

**THIS DATA PROCESSING ADDENDUM** is made on the \_\_\_\_\_ day of \_\_\_\_\_, 2016

**BETWEEN**

- (1) **SMITH & NEPHEW, INC** a company incorporated and registered in the United States of America with an office at 1450E Brooks Rd. Memphis, TN 38116, United States ("**S&N**"); and
- (2) **CUSTOMER** as identified below (the "**Customer**").  
(each a "**Party**" and together the "**Parties**").

**WHEREAS**

- (A) S&N and/or other members of the Smith & Nephew Group are party to an agreement with the Customer for the supply of VISIONAIRE Patient Matched Instrumentation process services (the "**Services**") to the Customer (the "**Agreement**"). In connection with the supply of the Services under the Agreement Personal Data is transferred to S&N by or on behalf of the Customer.
- (B) This Data Processing Addendum ("**Addendum**") forms part of the Agreement and is entered into to reflect the Parties' agreement with regard to the processing of Personal Data in connection with the Services in accordance with the requirements of applicable Data Protection Laws and Regulations.
- (C) The Standard Contractual Clauses set out in Schedule 1 are incorporated by reference and apply to any processing of Personal Data by S&N in the course of providing the Services.

**NOW IT IS HEREBY AGREED** by and between the Parties as follows:

**1. DEFINITIONS AND INTERPRETATION**

- 1.1 All undefined capitalised terms used in this Addendum shall have the same meanings as set out in the Agreement.
- 1.2 The terms "**Data Controller**", "**Data Processor**", "**personal data**", "**processing**" and "**appropriate technical and organisational measures**" shall have the meanings given to those terms in the UK Data Protection Act 1998, and "**process**" and "**processed**" shall be construed accordingly.

<b>"Affiliate"</b>	means, in relation to a Party, any of its subsidiary or holding companies, whether direct or indirect, or any subsidiary of any such holding company, the terms "subsidiary" and "holding company" having the meanings given to them under the applicable law;
<b>"Customer"</b>	means the Party who has executed this Addendum as the Customer;
<b>"DPA"</b>	means the Data Protection Act 1998;
<b>"Data Protection Laws and Regulations"</b>	means any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction which relates to the protection of individuals with regards to the processing of Personal Data and to which a Party to this Agreement is subject including where applicable the guidance and codes of practice issued by the Information Commissioner or any other supervisory authority, and the equivalent of any of the foregoing in any relevant jurisdiction;

<b>"Effective Date"</b>	means the date that this Addendum is executed by the last Party to execute this Addendum;
<b>"Personal Data"</b>	means any personal data for which the Customer is a Data Controller and which is processed in connection with the provision of the Services under the Agreement;
<b>"Standard Contractual Clauses"</b>	the standard contractual clauses for the transfer of Personal Data from the European Union to processors established in third countries (controller-to-processor transfers), as set out in the Annex to Commission Decision 2010/87/EU, a completed copy of which comprises Schedule 1.
<b>"Smith &amp; Nephew Group"</b>	means S&N and its Affiliates.

1.2 In this Agreement except where the context otherwise requires:

- 1.2.1 any reference to this Addendum includes the Schedule to it which forms part of this Addendum for all purposes;
- 1.2.2 In the event of any conflict or inconsistency between the terms of this Addendum and the terms of the Agreement in so far as they relate to the processing of Personal Data, the terms of this Addendum shall prevail to the extent of such conflict or inconsistency;
- 1.2.3 a reference to an enactment or statutory provision shall include a reference to any subordinate legislation made under the relevant enactment or statutory provision and is a reference to that enactment, statutory provision or subordinate legislation as from time to time amended, consolidated, modified, re-enacted or replaced;
- 1.2.4 words in the singular shall include the plural and vice versa;
- 1.2.5 references to one gender include other genders;
- 1.2.6 a reference to a person shall include a reference to a firm, a body corporate, an unincorporated association, a partnership or to an individual's executors or administrators;
- 1.2.7 references to writing shall include any modes of reproducing words in any legible form and shall include email except where expressly stated otherwise;
- 1.2.8 a reference to "includes" or "including" shall mean "includes without limitation" or "including without limitation";
- 1.2.9 the headings in this Addendum are for convenience only and shall not affect its interpretation;
- 1.2.10 references to this Addendum include this Addendum as amended or supplemented in accordance with its terms; and
- 1.2.11 references in this Addendum to any agreement or other instrument (other than an enactment or statutory provision) shall be deemed to be references to that agreement or instrument as from time to time amended, varied, supplemented or substituted.

