care to patient and shall not bill patients or third party payers for the provision of such samples. If training is provided for by TFD as indicated in the Contract / terms and conditions, as the case may be, the cost of this training and all expenses relating thereto are part of the total price agreed upon by TFD and the Customer in the Contract.

12.5 Assignment and other dealings.

(a) TFD may at any time assign, transfer, mortgage, charge, subcontract or deal in any other manner with all or any of its rights or obligations under the Contract. The Customer hereby agrees to do all such things and sign such documents as may be necessary for TFD to exercise its rights under this provision.

(b) The Customer may not assign, transfer, mortgage, charge, subcontract, declare a trust over or deal in any other manner with any or all of its rights or obligations under the Contract without the prior written consent of TFD. Any attempt to do this without the consent of TFD will be null and void.

12.6 Notices. Any notice or communication required or permitted hereunder shall be in writing and shall be sent by electronic certified mail or registered mail with advice of receipt to a party at the address specified in the

Contract or at such other address as either party may from time to time designate to the other by notice given in accordance with the provision of this Clause 12.6. 12.7 Severance.

(a) If any provision or part-provision of the Contract is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable. If such modification is not possible, the relevant provision or part-provision shall be deemed deleted. Any modification to or deletion of a provision or part-provision under this clause shall not affect the validity and enforceability of the rest of the Contract.

(b) If any provision or part-provision of this Contract is invalid, illegal or unenforceable, the parties shall negotiate in good faith to amend such provision so that, as amended, it is legal, valid and enforceable, and, to the greatest extent possible, achieves the intended commercial result of the original provision.

12.8 Waiver. A waiver of any right or remedy under the Contract or law is only effective if given in writing and shall not be deemed a waiver of any subsequent breach or default. No failure or delay by a party to exercise any right or remedy provided under the Contract or by law shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall prevent or restrict the further exercise of that or any other right or remedy.

12.9 Intellectual Property Rights. Nothing in these Conditions and the Contract shall constitute or be construed as a transfer of any intellectual property rights from TFD to Customer. For the purposes of this Clause 12.9, intellectual property rights means patents and innovations, copyright, trademark and trade name rights, know-how and trade secret rights, registered and unregistered designs, databases, mask-work protection rights, and any other intellectual or industrial property rights, and all applications therefor and registrations thereof.

12.10 Software. Any source code or software program incorporated into the Instrument or forming an integral part thereof are the property of TFD and are provided to the Customer by a non-exclusive licence to use such software in the Products (but without any right of reproduction). This licence shall cease when the legal user ceases to have legitimate possession of the hardware supplied, unless the Contract is terminated early pursuant to these Conditions. The licence and software may not be assigned or otherwise transferred by the Customer without the prior written consent of TFD, but may be assigned by way of sub-licence to the Customer's clients who have purchased the Instrument containing the software, on condition that the Customer communicate the name of the sublicensee at the time of the assignment of any sub-licence, and that TFD does not prohibit such sub-licensing. The Customer is expressly prohibited from duplicating and from wholly or partly forcing the software's protection system. TFD shall have the right to revoke this licence in the event that the Customer breach any requirement set out herein. TFD does not guarantee that software can be installed on any computer of the Customer and therefore any risk or cost arising from unsuccessful installation on other brands of computer than those specified in the Contract shall be borne by the Customer.

12.11 Medicare / Medicaid. If the Customer is a recipient of Medicare/Medicaid funds, the Customer acknowledges that it has been informed of and agrees to fully and accurately account for, and report, including on its cost report if applicable, the total value of any discount, rebate or other compensation paid hereunder in a way that complies with all applicable federal, state and local laws and regulations which establish 'Safe Harbor' for discounts. The Customer shall make written request to TFD in the event that the Customer requires additional information from TFD in order to meet its reporting requirements. The Customer acknowledges that agreement to such reporting requirement was a condition precedent to TFD's agreement to provide the Products and that TFD would not have entered into this Contract had the Customer not agreed to comply with such obligations.

12.12 Variation. Except as set out in these Conditions, no variation of the Contract, including the introduction of any additional terms and conditions, shall be effective unless it is in writing and signed by TFD.

# 13. <u>COOPERATION WITH NONCONFORMING</u> <u>PRODUCT/FIELD SAFETY CORRECTIVE ACTION</u>

13.1 Complaint. Customer shall report malfunctioning and/or mislabeled products to TFD without undue delay and provide relevant information.

13.2 Adverse Experience. Customer shall report to TFD any events that has or might have contributed to death, serious injury or indirect harm attributed to a Product or if Product may have been a factor in death, serious injury or indirect harm, including events occurring as a result of failure; malfunction; improper or inadequate design; manufacture; labeling or user error. The Customer shall without undue delay report such critical complaints to TFD by telephone or in writing (by facsimile). Reports to TFD shall contain (i) the patient's or other person's details; (ii) a description of the adverse experience; (iii) product name; (iv) article number and (v) any additional relevant information.

13.3 <u>Field actions</u>. In the event that any Product defect or regulatory or governmental directive requires a Product's recall, destruction, withholding

from the market, or in other Product market withdrawal the Customer shall assist and take appropriate actions according to field corrective actions including recalls, market withdrawals and field safety corrective action received from TFD.

14. <u>GOVERNING LAW AND JURISDICTION</u>14.1 Governing law. The Contract, and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims), shall be governed by, and construed in accordance with the laws of Portugal. The application to the Contract of the UN Convention on Contracts for the International Sale of Goods is hereby expressly excluded.

14.2 Jurisdiction. Each party irrevocably agrees that the courts of Lisbon shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with this Contract or its subject matter or formation (including noncontractual disputes or claims).