



Feidhmeannacht na Seirbhíse Sláinte  
Health Service Executive

And

[THE SUPPLIER]

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**DEED**  
in respect of the Loan of Medical Devices and supply of Consignment Stock to  
*[Name of Relevant Hospital]*

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## BETWEEN

1. **HEALTH SERVICE EXECUTIVE**, statutory body, having its principal headquarters at Oak House, Lime Tree Avenue, Millennium Park, Naas, Co. Kildare, or any successor body, (the “**Executive**”);

## AND

2. **[NAME OF SUPPLIER]**, having company registration number [ ] and having its registered office at *[address]*, (the “**Supplier**”).

## BACKGROUND

- (A) The Supplier is the owner of Medical Devices (defined below) and wishes to make the Medical Devices available to the Executive and the Relevant Hospital free of charge by way of loan and wishes to supply the Consignment Stock to the Executive and the Relevant Hospital for purchase by the Executive.
- (B) Now therefore the Executive and the Supplier enter into this Deed for the provision of the Medical Devices and Consignment Stock to the Executive on the terms and conditions specified below and in relation to the relevant Hospital, as hereinafter defined.

In consideration of the Supplier paying €1 to the Executive (the receipt and sufficiency of which is hereby acknowledged), **THE PARTIES AGREE** as follows:

### 1. Definitions and Interpretation

- 1.1 Save where the context otherwise requires, the following words and expressions shall have the following meanings:

“**Business Day**” means a day (other than a Saturday or a Sunday) on which banks are open for business in Ireland;

“**Consignment Stock**” means products (including but not limited to implants, screws, rods, plates, etc) supplied and owned by the Supplier for the purpose of clinical or surgical use whether or not such use occurs in conjunction with Medical Devices;

“**Crucial Performance Failure**” has the meaning given in Clause 8 (*Liquidated Damages*);

“**DPA**” has the meaning given in Clause 14 (*Data Protection*);

“**Duration of the Deed**” means a period commencing on the execution of this Deed and continuing until it is terminated in accordance with Clause 17 (*Termination*);

“**Electrical Medical Devices**” means all Medical Devices which relies for its functioning on a source of electrical energy;

“**Expiration Date**” means the length of time that the Medical Devices and/ or the Consignment Stock can be safely used before considered to have expired or no longer fit and/ or suitable for use or consumption;

“**Internal Controls**” means the relevant department within the Relevant Hospital with responsibility for recording and monitoring the location of Medical Devices

within the Relevant Hospital and the receipt and/ or transfer of the Medical Devices to or from suppliers;

“**Legal and Regulatory Requirements**” means the requirements of:

- (a) any governing law, rule or statutory regulation applicable in Ireland;
- (b) any court with the relevant jurisdiction and any local, national or supranational agency, inspectorate, minister, ministry, official or public or statutory person of the government or of the European Union with which the Supplier is required to comply;
- (c) any guidance, policy, directions, codes of conduct or codes of professional practice of the Irish Medicines Board or of any third party or body with which the Supplier or the Executive is required to comply; and
- (d) any guidance, policy, directions, codes of conduct or codes of professional practice of the Executive which are known by, or have been made known to, the Supplier prior to the execution of this Deed and, following such date at any time during the term of this Deed;

“**Medical Device**” means any instrument, apparatus, appliance, software, material or other article, supplied and owned by the Supplier pursuant to this Deed, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- (a) diagnosis, prevention, monitoring, treatment or alleviation of disease,
- (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- (c) investigation, replacement or modification of the anatomy or of a physiological process,
- (d) control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (as such definition may be amended, restated or modified from time to time for the purposes of Council Directive 93/42/EEC concerning medical devices (as amended and implemented in Ireland, where appropriate)) and for the avoidance of doubt shall include any such device supplied and owned by the Supplier for the purposes of demonstration, trial or evaluation;

“**Pre-contractual Statement**” has the meaning given in Clause 18.7(a) (*Entire Agreement*);

“**Relevant Hospital**” means [*details of hospital to be entered*];

“**RIMD**” means a re-useable invasive medical device;

“**Supplier Personnel**” means all officers, employees, volunteers, agents and contractors employed, engaged, supplied or utilised by the Supplier or by any subcontractor or agent of the Supplier for any purpose whatsoever;

“**System of Oversight**” has the meaning given in Clause 2.6;

“**Working Hours**” means 9.00a.m. to 5.00p.m.;

1.2 In this Deed:

- (a) references to Clauses, paragraphs and Schedules are to Clauses, paragraphs and Schedules to this Deed;
- (b) references to a “company” shall be construed so as to include any company, corporation or other body corporate, wherever and however incorporated or established;
- (c) references to a “person” shall be construed so as to include any individual, firm, company, government, state or agency of a state, local authority or government body or any joint venture, association or partnership (whether or not having separate legal personality);
- (d) a reference to any statute or statutory provision shall be construed as a reference to the same as it may have been, or may from time to time be, amended, modified or re-enacted;
- (e) any reference to a “day” or a “Business Day” shall mean a period of twenty-four (24) hours running from midnight to midnight except in Clause 18.2 (*Notices*) where it means a weekday (excluding a Saturday, Sunday or any public or bank holiday);
- (f) references to times are to times in Ireland;
- (g) references to a “month” shall mean a calendar month;
- (h) a reference to any other document referred to in this Deed is a reference to that other document as amended, varied, novated or supplemented at any time;
- (i) references to written notification or to any other form of communication between the parties shall include all forms of electronic communication as defined under the Electronic Commerce Act, 2000, provided always that communication by electronic mail or other electronic methods of writing shall not be effective under this Deed in respect of any notices issued pursuant to this Deed including those issued under Clause 16 (Dispute Resolution) and/ or 17 (Termination);
- (j) any phrase introduced by the terms “including”, “include”, “in particular” or other similar expression shall be construed as illustrative and shall not limit the sense or meaning of the words preceding those terms;
- (k) references to the singular include the plural and vice versa; and
- (l) references to the masculine include the feminine and vice versa