## 2. **APPLICATION OF THIS ADDENDUM**

- 2.1 With effect from the Effective Date the Agreement shall be construed as amended to include the terms of this Addendum.
- 2.2 This Addendum shall operate as a standalone document to reflect the Parties' agreement relating to the processing of Personal Data, in accordance with the requirements of applicable Data Protection Laws and Regulations.
- 2.3 In the course of providing the Services pursuant to the Agreement, S&N may Process Personal Data on behalf of the Customer and each Party shall be responsible for complying with their respective obligations under Data Protection Laws and Regulations.

## 3. **PROCESSING OF PERSONAL DATA**

- 3.1 The Customer (as Data Controller) has appointed S&N as a Data Processor in respect of the Personal Data processed by S&N in connection with the Services.
- 3.2 The Customer shall provide all such co-operation and information as S&N may reasonably require to enable S&N to comply with its obligations under applicable Data Protection Laws and Regulations including taking all such actions as are required to ensure that S&N is entitled lawfully to process the Personal Data in connection with the Services.
- 3.3 The Customer authorises S&N to appoint sub-contractors or other members of the Smith & Nephew Group involved in providing the Services as further Data Processors on behalf of the Customer provided that such further Data Processors are engaged on terms providing equivalent protections in relation to the Personal Data processed in connection with the Services to those set out in this Addendum.
- 3.4 S&N agrees that:
  - 3.4.1 it shall process the Personal Data in connection with the Services only to the extent and in such a manner as is necessary for the provision of the Services and in accordance with the terms of this Addendum and shall not process such Personal Data for any other purpose unless otherwise instructed by the Customer in writing;
  - 3.4.2 it has appropriate technical and organisational measures in place to safeguard against any unauthorised or unlawful processing and against accidental loss or destruction of or damage to the Personal Data processed in connection with the Services and shall ensure that such measures provide a level of security appropriate to the harm that might result from such unauthorised or unlawful processing or accidental loss, destruction or damage and the nature of the Personal Data to be protected;
  - 3.4.3 it shall take reasonable steps to ensure the reliability of any its employees who have access to the Personal Data;
  - 3.4.4 it shall allow representatives of the Customer to audit S&N's compliance with the requirements of this Clause 3.4 on reasonable notice and/or, at the option of the Customer, on request to provide the Customer with evidence of its compliance with such requirements.

## 4. **APPLICATION OF THE STANDARD CONTRACTUAL CLAUSES**

- 4.1 The Standard Contractual Clauses set out in Schedule 1 will apply to the processing of Personal Data by S&N in the course of providing the Services.
- 4.2 The Standard Contractual Clauses shall apply only to Personal Data transferred from the European Economic Area (EEA) and/or Switzerland by or on behalf of the Customer to S&N's personnel, locations or systems located outside the EEA. The Standard Contractual Clauses apply to the Customer who shall be deemed to be the "Data Exporter".

4.3 In the event of any conflict or inconsistency between this Addendum and the Standard Contractual Clauses in Schedule 1, the Standard Contractual Clauses shall prevail.

## 5. **NOTICES**

5.1 Any notice or other communication given to a Party under or in connection with this Addendum shall be in writing and shall be delivered by hand or by pre-paid first class post or other next working day delivery service at its registered office (if a company) or its principal place of business (in any other case).

5.2 Any notice or communication shall be deemed to have been received:

5.2.1 if delivered by hand on signature of a delivery receipt or at the time the notice is left at the proper address;

5.2.2 if sent by pre-paid first-class post or other next working day delivery service, at 9.00 am on the second Business Day after posting or at the time recorded by the delivery service;

5.2.3 if sent by fax, at 9.00 am on the next Business Day after transmission.

