This Data Processing and Business Associate Agreement addendum (the "Agreement") is entered into between:

(A) You, also referred to as the "Customer" or "Covered Entity", and

(B) 3SHAPE A/S, a company incorporated in Denmark under the register no. 25553489, for data about Customer's patients generated through the use of products marketed under the "Lab Studio", "Audio Systems" and/or "Dental Systems" brands and related brands;

3SHAPE TRIOS A/S, a company incorporated in Denmark under the register no. 33368771 for data about Customer's patients generated through the use of products marketed under the "TRIOS" brand and related brands; and/or

3SHAPE MEDICAL A/S, a company incorporated in Denmark under the register no. 35802940, for data about Customer's patients generated through the use of products marketed under the "Implant Studio" and/or "X1" brand;

the relevant company hereinafter referred to as the "Supplier" or "Business Associate."

The Customer and the Supplier are hereinafter collectively referred to as the "Parties" and separately as a "Party."

1 DEFINITIONS

1.1 "Data Subjects" has the meaning set forth in Annex 1(b).

1.2 "Disclose" or "Disclosure" means the release, transfer, provision of access to, or divulging in any manner of Protected Health Information outside the entity holding the Protected Health Information.

1.3 "GDPR" means the General Data Protection Regulation (Regulation (EU) 2016/679).

1.4 "HIPAA" means the Health Insurance Portability and Accountability Act of 1996, as amended.

1.5 "HITECH" means the provisions of the American Recovery and Reinvestment Act of 2009 known as the HITECH Act, as amended.

1.6 "Individually Identifiable Health Information" means information, including demographic and genetic information, collected from an individual that:

a) Is created or received by a health care provider, health plan, employer, or health care clearinghouse;

b) Relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and

c) Identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

1.7 "Personal Data" means any information relating to an identified or identifiable natural person as defined in 4(1) of the GDPR.

1.8 "Protected Health Information" or "PHI" means any Individually Identifiable Health Information created or received by Supplier from or on behalf of Customer, that is transmitted or maintained in any form or medium, but excludes (a) Individually Identifiable Health Information in education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. § 1232g; (b) records made with respect to providing treatment to a student who is at least eighteen (18) years old or attending a post-secondary school that are described in 20 U.S.C. § 1232g(a)(4)(B)(iv); and (c) employment records held

by Plan Sponsor in its role as employer. Protected Health Information pertains to both living and deceased individuals.

1.9 "Process" or "Processing" means any operation or set of operations which is performed upon the Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

1.10 "Secretary" means the Secretary of the United States Department of Health and Human Services or his designee.

1.11 "Security Incident" means a breach of security leading to the accidental, unlawful or attempted destruction, loss, alteration, unauthorized Disclosure of, or access to, Data transmitted, stored or otherwise Processed by the Supplier under this Agreement, or information or interference with system operations in an information system.

1.12 "Subsupplier" means any person to whom Supplier delegates a function, activity, or service, other than in the capacity of a member of the workforce of such Supplier, to assist Supplier in carrying out its responsibilities hereunder and otherwise.

1.13 "Use" or "Using" means, with respect to Personal Data and Individually Identifiably Health Information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

1.14 "Personal Data" and PHI are collectively referred to as "Data."

2 SCOPE OF THE AGREEMENT

2.1 This Agreement forms part of the General License Terms and Conditions between Customer and the applicable Supplier to reflect the Parties' agreement with regard to the Processing of Personal Data under the GDPR and PHI in accordance with HIPAA and HITECH, provided the Customer uses Supplier products. If the Customer does not use Supplier products, this Agreement is a stand alone agreement and this Agreement reflects the Parties' agreement with regard to the Processing of Personal Data under the GDPR and PHI in accordance with HIPAA and HITECH.

2.2 The applicable Supplier acts as a data processor for the Customer, as the Supplier Processes Personal Data for the Customer as set out in Annex 1. Each Supplier acts independently and shall be a separate Party to an agreement with the Customer.

2.3 The Data to be Processed by Supplier concerns the categories of Data, the categories of Data Subjects, special categories of Data, and the location, purpose and nature of the Processing set out in Annex 1.

3 PROCESSING, USE AND DISCLOSURE OF DATA

3.1 Instructions: The Supplier is instructed to Process the Data only for the purposes of providing the Data Processing services set out in Annex 1. The Supplier may not Process the Customer's Data for any other purpose than provided in the instructions, including the transfer or Disclosure of Data to any third country or an international organization, unless the Supplier is required to do so according to applicable laws and regulations. In that case, to the extent required by applicable law, the Supplier shall inform the Customer in writing of that legal requirement before Processing, unless that law prohibits such information on important grounds of public interest.

3.2 If the Customer in the instructions in Annex 1 or otherwise has given permission to a transfer of Personal Data to a third country or to international organizations, the Supplier must ensure that there is a legal basis for the transfer, e.g. the EU Commission's Standard Contractual Clauses for the transfer of Personal Data to third countries.