1.3 All headings and titles are inserted for convenience only. They are to be ignored in the interpretation of this Deed.

## 2. General Principles

- 2.1 The Supplier shall supply to, and make the Medical Devices available at, the Relevant Hospital by way of loan free of charge for such period(s) as the Medical Devices are required by the Executive and the Executive shall be entitled to use the Medical Devices as it requires whether at the Relevant Hospital or otherwise.
- 2.2 The Supplier shall ensure that a minimum level of Medical Devices is available for use by the Relevant Hospital at all times. The minimum level of Medical Devices shall be notified by the Relevant Hospital<sup>1</sup> to the Supplier from time to time.
- 2.3 The Supplier shall supply such quantities of the Consignment Stock to the Relevant Hospital as the Relevant Hospital may request from time to time and the Supplier shall maintain supplies of the Consignment Stock at the levels notified by the Relevant Hospital to the Supplier from time to time. Time of delivery of the Medical Devices shall be of the essence of this Deed
- 2.4 The Executive shall be entitled to use and/ or consume the Medical Devices and/ or the Consignment Stock as it requires whether at the Relevant Hospital or otherwise.
- 2.5 In supplying the Medical Devices and/ or the Consignment Stock the Supplier shall comply with:
- (a) all applicable laws and regulations (including, without limitation, Council Directive 93/42/EEC in respect of medical devices (as amended and implemented in Ireland, where appropriate), Council Directive 90/385/EEC in respect of active implantable medical devices (as amended and implemented in Ireland, where appropriate), the Safety, Health and Welfare at Work Act 2005 (as amended and including any regulations made pursuant thereto);
  - (b) the procedures, standards and requirements of any relevant governmental bodies (including but not limited to those of the Irish Medicines Board);
  - (c) the Irish Medicines Board Safety Notice 2010(09) on the Effective Traceability of Medical Devices;
  - (d) the HSE's National Financial Guidelines and the HSE's procurement policies (as the same may be updated, modified or replaced from time to time) (the provisions of which are hereby incorporated by reference); and
  - (e) any statutory safety requirements in force for the time being and any safety or security requirements of the Executive and/ or the Relevant Hospital notified to the Supplier from time to time;
- and the Supplier shall procure that the above requirements are complied with in all respects by all the Supplier's Personnel.
- 2.6 The Supplier shall establish and maintain proper procedures and processes to maintain a complete, accurate and comprehensive system of oversight of the Medical Devices and the Consignment Stock (the "**System of Oversight**"), whereby the Supplier shall ensure that all Medical Devices and/ or the Consignment Stock which

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<sup>1</sup> Note to HSE: Each hospital's local policy in respect of loan sets, consignment stock and medical devices can specify the relevant HSE person who will be responsible for notifying the supplier e.g. a CNMII or DEPUTY CNMII

has been supplied to the Executive at a Relevant Hospital is within the relevant Expiration Date, in good and proper condition and fit for use.

- 2.7 Prior to implementing a System of Oversight, the Supplier shall consult with the Executive and/ or the Relevant Hospital to discuss *inter alia* access arrangements, frequency of rotation, arrangements for repair and replacement, arrangements for the inspection and functionality of the Medical Devices and/ or the Consignment Stock and such other matters as the Executive may require from time to time.
- 2.8 The Executive or the Relevant Hospital shall notify the Supplier promptly of any damage to the Medical Devices and/ or the Consignment Stock, and/ or any fault or safety issue relating to the Medical Devices and/ or the Consignment Stock which comes to its attention and will use its reasonable endeavours to ensure that none of the Executive's employees use the Medical Devices and/ or the Consignment Stock unless it has been replaced or repaired by, or on behalf of, the Supplier.
- 2.9 The Executive agrees that it shall instruct its employees not to (and not to attempt to) modify, repair or otherwise interfere with the Medical Devices and/ or the Consignment Stock without the prior written consent of the Supplier.
- 2.10 The Supplier agrees that the terms of this Deed shall apply to all supplies of Medical Devices and/ or the Consignment Stock made by the Supplier to the Executive and/ or the Relevant Hospital. The Supplier agrees that it will not in its dealings with the Executive and/ or the Relevant Hospital seek to impose or rely on any other contractual terms which in any way vary or contradict the terms of this Deed.
- 2.11 Nothing in this Deed shall operate so as to prevent the Executive and/ or the Relevant Hospital (without prejudice to its liability under this Deed) to carry out any additional testing and/ or safety procedures in respect of any Electrical Medical Devices in the Relevant Hospital prior to any such equipment being accepted and/ or utilised by the Executive and/ or the Relevant Hospital.
- 2.12 The Supplier shall, at its own cost, inspect and carry out a complete service of all Medical Devices and/ or the Consignment Stock supplied pursuant to this Deed not less than once a year, or more frequently, if so recommended by the manufacturer of the Medical Devices and/ or the Consignment Stock.
- 2.13 Neither the Executive nor the Relevant Hospital shall be liable for any charge for maintenance, repair, consumable materials or accessories required for the operation of, the Medical Devices and/ or the Consignment Stock while any Medical Devices and/ or Consignment Stock is supplied to the Executive and/ or the Relevant Hospital, or for any carriage or installation charges except as provided in this Deed.