5.3 This clause does not apply to the service of any proceedings or other documents in any legal action or, where applicable, any arbitration or other method of dispute resolution. For the purposes of this clause, writing shall not include e-mail.

5.4 A notice given under this Addendum is not valid if sent by email.

## 6. **COUNTERPARTS AND LEGAL EFFECT**

6.1 This Addendum may be executed in any number of counterparts, each of which when executed shall constitute a duplicate original, but all the counterparts shall together constitute one agreement.

## 7. **MISCELLANEOUS**

7.1 Any change to this Addendum must be made in writing and signed by all Parties affected by the change in order to be effective.

7.2 Nothing in this Addendum is intended to establish or shall be construed as establishing joint and several liability between the Parties and each Party shall be individually responsible and liable for its own acts and/or omissions.

7.3 Should any provision of this Addendum be or become invalid or unenforceable in whole or in part this shall not affect the validity of the remainder of this Addendum. The invalid or unenforceable provision shall automatically be replaced by a valid and enforceable provision that comes closest to the intention and purpose of the original provision.

## 8. **GOVERNING LAW AND JURISDICTION**

8.1 This Addendum will be governed by and interpreted in accordance with the laws of England and Wales.

8.2 Each Party irrevocably submits to the exclusive jurisdiction of the courts of England and Wales over any claim or matter arising under or in connection with this Addendum.

The Parties have executed this Addendum on the dates shown below:

For and on behalf of SMITH & NEPHEW, INC:

SIGNATURE: \_\_\_\_\_

NAME: \_\_\_\_\_

TITLE: \_\_\_\_\_

DATE: \_\_\_\_\_

For and on behalf of CUSTOMER: \_\_\_\_\_

SIGNATURE: \_\_\_\_\_

NAME: \_\_\_\_\_

TITLE: \_\_\_\_\_

DATE: \_\_\_\_\_

## SCHEDULE 1

### Standard Contractual Clauses (processors)

For the purposes of Article 26(2) of Directive 95/46/EC for the transfer of personal data to processors established in third countries which do not ensure an adequate level of data protection

Name of the data exporting organisation: \_\_\_\_\_

Address: \_\_\_\_\_

Tel: \_\_\_\_\_ Fax: \_\_\_\_\_ e-mail: \_\_\_\_\_

Other information needed to identify the organisation

\_\_\_\_\_  
(the data **exporter**)

And

Name of the data importing organisation: **Smith & Nephew, Inc.**

Address: **1450 Brooks Rd. Memphis, TN 38116, United States**

Tel.: **++1-(800)-262-3536**; fax: **++1-(888)-399-4198**; e-mail: [VisionaireSupport@smith-nephew.com](mailto:VisionaireSupport@smith-nephew.com)

Other information needed to identify the organisation:

**"S&N"**  
(the data **importer**)

each a "party"; together "the parties",

HAVE AGREED on the following Contractual Clauses (the Clauses) in order to adduce adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals for the transfer by the data exporter to the data importer of the personal data specified in Appendix 1.

## Clause 1

### **Definitions**

For the purposes of the Clauses:

- (a) *'personal data', 'special categories of data', 'process/processing', 'controller', 'processor', 'data subject' and 'supervisory authority'* shall have the same meaning as in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data;
- (b) *'the data exporter'* means the controller who transfers the personal data;
- (c) *'the data importer'* means the processor who agrees to receive from the data exporter personal data intended for processing on his behalf after the transfer in accordance with his instructions and the terms of the Clauses and who is not subject to a third country's system ensuring adequate protection within the meaning of Article 25(1) of Directive 95/46/EC;
- (d) *'the subprocessor'* means any processor engaged by the data importer or by any other subprocessor of the data importer who agrees to receive from the data importer or from any other subprocessor of the data importer personal data exclusively intended for processing activities to be carried out on behalf of the data exporter after the transfer in accordance with his instructions, the terms of the Clauses and the terms of the written subcontract;
- (e) *'the applicable data protection law'* means the legislation protecting the fundamental rights and freedoms of individuals and, in particular, their right to privacy with respect to the processing of personal data applicable to a data controller in the Member State in which the data exporter is established;
- (f) *'technical and organisational security measures'* means those measures aimed at protecting personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing.