3.3 With respect to PHI, Supplier may Use or Disclose PHI for the following purposes:

(i) Except as otherwise expressly limited in this Agreement, to perform all functions, activities or services for, or on behalf of, the Customer, in connection with the Parties' agreement, provided that such Use or Disclosure would not violate HIPAA (including the minimum necessary standard set forth in § 164.502 (b) of HIPAA).

(ii) Except as otherwise expressly limited in this Agreement, the Supplier may Use or Disclose PHI (i) for the proper management and administration of Supplier's operations, (ii) to the Customer, or person designated by the Customer or Data Subject as necessary to satisfy the Customer's obligations under appropriate laws and regulations, (iii) to carry out the legal responsibilities of Supplier, or (iv) to provide data aggregation services to the Customer as permitted by § 164.504(e)(2)(i)(B) of HIPAA.

(iii) If requested by the Customer in writing, the Supplier is authorized to Use PHI to de-identify such information in accordance with § 164.514(a)-(c) or as directed by the Customer.

(iv) The Supplier may, furthermore, Use PHI to report violations of law to appropriate Federal and State authorities consistent with § 164.502(j)(1) of HIPAA.

3.4 If Supplier considers an instruction from Customer to be in violation of the GDPR, or other Union or member state data protection provisions, or of HIPAA/HITECH, Supplier shall immediately inform Customer in writing.

4 THE SUPPLIER'S GENERAL OBLIGATIONS

4.1 The Supplier must ensure that persons authorized to Process the Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.

4.2 The Supplier shall implement appropriate administrative, technical, physical and organizational measures to prevent the Data Processed from being

(i) accidentally or unlawfully destroyed, lost or altered,

(ii) Disclosed or made available without authorization,

(iii) otherwise Processed in violation of applicable laws, including the GDPR and HIPAA, or

(iv) otherwise Used or Disclosed other than as provided for by this Agreement.

4.3 The appropriate administrative, technical, physical and organizational safeguards must be implemented and addressed with due regard for:

(i) the current state of the art,

(ii) the cost of their implementation, and

(iii) the nature, scope, context and purposes of Processing as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons.

4.4 The Supplier also must comply with the special Data security requirements that apply to the Customer, if agreed (provided, however, that where any such special Data security requirements, extend beyond the standard measures/safeguards implemented by the Supplier pursuant to Clauses 4.2 and 4.3, the Supplier shall be entitled, at its discretion, (i) to refuse to provide the Data Processing services or (ii) only to provide the Data Processing services subject to the Customer's payment to the Supplier of appropriate additional remuneration taking into account any costs attributable to complying with such special Data security requirements), and with any other applicable Data security requirements that are directly incumbent on the Supplier; including the Data security requirements in the country of establishment of the Supplier, or in the country where the Data Processing will be performed, such as Subpart C of Part 164 of HIPAA.

4.5 The Supplier shall, upon request, provide the Customer with sufficient information to enable the Customer to ensure that the Supplier is in compliance with its obligations under this Agreement and with

the applicable laws and regulations, including that the appropriate administrative, technical, physical and organizational safeguards have been implemented.

4.6 The Customer is entitled, at its own cost, to appoint an independent expert who shall have access to the Supplier's Data Processing facilities and receive the necessary information in order to be able to audit whether the Supplier has implemented and maintained said administrative, technical, physical and organizational security safeguards, and other applicable procedures, including for compliance with Parts 160, 162 and 164 of title 45 of the Code of Federal Regulations for PHI. The expert shall upon the Supplier's request sign a customary non-disclosure agreement, and treat all information obtained or received from the Supplier confidentially, and must only share the information with the Customer.

4.7 The Supplier must provide information related to the provision of the services to authorities or the Customer's external advisors, including auditors, if this is necessary for the performance of their duties in accordance with applicable laws and regulations.

4.8 The Supplier must, without undue delay after becoming aware of the facts below, notify the Customer in writing about:

(i) any request for Disclosure of Data Processed under the Agreement by legal or government authorities, unless expressly prohibited under applicable laws and regulations,

(ii) any suspicion or finding of (a) a Security Incident, or (b) other failure to comply with the Supplier's obligations under Clause 4.1 through 4.4, or

(iii) any request for access to the Data received directly from the Data Subjects or from third parties.

4.9 The Supplier must promptly assist the Customer with the handling of any requests from Data Subjects under Chapter III of the GDPR with respect to their Personal Data, including requests for access, rectification, blocking or deletion. The Supplier also must assist Customer by implementing appropriate technical and organizational measures, for the fulfilment of the Customer's obligation to respond to such requests. With respect to PHI, if the Customer requests information related to a Data Subject located in the United States, Supplier shall provide Customer or an individual representing Customer, within five (5) business days of a request by Customer, with information collected about the Data Subject, to permit Customer to respond to a request by a Data Subject of Data in accordance with § 164.528 of HIPAA. Supplier shall document such Disclosure.