### **3. Supply of, and Payment for, the Consignment Stock**

- 3.1 The Executive and/ or the Relevant Hospital shall monitor the usage levels of Consignment Stock on a daily and/ or weekly basis (at the option of the Relevant Hospital) and when the Relevant Hospital requires a delivery of Consignment Stock to be made, the Executive and/ or Relevant Hospital shall give written notification of the Consignment Stock required by it and the date, time and place of delivery at the Relevant Hospital and the Supplier shall, subject to Clause 3.2, deliver the Consignment Stock requested during Working Hours no later than the next Business Day following the date of the notification.
- 3.2 If the Executive and/ or Relevant Hospital specify in any notification in respect of the Consignment Stock, that the Consignment Stock is required urgently and in advance

of a specified time, the Supplier shall deliver the Consignment Stock at, or prior to, the time so specified, bearing in mind that medical emergencies may arise at any time of the day or night.

- 3.3 Time of delivery of the Consignment Stock shall be of the essence of this Deed.
- 3.4 The Supplier shall issue an invoice to the Executive in respect of the Consignment Stock consumed within, at the option of the Supplier, either 5 Business Days or by the end of the month. The Executive shall pay any invoice raised by the Supplier within 30 days of receipt (unless a dispute arises in respect of the invoice).
- 3.5 Both the Relevant Hospital and the Supplier shall carry out joint stock-takes of the Consignment Stock on a regular basis, following which both parties will mutually agree the amounts of Consignment Stock supplied under this Deed and held by the Relevant Hospital and shall agree whether the Executive is to be credited or invoiced for any discrepancies arising in either party's records and the amount to be credited or invoiced.

#### **4. Supply of Medical Devices and Consignment Stock**

- 4.1 All Medical Devices and Consignment Stock supplied by the Supplier pursuant to this Deed shall:
  - (a) be intact;
  - (b) be sterile (where relevant);
  - (c) within the Expiration Date (where relevant);
  - (d) have details of the manufacturer contact details attached thereto;
  - (e) contain a product description, bar code, identifying lot/ batch number and individual identification number;
  - (f) be accompanied by a summary sheet setting out the Expiration Date of the Medical Device(s) and/ or Consignment Stock (where relevant) and when the Medical Device was last inspected and/ or serviced;
  - (g) be accompanied by written evidence of the safety of the Medical Devices and/or Consignment Stock, drawing attention to any failures to comply with relevant European or Irish standard specifications or aspects of safety that have not been fully tested and any restrictions on the use of the Medical Devices and/or Consignment Stock necessary to ensure the safety of Executive employees or patients, where applicable; and
  - (h) be accompanied by a decontamination certificate verifying that the Medical Device has been subject to a process of decontamination in accordance with the HSE Code of Practice for Decontamination of RIMD (Version 1 2007 Part 3) "Recommended Practices for Decontamination Units" or such other policies as HSE may from time to time specify, which shall set out:
    - (i) the date when the Medical Device was last decontaminated; and
    - (ii) the relevant person, role and location of the person responsible for decontamination.



- 4.2 The Supplier shall maintain accurate and complete records of each of the items listed at Clause 4.1(h) above and Clause 12.3, together with the current location of the Medical Device(s) and/or Consignment Stock in respect of all Medical Devices and Consignment Stock supplied to the Executive and/ or Relevant Hospital pursuant to this Deed.
- 4.3 Unless otherwise agreed, the Supplier shall access, and maintain records on, the HSE electronic tracking system in respect of such categories of Medical Devices as HSE may specify, and the Supplier shall ensure that any information or records maintained by the Supplier in respect of the Medical Devices (whether pursuant to its obligations under this Deed or otherwise) are capable of being integrated in, and interfacing with, the HSE electronic tracking system such that the information and/ or records in respect of the Medical Devices may be accessed and/ or viewed by HSE and shall have such other functionality as the HSE may specify from time to time.

## **5. Tax Clearance Certificates**

- 5.1 It shall be a condition precedent to this Deed that the Supplier has and shall at all times maintain a current tax clearance certificate from the Revenue Commissioners and that the Supplier shall produce a current tax clearance certificate from the Revenue Commissioners to the HSE on written request.
- 5.2 Any payment to the Supplier under this Deed is conditional on the HSE having in its possession at the time of payment a current tax clearance certificate (or where the Supplier is non-resident in Ireland and whose business is not registered in Ireland, a statement from the Office of the Revenue Commissioners as to its suitability on tax grounds to be receive payments pursuant to this Deed).