## Clause 2

### **Details of the transfer**

The details of the transfer and in particular the special categories of personal data where applicable are specified in Appendix 1 which forms an integral part of the Clauses.

## Clause 3

### **Third-party beneficiary clause**

1. The data subject can enforce against the data exporter this Clause, Clause 4(b) to (i), Clause 5(a) to (e), and (g) to (j), Clause 6(1) and (2), Clause 7, Clause 8(2), and Clauses 9 to 12 as third-party beneficiary.
2. The data subject can enforce against the data importer this Clause, Clause 5(a) to (e) and (g), Clause 6, Clause 7, Clause 8(2), and Clauses 9 to 12, in cases where the data exporter has factually disappeared or has ceased to exist in law unless any successor entity has assumed the entire legal obligations of the data exporter by contract or by operation of law, as a result of which it takes on the rights and obligations of the data exporter, in which case the data subject can enforce them against such entity.
3. The data subject can enforce against the subprocessor this Clause, Clause 5(a) to (e) and (g), Clause 6, Clause 7, Clause 8(2), and Clauses 9 to 12, in cases where both the data exporter and the data importer have factually disappeared or ceased to exist in law or have become insolvent, unless any successor entity has assumed the entire legal obligations of the data exporter by contract or by operation of law as a result of which it takes on the rights and

obligations of the data exporter, in which case the data subject can enforce them against such entity. Such third-party liability of the subprocessor shall be limited to its own processing operations under the Clauses.

4. The parties do not object to a data subject being represented by an association or other body if the data subject so expressly wishes and if permitted by national law.

#### *Clause 4*

##### ***Obligations of the data exporter***

The data exporter agrees and warrants:

- (a) that the processing, including the transfer itself, of the personal data has been and will continue to be carried out in accordance with the relevant provisions of the applicable data protection law (and, where applicable, has been notified to the relevant authorities of the Member State where the data exporter is established) and does not violate the relevant provisions of that State;
- (b) that it has instructed and throughout the duration of the personal data processing services will instruct the data importer to process the personal data transferred only on the data exporter's behalf and in accordance with the applicable data protection law and the Clauses;
- (c) that the data importer will provide sufficient guarantees in respect of the technical and organisational security measures specified in Appendix 2 to this contract;
- (d) that after assessment of the requirements of the applicable data protection law, the security measures are appropriate to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing, and that these measures ensure a level of security appropriate to the risks presented by the processing and the nature of the data to be protected having regard to the state of the art and the cost of their implementation;
- (e) that it will ensure compliance with the security measures;
- (f) that, if the transfer involves special categories of data, the data subject has been informed or will be informed before, or as soon as possible after, the transfer that its data could be transmitted to a third country not providing adequate protection within the meaning of Directive 95/46/EC;
- (g) to forward any notification received from the data importer or any subprocessor pursuant to Clause 5(b) and Clause 8(3) to the data protection supervisory authority if the data exporter decides to continue the transfer or to lift the suspension;
- (h) to make available to the data subjects upon request a copy of the Clauses, with the exception of Appendix 2, and a summary description of the security measures, as well as a copy of any contract for subprocessing services which has to be made in accordance with the Clauses, unless the Clauses or the contract contain commercial information, in which case it may remove such commercial information;
- (i) that, in the event of subprocessing, the processing activity is carried out in accordance with Clause 11 by a subprocessor providing at least the same level of protection for the personal data and the rights of data subject as the data importer under the Clauses; and
- (j) that it will ensure compliance with Clause 4(a) to (i).

#### *Clause 5*

##### ***Obligations of the data importer***

The data importer agrees and warrants:

- (a) to process the personal data only on behalf of the data exporter and in compliance with its instructions and the Clauses; if it cannot provide such compliance for whatever reasons, it



- agrees to inform promptly the data exporter of its inability to comply, in which case the data exporter is entitled to suspend the transfer of data and/or terminate the contract;
- (b) that it has no reason to believe that the legislation applicable to it prevents it from fulfilling the instructions received from the data exporter and its obligations under the contract and that in the event of a change in this legislation which is likely to have a substantial adverse effect on the warranties and obligations provided by the Clauses, it will promptly notify the change to the data exporter as soon as it is aware, in which case the data exporter is entitled to suspend the transfer of data and/or terminate the contract;
  - (c) that it has implemented the technical and organisational security measures specified in Appendix 2 before processing the personal data transferred;
  - (d) that it will promptly notify the data exporter about:
    - (i) any legally binding request for disclosure of the personal data by a law enforcement authority unless otherwise prohibited, such as a prohibition under criminal law to preserve the confidentiality of a law enforcement investigation,
    - (ii) any accidental or unauthorised access, and
    - (iii) any request received directly from the data subjects without responding to that request, unless it has been otherwise authorised to do so;
  - (e) to deal promptly and properly with all inquiries from the data exporter relating to its processing of the personal data subject to the transfer and to abide by the advice of the supervisory authority with regard to the processing of the data transferred;
  - (f) at the request of the data exporter to submit its data processing facilities for audit of the processing activities covered by the Clauses which shall be carried out by the data exporter or an inspection body composed of independent members and in possession of the required professional qualifications bound by a duty of confidentiality, selected by the data exporter, where applicable, in agreement with the supervisory authority;
  - (g) to make available to the data subject upon request a copy of the Clauses, or any existing contract for subprocessing, unless the Clauses or contract contain commercial information, in which case it may remove such commercial information, with the exception of Appendix 2 which shall be replaced by a summary description of the security measures in those cases where the data subject is unable to obtain a copy from the data exporter;
  - (h) that, in the event of subprocessing, it has previously informed the data exporter and obtained its prior written consent;
  - (i) that the processing services by the subprocessor will be carried out in accordance with Clause 11;
  - (j) to send promptly a copy of any subprocessor agreement it concludes under the Clauses to the data exporter.

#### *Clause 6*

#### ***Liability***

1. The parties agree that any data subject, who has suffered damage as a result of any breach of the obligations referred to in Clause 3 or in Clause 11 by any party or subprocessor is entitled to receive compensation from the data exporter for the damage suffered.
2. If a data subject is not able to bring a claim for compensation in accordance with paragraph 1 against the data exporter, arising out of a breach by the data importer or his subprocessor of any of their obligations referred to in Clause 3 or in Clause 11, because the data exporter has factually disappeared or ceased to exist in law or has become insolvent, the data importer agrees that the data subject may issue a claim against the data importer as if it were the data exporter, unless any successor entity has assumed the entire legal obligations of the data exporter by contract or by operation of law, in which case the data subject can enforce its rights against such entity.

The data importer may not rely on a breach by a subprocessor of its obligations in order to avoid its own liabilities.

3. If a data subject is not able to bring a claim against the data exporter or the data importer referred to in paragraphs 1 and 2, arising out of a breach by the subprocessor of any of their obligations referred to in Clause 3 or in Clause 11 because both the data exporter and the data importer have factually disappeared or ceased to exist in law or have become insolvent, the subprocessor agrees that the data subject may issue a claim against the data subprocessor with regard to its own processing operations under the Clauses as if it were the data exporter or the data importer, unless any successor entity has assumed the entire legal obligations of the data exporter or data importer by contract or by operation of law, in which case the data subject can enforce its rights against such entity. The liability of the subprocessor shall be limited to its own processing operations under the Clauses.

#### *Clause 7*

##### ***Mediation and jurisdiction***

1. The data importer agrees that if the data subject invokes against it third-party beneficiary rights and/or claims compensation for damages under the Clauses, the data importer will accept the decision of the data subject:
  - (a) to refer the dispute to mediation, by an independent person or, where applicable, by the supervisory authority;
  - (b) to refer the dispute to the courts in the Member State in which the data exporter is established.
2. The parties agree that the choice made by the data subject will not prejudice its substantive or procedural rights to seek remedies in accordance with other provisions of national or international law.