## **6. Ownership of the Medical Devices**

- 6.1 Notwithstanding that the Medical Devices may be in the possession of the Executive at the Relevant Hospital from time to time, title to, and property in, the Medical Devices shall remain at all times and for all purposes fully vested in the Supplier.
- 6.2 Notwithstanding that the Consignment Stock may be in the possession or under the control of the Executive at the Relevant Hospital from time to time, title to, and property in, the Consignment Stock shall remain fully vested in the Supplier at all times up to such time as the Relevant Hospital utilises or consumes the Consignment Stock, at which point title in such Consignment Stock shall be deemed to have immediately transferred to the Executive.
- 6.3 For the avoidance of doubt, the Medical Devices and the Consignment Stock shall at all times (including after its delivery to the Executive and/ or the Relevant Hospital and any subsequent use by or on behalf of the Executive) remain continuously at the risk of the Supplier and the Supplier shall be at risk and liable for any loss, damage, theft, destruction of the Medical Devices and Consignment Stock provided always that the Executive shall be liable for the costs of repair or replacement of any Medical Devices and/or Consignment Stock which is damaged, destroyed or rendered inoperable due to the wilful misuse of such Medical Devices and/or Consignment Stock by the Executive or any of its employees or agents while such Medical Devices and/or Consignment Stock is in its possession. Neither the Executive nor the Relevant Hospital shall be under any obligation to keep the Medical Devices and/or Consignment Stock insured.

## 7. **Training and Education**

- 7.1 The Supplier shall provide training, instruction, ongoing education and support to all staff at the Relevant Hospital in:
- (a) the use, preparation for use, operation, maintenance, cleaning, sterilisation, storage, dis-assembly and re-assembly and decontamination of the Medical Devices; and
  - (b) the use, preparation for use, operation, installation, fitting, removal, maintenance, cleaning, sterilisation, storage, dis-assembly and re-assembly and decontamination of all Consignment Stock (“**Training**”).
- 7.2 The Relevant Hospital shall notify the Supplier in writing from time to time of the relevant staff who require such Training and the Supplier shall promptly (and within not later than 3 days following any such request) deliver or make arrangements for the delivery of, Training by an appropriately qualified person.
- 7.3 The Supplier shall provide instruction manuals in the English language for the proper use of the Medical Devices and the proper use, installation, fitting, removal and maintenance of the Consignment Stock including any information and documents required by, or pursuant to the Safety, Health and Welfare at Work Act 2005 and any regulations made thereunder.
- 7.4 The Supplier shall comply with all requests from the Relevant Hospital in respect of the operation, use, storage, cleaning and decontamination of the Medical Devices and/ or to deliver Training and shall ensure that the relevant staff in the Relevant Hospital are familiar with and fully trained in all respects of, the Medical Devices and Consignment Stock.
- 7.5 The Supplier make a telephone helpline number (the “**Helpline**”) available to the Executive and the Relevant Hospital, which shall be staffed and calls answered at all times by personnel who are fully trained and qualified to respond to any queries of the Executive and/ or the Relevant Hospital which may arise in relation to the Medical Devices and Consignment Stock.
- 7.6 The Supplier shall notify the Relevant Hospital of its nominated representative (the “**Representative**”) from time to time and shall ensure that the Representative is available by telephone to the Relevant Hospital at all times and particularly in the event that any Medical Device and/or Consignment Stock is urgently required, to provide such assistance and guidance as the Relevant Hospital may require in respect of the use of the Medical Device and/or Consignment Stock.

## 8. **Liquidated Damages**

- 8.1 In the event that the Supplier fails to comply with its obligations pursuant to the Deed or the Supplier delays in performing its obligations pursuant to the Deed which has in either case a material impact (in the opinion of the Executive) on the provision of an operation or other clinical service by the Relevant Hospital (“**Crucial Performance Failure**”), the Supplier shall pay to the Executive liquidated damages commensurate with the costs incurred by the Executive and/ or Relevant Hospital as a result of the failure by the Supplier to perform its obligations under this Deed, including but not limited to the costs of making alternative arrangements for the supply of the Medical Devices and/or Consignment Stock and/ or for the provision of an operation or other

clinical service (whether or not by the Executive and whether or not at the Relevant Hospital) and all attendant costs thereby incurred (the “**Liquidated Damages**”).

- 8.2 The parties agree that the Liquidated Damages are a genuine pre-estimate of the minimum loss which would be suffered by the Executive as a result of the circumstances under which they arise.
- 8.3 Without prejudice to its other rights and remedies, the Executive may elect to claim the Liquidated Damages and if appropriate to bring an action to claim damages for the breach in relation to which Liquidated Damages are payable. The receipt by the Executive of Liquidated Damages shall not affect its other rights pursuant to this Deed.