#### *Clause 8*

##### ***Cooperation with supervisory authorities***

1. The data exporter agrees to deposit a copy of this contract with the supervisory authority if it so requests or if such deposit is required under the applicable data protection law.
2. The parties agree that the supervisory authority has the right to conduct an audit of the data importer, and of any subprocessor, which has the same scope and is subject to the same conditions as would apply to an audit of the data exporter under the applicable data protection law.
3. The data importer shall promptly inform the data exporter about the existence of legislation applicable to it or any subprocessor preventing the conduct of an audit of the data importer, or any subprocessor, pursuant to paragraph 2. In such a case the data exporter shall be entitled to take the measures foreseen in Clause 5 (b).

#### *Clause 9*

##### ***Governing Law***

The Clauses shall be governed by the law of the Member State in which the data exporter is established, namely [ \_\_\_\_\_ ]

***Insert appropriate country which will depend on where in the EU the data exporter is established.***

Clause 10

**Variation of the contract**

The parties undertake not to vary or modify the Clauses. This does not preclude the parties from adding clauses on business related issues where required as long as they do not contradict the Clause.

Clause 11

**Subprocessing**

1. The data importer shall not subcontract any of its processing operations performed on behalf of the data exporter under the Clauses without the prior written consent of the data exporter. Where the data importer subcontracts its obligations under the Clauses, with the consent of the data exporter, it shall do so only by way of a written agreement with the subprocessor which imposes the same obligations on the subprocessor as are imposed on the data importer under the Clauses. Where the subprocessor fails to fulfil its data protection obligations under such written agreement the data importer shall remain fully liable to the data exporter for the performance of the subprocessor's obligations under such agreement.
2. The prior written contract between the data importer and the subprocessor shall also provide for a third-party beneficiary clause as laid down in Clause 3 for cases where the data subject is not able to bring the claim for compensation referred to in paragraph 1 of Clause 6 against the data exporter or the data importer because they have factually disappeared or have ceased to exist in law or have become insolvent and no successor entity has assumed the entire legal obligations of the data exporter or data importer by contract or by operation of law. Such third-party liability of the subprocessor shall be limited to its own processing operations under the Clauses.
3. The provisions relating to data protection aspects for subprocessing of the contract referred to in paragraph 1 shall be governed by the law of the Member State in which the data exporter is established, namely [ \_\_\_\_\_ ]. **[Insert appropriate country which will depend on where in the EU the data exporter is established.]**
4. The data exporter shall keep a list of subprocessing agreements concluded under the Clauses and notified by the data importer pursuant to Clause 5 (j), which shall be updated at least once a year. The list shall be available to the data exporter's data protection supervisory authority.

Clause 12

**Obligation after the termination of personal data processing services**

1. The parties agree that on the termination of the provision of data processing services, the data importer and the subprocessor shall, at the choice of the data exporter, return all the personal data transferred and the copies thereof to the data exporter or shall destroy all the personal data and certify to the data exporter that it has done so, unless legislation imposed upon the data importer prevents it from returning or destroying all or part of the personal data transferred. In that case, the data importer warrants that it will guarantee the confidentiality of the personal data transferred and will not actively process the personal data transferred anymore.
2. The data importer and the subprocessor warrant that upon request of the data exporter and/or of the supervisory authority, it will submit its data processing facilities for an audit of the measures referred to in paragraph 1.