## 9. **Removal of Medical Devices**

- 9.1 Subject to Clause 9.3, the Supplier shall be entitled from time to time upon written notice of not less than 2 Business Days to Internal Controls and such other person(s) as the Relevant Hospital and/ or the Executive may specify to remove all or any part of the Medical Devices from the Relevant Hospital and the Executive and the Relevant Hospital shall provide reasonable facilities and access to the Supplier’s Representative (or such other persons as the Supplier may specify) to enter onto the Relevant Hospital’s premises to perform such removal, provided always that where the removal would cause the Medical Devices to fall below the minimum levels specified by the Relevant Hospital, the Supplier shall arrange to provide a substitute, of equivalent standard to the Medical Devices being removed, to the Relevant Hospital in advance of any removal taking place.
- 9.2 The Supplier shall bear the costs of, and use all practicable speed in, exercising its rights pursuant to this Clause. The Supplier shall provide the Relevant Hospital with such details as it may require in respect of any Medical Devices removed by the Supplier.
- 9.3 Nothing in this Clause shall entitle the Supplier to remove any Medical Devices which is in any way attached or fixed to the Premises or where removal of the Medical Devices would result in damage to the Premises.
- 9.4 The Supplier agrees that it shall not be entitled to remove the Consignment Stock except in exceptional circumstances and only by prior agreement with the head of the relevant department of the Executive and/ or theatre manager of the Relevant Hospital. Where it has been agreed in advance that any Consignment Stock may be removed, then the Supplier shall provide written details to Internal Controls and such other person(s) as the Relevant Hospital and/ or the Executive may specify of the Consignment Stock to be removed and the intended date for collecting and removing such Consignment Stock.

## 10. **Warranties**

### 10.1 **Warranties in respect of the Supplier’s capacity and authority**

The Supplier warrants that:

- (a) it is duly organised and validly existing under the laws of Ireland and has the power and authority to own its assets and to carry on its business as it is now being conducted;

- (b) all necessary approvals and authorisations for the execution of, and the performance of its obligations under, this Deed have been obtained;
- (c) no claim, demand, proceedings or liability is presently being assessed and no litigation, arbitration or administrative proceeding is presently in progress or to the best of the knowledge of the Supplier, pending or threatened against it or its assets or revenues which (in each case) would have a material adverse effect on the ability of the Supplier to perform its obligations under this Deed;
- (d) no proceedings or other steps have been taken and not discharged (nor, to the best of the knowledge of the Supplier, threatened) for its winding up or dissolution or for the appointment of a liquidator, examiner, receiver, administrative receiver, manager, trustee or similar officer in relation to any of its assets or revenues;
- (e) it has the appropriate qualifications, competence, financial and organisational resources required to perform its obligations under this Deed.

## 10.2 Warranties in respect of the Medical Devices

The Supplier further warrants that:

- (a) the Medical Devices and/or Consignment Stock is in good and proper condition and fit for the intended purpose for which the Medical Device and/or Consignment Stock is supplied;
- (b) prior to each and every supply to the Relevant Hospital, the Medical Device and/or Consignment Stock is (where appropriate) properly sterilised and decontaminated in accordance with the HSE code of practice for decontamination of RIMD (Version 1 2007 Part 3) "Recommended Practices for Decontamination Units" or such other policies as HSE may specify from time to time;
- (c) the Medical Device and/or Consignment Stock, where appropriate, complies with the essential requirements of the Medical Devices Directive (Council Directive 93/42/EEC) as amended and where appropriate, is CE marked for the appropriate intended use; and
- (d) the Consignment Stock and/ or the Medical Devices, where appropriate, complies with Council Directive 90/385/EEC in respect of active implantable medical devices (as amended and implemented in Ireland).

The warranties given by the Supplier pursuant to 10.2(a) to 10.2(d) above shall be deemed to be repeated on each day upon which a supply of Medical Devices and/or Consignment Stock is made pursuant to this Deed.

## 11. Indemnities

11.1 The Supplier shall indemnify and hold harmless the Executive, the Relevant Hospital, the Executive's employees, agents, officers, and sub-contractors against any claims, losses, damages, costs, proceedings, and expenses (including legal expenses) arising out of or in connection with:

- (a) any breach of any warranty or provision of this Deed by the Supplier;

- (b) any act or omission of the Supplier, the Representative, the Supplier's employees, agents or sub-contractors in performing its obligations under this Deed, including but not limited to failure to adequately and safely perform any of its obligations under this Deed;
- (c) any defect in the design, manufacture or supply of the Medical Devices and/or Consignment Stock or any part thereof;
- (d) the inadequacy of, or deficiencies, in any Training or instructions provided by the Supplier pursuant to this Deed; or
- (e) any injury, (including but not limited to mental injury) and/ or death to any person arising directly or indirectly from the supply or use of the Medical Devices and/or Consignment Stock supplied pursuant to this Deed;

provided always that that this indemnity shall not apply to any liability of the Supplier in respect of:

- (i) death or personal injury caused by the negligence of the Executive, the Relevant Hospital or that of its officers or employees;
- (ii) fraud or fraudulent misrepresentation by the Executive, the Relevant Hospital, its officers or employees; nor
- (iii) any liability to the extent that it cannot be limited or excluded by Legal and Regulatory Requirements.

11.2 Without prejudice to any other rights or remedies of the Executive under this Deed, where the Supplier fails to comply with the terms of this Deed and such failure has a material adverse impact on the operations of the Executive and/ or the Relevant Hospital (as determined by the Executive), the Supplier shall indemnify the Executive for any and all costs incurred by the Executive and/ or the Relevant Hospital arising out of or in connection with such failure (including but not limited to the costs of any action taken by the Executive to mitigate, alleviate or remedy the impact of such failure).

## 12. Information Requirements

12.1 The Supplier shall maintain:

- (a) detailed, accurate and up to date records and an asset register of the Medical Devices and Consignment Stock supplied by it pursuant to this Deed; and
- (b) a complaint and incident reporting system.

12.2 The Executive shall be entitled by providing reasonable notice in writing to the Supplier to enter the Supplier's normal place of business during normal office hours to inspect and/ or copy such records.

12.3 In respect of all Medical Devices and Consignment Stock supplied by the Supplier pursuant to this Deed the Supplier shall maintain and make available to the Executive and/ or the Relevant Hospital upon request a log book (or equivalent, whether in electronic form or otherwise) which shall contain the following particulars:

- (a) the complete history of the prior use of the Medical Devices;

- (b) an inspection and servicing schedule setting out when the Medical Devices and any parts thereof was last inspected and/ or serviced and details of all inspections, maintenance, repair and replacements of that Medical Devices and any parts thereof;
  - (c) records of tests, calibration, repair or maintenance of the Medical Devices and/ or any parts thereof; and
  - (d) where relevant, all decontamination certificates relating to the Medical Devices and/or Consignment Stock containing the information set out in Clause 4.1(h).
- 12.4 Without prejudice to the foregoing, the Executive shall be entitled upon written request to require the Supplier to provide the Executive within 2 days of receipt of any such request with the log book containing such information as set out in Clause 12.3, accurate and complete particulars (including the quantity and value) of the Medical Devices and/or Consignment Stock or such other information specified in any such request relating to the Medical Devices and/or Consignment Stock supplied by the Supplier to the Executive and/ or the Relevant Hospital pursuant to this Deed and the Supplier shall comply with any such request.
- 12.5 The Supplier shall not be obliged to comply with a request for information where the consent of a third party to the release of the information is required until such consent has been obtained and the Supplier will use reasonable efforts to obtain such consent promptly.

### 13. **Confidentiality**

- 13.1 Subject to Clause 13.3, each party will ensure that any information acquired in or in connection with the performance of its obligations under this Deed concerning the other or the other's business, affairs, personnel, procedures or relating to the provisions of this Deed and any negotiations or disputes between the parties to this Deed will be treated as confidential and will not be disclosed to any person, other than a person expressly authorised by the other party.
- 13.2 Upon the termination of this Deed the Supplier will ensure that it holds, manages and transfers all confidential information it has received or prepared in connection with its obligations under this Deed in whatever format it is held in accordance with all Legal and Regulatory Requirements.
- 13.3 Either party may disclose information which would otherwise be confidential:
- (a) if and to the extent required by law or for the purpose of any judicial inquiry or proceedings;
  - (b) if and to the extent required by any regulatory or governmental authority in Ireland to which that party is subject;
  - (c) if and to the extent necessary or desirable for the conduct of any arbitration pursuant to Clause 16;
  - (d) to its professional advisers, auditors, bankers and insurers on a strictly confidential basis;
  - (e) if and to the extent the other party has given prior written consent to the disclosure, such consent not to be unreasonably withheld or delayed; or

(f) if necessary for the Executive to fulfil its statutory object and functions pursuant to Section 7 of the Health Act 2004.

13.4 Any information to be disclosed pursuant to Clause 13.3 shall be disclosed only after notice to the other party.

13.5 The provisions of this Clause 13 shall continue to apply notwithstanding the termination of this Deed for any reason.

#### 14. **Data Protection**

14.1 Both the Executive and the Supplier shall comply with their statutory obligations under the Data Protection Acts 1988 and 2003 (“**DPA**”).

14.2 The Supplier undertakes to use its best endeavours to ensure that it has all consents, authorisations and permissions necessary to enable the Supplier to access and disclose any data, to the extent that the Supplier may require access to or the ability to disclose such data in the lawful performance of its functions pursuant to this Deed.

14.3 The Supplier hereby undertakes to comply with its obligations under the DPA and to indemnify the Executive and the Relevant Hospital against any loss, compensation, damages, expenses and costs which become payable or are incurred by the Executive and the Relevant Hospital in respect of or as a result of a breach by the Supplier of this Clause 14 or a breach of the DPA.

14.4 Where personal data is given by either party to the other for the purpose of this Deed, it shall be used solely and exclusively for the purposes for which it is expressly provided and for other purposes permitted by law.

#### 15. **Insurance**

15.1 The Supplier shall effect and maintain the following insurances with insurers regulated by, or authorised to operate on a freedom of services basis by, the Central Bank for the duration of this Deed:

(a) public liability insurance with a limit of indemnity of €6,500,000 (€6.5 million) any one occurrence;

(b) employer’s liability insurance with a limit of indemnity of €12,700,000 (€12.7 million) any one occurrence; and

(c) product liability insurance with a limit of indemnity of not less than €6,500,000 (€6.5 million) any one occurrence

which will include an indemnity in favour of the Executive and the Relevant Hospital.

15.2 Upon the written request of the Executive, the Supplier shall provide evidence in a form reasonably acceptable to the Executive of such insurance and endorsement in the Supplier’s public liability and employer’s liability insurance policies in favour of the Executive being in force<sup>2</sup>.

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<sup>2</sup> Note to HSE: You may wish to build in to any internal policies or procedures that HSE will request evidence of the Supplier’s compliance with the insurance provisions of the agreement on an annual basis and place a copy of the relevant policies/ letter from the insurers confirming the existence of the policies on the HSE’s files.