**On behalf of the data exporter:**

Name (written out in full): \_\_\_\_\_

Position: \_\_\_\_\_

Address: \_\_\_\_\_

Other information necessary in order for the contract to be binding (if any): \_\_\_\_\_

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

(stamp of organisation)

**On behalf of the data importer:**

Name (written out in full): \_\_\_\_\_

Position: \_\_\_\_\_

Address: **Smith & Nephew, Inc., 1450 Brooks Rd., Memphis, TN 38116, United States**

Other information necessary in order for the contract to be binding (if any): \_\_\_\_\_

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

(stamp of organisation)

**APPENDIX 1 TO THE STANDARD CONTRACTUAL CLAUSES**

This Appendix forms part of the Clauses and must be completed and signed by the parties

The Member States may complete or specify, according to their national procedures, any additional necessary information to be contained in this Appendix

**Data exporter**

The data exporter is (please specify briefly your activities relevant to the transfer):

Exporter is a physician, hospital and/or other healthcare professional or institution who provides medical treatment to orthopaedic patients in need of a medical device or implant.

**Data importer**

The data importer is (please specify briefly activities relevant to the transfer):

S&N customizes medical devices for patients to be used by the Data Exporter through the Visionaire Patient Matched Instrumentation process.

**Data subjects**

The personal data transferred concern the following categories of data subjects (please specify):  
Patients; surgeons or other health care professionals or administrators.

**Categories of data**

The personal data transferred concern the following categories of data (please specify):

Patient Personal Health Information (PHI); Surgeon or other health care professional or administrator  
Business Contact Information.

**Special categories of data (if appropriate)**

The personal data transferred concern the following special categories of data (please specify):

PHI which specifies medical or health conditions about the patient. This information includes: name, date of birth, body part, image and header information (which may include, hospital patient ID number and other information which may identify the individual ).

**Processing operations**

The personal data transferred will be subject to the following basic processing activities (please specify):

PHI will be transferred to the Importer for the design, construction, and delivery activities of the Patient Matched Instrumentation process.

Data importer contracts with the following subcontractors to assist in the execution of processing activities: (i) Cap Gemini (manages infrastructure and data centre hosting), (ii) TATA (supports creation of 3D CAD files).

DATA EXPORTER

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

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

DATA IMPORTER

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

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

**APPENDIX 2 TO THE STANDARD CONTRACTUAL CLAUSES**

This Appendix forms part of the Clauses and must be completed and signed by the parties

**Description of the technical and organisational security measures implemented by the data importer in accordance with Clauses 4(d) and 5(c) (or document/legislation attached):**

**Standards:** S&N complies with a variety of legal and regulatory standards. These include specific country laws globally (including EU Data Protection Directive in Europe) and certain technical standards.

**Secure Procedures:** Specifically, S&N undertakes the following steps to ensure the security of the PHI in the VISIONAIRE Patient Matched Instrumentation process:

- **Secure Uploading of Data.** Image data is uploaded by the imaging centre and/or surgeon to a data storage location via secure/encrypted connection. This data can only be viewed using a specific software application.
- **Secure Storage.** Image data is stored on an access controlled standalone file store. The file store has a hidden share created on it; this share stores all of the data.
- **Limited Use and Access.** This personal, medical data is only used to design, construct and deliver the VISIONAIRE Patient Matched Instrumentation. Only individuals actively involved in this endeavour have access to this data.
- **Limited and Secure Retention.** Processed data is then saved to S&N secure storage (which is also access controlled).

**Secure Website Infrastructure.** Further, to ensure the protection of information on the Secure Visionaire website, S&N's (and any hosting partner that S&N may use) has an extensive security background and deployment architecture including:

- **Secure Hosting Facility.** Web servers are located in a world class Internet hosting environment with several layers of physical security and power, network and Internet redundancy.
- **Secure Authentication.** Account login authentication.
- **Encrypted, Unique Passwords.** Passwords are 'hashed' on the server so they are not stored in clear text.
- **Secure Organization.** Case files for each user are separated in the database by each independent user.
- **Secure Encrypted Website Transmissions.** Encrypted website (https; SSL 3.0) for data in transit between the servers and Customer machine.
- **Secure Back-Up.** "Real-time" off-site data backup.
- **Secure Data Transfer.** Transfer of data within the S&N environment utilises Multiprotocol Label Switching (MPLS) providing a highly secure networking environment.
- **Secure Firewall.** A corporate hardware firewall is in place which protects all external interaction with data on S&N hosted sites.

DATA EXPORTER

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

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

DATA IMPORTER

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

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