## 16. **Dispute Resolution**

16.1 The parties to this Deed agree to avoid disputes and deal with issues as they arise. It is expected that any disputes in relation to this Deed shall be resolved through direct discussion between the following representative(s) of the Executive and/ or Relevant Hospital and representative(s) of the Supplier:

- (a) Executive's Representative: \_\_\_\_\_ [*details to be inserted*];
- (b) Relevant Hospital's Representative: \_\_\_\_\_ [*details to be inserted*];
- (c) Supplier's Representative: \_\_\_\_\_ [*details to be inserted*].

16.2 In the event any dispute arising out of or in connection with this Deed remains unresolved as between the parties then either party may refer the dispute for full and final resolution to arbitration (by notice to the other party) in accordance with the following:

- (a) The arbitrator shall be nominated by agreement in writing between the parties. In the event that agreement on the appointment of an arbitrator cannot be reached between the parties within fourteen (14) days of the referral to arbitration (or such other period as is agreed in writing between the parties), then the parties hereby agree that the arbitrator shall be appointed by the President of the Law Society of Ireland for the time being.
- (b) The arbitration shall be governed by Irish law and by the provisions of the Arbitration Act 2010 and any re-enactment, adaptation, amendment or extension of same for the time-being in force;
- (c) The award of the arbitrator shall be final and binding on both parties;
- (d) The arbitrator shall have power to determine all disputes arising out of or in connection with the Deed between the parties;
- (e) The seat of arbitration shall be Dublin, Ireland and the language of the arbitration shall be English; and
- (f) The parties shall bear their own costs in respect of any arbitration pursuant to this Clause.

## 17. **Termination**

17.1 This Deed may be terminated by either party giving not less than three months notice in writing to the other party specifying the date (which shall not be less than three months from the date of the notice) upon which the obligations pursuant to this Deed shall terminate.

17.2 In the event of termination of this Deed for any reason, the provisions of this Deed shall continue to bind each party insofar as and for as long as may be necessary to give effect to their respective rights and obligations.

17.3 Without prejudice to the foregoing, the provisions of Clauses 8 (*Liquidated Damages*), 11 (*Indemnities*), 12 (*Information Requirements*) and 13 (*Confidentiality*) and this Clause shall survive the termination of this Deed.



- 17.4 Neither party shall be liable to the other party for any loss of profit, contracts, goodwill, business opportunity or anticipated saving arising out of or in connection with the termination of this Deed for any reason or any consequential loss or damage that may arise out of termination of this Deed.
- 17.5 Termination of this Deed for any reason shall be without prejudice to the rights and remedies of either party in relation to any negligence, omission or default of the other party prior to termination.
- 17.6 Upon termination of this Deed for whatever reason the Executive and/ or the Relevant Hospital shall forthwith provide the Supplier with written particulars of any contamination or other hazard including any safety hazard that has arisen in respect of the Medical Devices and/or Consignment Stock during the period in which the Medical Devices and/or Consignment Stock was in the possession of the Executive and/ or the Relevant Hospital so that the equipment or any part thereof may be maintained, repaired, removed, transported, made safe or otherwise dealt with by the Supplier as may be appropriate provided that the Executive and the Relevant Hospital shall have no liability whatsoever for any failure by the Supplier to maintain, repair, remove, transport, make safe or otherwise deal with the Medical Devices and/or Consignment Stock whether or not such failure has arisen out of or is connected with any written particulars provided by the Executive and/ or the Relevant Hospital pursuant to this Clause.
- 17.7 Upon termination of this Deed for whatever reason the Executive and/ or the Relevant Hospital shall forthwith return any Medical Devices and/or Consignment Stock supplied pursuant to this Deed to the Supplier, unless otherwise agreed.

18. **General**

18.1 **No future commitments**

Nothing in this Deed shall create any obligation on the Executive nor the Relevant Hospital to purchase or take on paid hire either during the period of this Deed or at any time thereafter any quantity of the Medical Devices and/or Consignment Stock and the Supplier acknowledges that it has not relied on any representation on behalf of the Executive and/ or the Relevant Hospital as to any future business between the Supplier and the Executive and/ or the Relevant Hospital (except that nothing in this clause shall exclude the Executive's liability for fraudulent misrepresentations) and the Supplier warrants that neither the Executive nor the Relevant Hospital is under any obligation to the Supplier in connection with the Medical Devices and/or Consignment Stock (save as expressly set out herein) or future orders thereof.

18.2 **Notices**

- (a) Any notice or other communication under this Deed shall only be effective if it is in writing.
- (b) Subject to Clause 18.2(c), communication by electronic mail or other electronic methods of writing shall be effective under this Deed in respect of day-to-day operational communications.
- (c) Communication by electronic mail or other electronic methods of writing shall not be effective under this Deed in respect of any notices issued pursuant to Clause 16 (Dispute Resolution) and/ or 17 (Termination) of this Deed.

- (d) No notice or other communication given or made under this Deed may be withdrawn or revoked.
- (e) Any notice or other communication given or made under this Deed shall be addressed as provided in Clause 18.2(g) and, if so addressed, shall, in the absence of earlier receipt, be deemed to have been duly given or made as follows:
  - (i) if sent by personal delivery, on delivery at the address of the relevant party;
  - (ii) if sent by pre-paid post, two (2) clear Business Days after the date of posting;
  - (iii) if sent by facsimile, when the sender receives a completed transmission sheet or otherwise receives a mechanical confirmation of transmission
  - (iv) if sent by email, upon transmission from the sender.
- (f) Any notice or other communication given or made, or deemed to have been given or made, outside Working Hours will be deemed not to have been given or made until the start of the next period of Working Hours.
- (g) The relevant notice details are:

|                     |          |                   |
|---------------------|----------|-------------------|
| Title of recipient: | Address: | Facsimile number: |
|---------------------|----------|-------------------|

|   |  |            |
|---|--|------------|
| <i>[Insert name of HSE Responsible Contact]</i> | <i>[Insert Address of HSE Responsible Contact]</i> | <i>xxx</i> |
|---|--|------------|

|  |   |            |
|--|---|------------|
| <i>[Insert name of Supplier Responsible Contact]</i> | <i>[Insert address of the Registered office of the Supplier &amp; Responsible Contact (if different)]</i> | <i>xxx</i> |
|--|---|------------|

- (h) A party may notify the other parties of a change to its notice details. That notification shall only be effective on:
  - (i) any effective date specified in the notification; or
  - (ii) if no effective date is specified or the effective date specified is less than five (5) clear Business Days after the date when notice is received, the date falling five (5) clear Business Days after the notification has been received.
- (i) The provisions of this Clause shall not apply in relation to the legal service of documents.

### 18.3 Remedies and Waivers

- (a) No delay or omission by any party to this Deed in exercising any right, power or remedy provided by law or under this Deed shall:
  - (i) affect that right, power or remedy; or
  - (ii) operate as a waiver of it.
- (b) The exercise or partial exercise of any right, power or remedy provided by law or under this Deed shall not preclude any other or further exercise of it or the exercise of any other right, power or remedy.
- (c) The rights, powers and remedies provided in this Deed are cumulative and not exclusive of any rights, powers and remedies provided by law.

### 18.4 Severability

If at any time any provision of this Deed is or becomes illegal, invalid or unenforceable in any respect under the law of any jurisdiction that shall not affect or impair:

- (a) the legality, validity or enforceability in that jurisdiction of any other provision of this Deed; or
- (b) the legality, validity or enforceability under the law of any other jurisdiction of that or any other provision of this Deed.

### 18.5 No Partnership and No Agency

- (a) Nothing in this Deed and no action taken by the parties pursuant to this Deed shall constitute, or be deemed to constitute, a partnership, association, joint venture or other co-operative entity between any of the parties.
- (b) Nothing in this Deed and no action taken by the parties pursuant to this Deed shall constitute, or be deemed to constitute, any party as the agent of any other party for any purpose. Neither party has, pursuant to this Deed, any authority or power to bind or to contract in the name of the other party to this Deed.

### 18.6 Further Assurance

Either party shall, from time to time on request, do or procure the doing of all acts and/ or the execution of all documents in a form satisfactory to the other party which the other party may reasonably consider necessary for giving full effect to this Deed and securing to the other party the full benefit of the rights, powers and remedies conferred upon it in or by this Deed.

### 18.7 Entire Agreement

- (a) For the purposes of this Clause, "Pre-contractual Statement" means a draft agreement, undertaking, representation, warranty, promise, assurance or Deed of any nature whatsoever, whether or not in writing, relating to this Deed made or given by a party to this Deed or any other person at any time prior to the date of this Deed.

- (b) This Deed constitutes the whole and only agreement between the parties relating to the provision of the Services.
- (c) Except to the extent repeated in this Deed, this Deed supersedes and extinguishes any Pre-contractual Statement.
- (d) Each party acknowledges that in entering into this Deed it is not relying upon any Pre-contractual Statement which is not set out in this Deed.
- (e) No party shall have any right of action against any other party to this Deed arising out of or in connection with any Pre-contractual Statement (except in the case of fraud) except to the extent repeated in this Deed.

**18.8 Amendment**

This Deed may be varied in writing (excluding electronic methods of writing) signed by each of the parties. The Executive reserves the right to amend this Deed by notice in writing to the Supplier should there be a change in legislation or an order of the Minister necessitating such amendment and the Supplier shall be bound by such amendment.

**18.9 No hire purchase**

For the avoidance of doubt, this Deed is not a hire purchase agreement pursuant to Part III of the Sale of Goods and Supply of Services Act 1980.

**18.10 Costs and Expenses**

Each party shall pay its own costs and expenses in relation to the negotiation, preparation, execution, implementation and interpretation of this Deed.

**18.11 Counterparts**

- (a) This Deed may be executed in any number of counterparts, and by the parties on separate counterparts, but shall not be effective until each party has executed at least one counterpart.
- (b) Each counterpart shall constitute an original of this Deed, but all the counterparts shall together constitute but one and the same instrument.

**18.12 Governing Law**

This Deed shall be governed by and construed in accordance with the laws of Ireland.

**IN WITNESS WHEREOF** this Deed is executed by the parties as follows:-

The Seal of the  
HEALTH SERVICE EXECUTIVE  
affixed hereto  
was authenticated by

*[place seal here]*

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

GIVEN under the common seal of  
*[Name of Supplier]*

\_\_\_\_\_  
Director

\_\_\_\_\_  
Director/ Secretary