4.10 The Supplier must assist the Customer with meeting the other obligations that may be incumbent on the Customer according to applicable laws and regulations where the assistance of Supplier is implied, and where the assistance of the Supplier is necessary for the Customer to comply with its obligations. This includes, but is not limited to, at the request of the Customer to provide the Customer with all necessary information about a Security Incident under Clause 4.8 (ii), and all necessary information for a Personal Data impact assessment in accordance with Article 35 and 36 of the GDPR.

4.11 With respect to the Use and Disclosure of PHI, the Supplier shall:

(i) Mitigate, to the extent practicable and as may be determined by Supplier in its discretion, any harmful effect that is known to Supplier of a Use or Disclosure of PHI by Supplier in violation of the requirements of this Agreement;

(ii) Amend and incorporate any amendments to PHI in accordance with § 164.526 of HIPAA, within ten (10) business days of receipt of a written request of Customer;

(iii) Make its internal practices, books, and records relating to the Use and Disclosure of PHI received from, or created or received by the Supplier on behalf of, the Customer available to the Secretary for purposes of determining the Customer's or the Supplier's compliance with applicable provisions and requirements of HIPAA, in a time and manner designated by the Secretary; and

(iv) Maintain documentation sufficient for the Customer to meet its burden of proof under 45 C.F.R. § 164.414(b) of HIPAA with regard to any Use or Disclosure by the Supplier and to maintain a

written or electronic record of any action, activity, or designation that is required to be documented in accordance with subparts C, D, or E of part 164 of Title 45 of the Code of Federal Regulations (including any risk assessment demonstrating that an impermissible Use or Disclosure did not constitute a Breach). Supplier shall retain such documentation for a period of six (6) years from the date it is created or the date when it was last in effect, whichever is later.

For purposes of § 164.502(b) of HIPAA, in the case of the Disclosure of PHI, the Party Disclosing such information shall determine what constitutes the minimum necessary to accomplish the intended purpose of such Disclosure.

4.12 Any services from the Supplier as set out in Clause 4.8 to 4.11 with respect to Personal Data of Data Subjects in the EU are billable and will be charged in accordance with the price list made available to the Customer upon entering into this Agreement. For PHI, Supplier may charge a reasonable cost-based fee for copying, postage and preparing an explanation or summary that may be required to comply with Clause 4.11, provided the fee is agreed to in advance of providing the services.

5 THE CUSTOMER'S GENERAL OBLIGATIONS

5.1 The Customer shall notify the Supplier of any restriction on the Processing, Use or Disclosure of Data that the Supplier may agree to with respect to a Data Subject, to the extent that such restriction may affect the Supplier's Use or Disclosure of Data. The Supplier shall notify the Customer of any changes in, or revocation of, permission by an Data Subject to Use or Disclose Data, if such revocation or changes affect the Supplier's permitted Uses or Disclosures.

5.2 The Customer may request the Supplier to Disclose Data to other suppliers of Customer; provided, that such other suppliers must agree to similar terms and conditions as are contained in this Agreement in accordance with applicable laws and regulations. Such requests must be made in writing and specify the authorized supplier recipient and the nature and duration of the Disclosure.

5.3 The Customer shall not request Supplier to Use or Disclose Data in any manner that would not be permissible under applicable law, if done by Customer.

5.4. The Customer represents and warrants to the Supplier that it: (1) has included, and will include, in its Notice of Privacy Practices that it may Disclose PHI for health care operations purposes; and (2) has obtained, and will obtain, from Data Subjects, consents, authorizations and other permissions necessary or required by all applicable laws and regulations applicable to Customer for Supplier and Customer to fulfil their obligations under this Agreement. Customer shall provide Supplier with a copy of its notice of privacy practices, developed in accordance with applicable laws and regulations, and any changes thereto, and Supplier shall keep adequate records documenting the distribution of the notice of privacy practices.

6 SUBSUPPLIERS

6.1 The Supplier may engage a subsupplier to Process Data on the Customer's behalf. At the time of the Agreement, the Supplier uses the subsuppliers set out in Annex 2. The Supplier undertakes to inform the Customer of any intended changes concerning the addition or replacement of a subsupplier by providing a prior written notice of two weeks to the Customer. The Customer may object to the use of subsuppliers if such objection is relevant and reasoned in regard to Data protection issues. If the objection is justified in regard to Data protection issues the Supplier will suggest two (2) new sub-suppliers in order for the Customer to accept one of them. The Supplier must inform the Customer in writing of the discontinued use of a subsupplier.

6.2 Prior to the engagement of a subsupplier, the Supplier shall conclude a written agreement with the subsupplier, in which at least the same Data protection obligations, restrictions and conditions as set out in this Agreement shall be imposed on the subsupplier, including an obligation to implement appropriate

administrative, technical, physical and organizational security safeguards in such a manner that the Processing will meet the requirements of the GDPR and HIPAA/TECH. If Supplier becomes aware of a pattern or practice of activity of subsupplier that would constitute a material breach or violation of the written agreement between Supplier and such subsupplier, Supplier shall take reasonable steps to cure such breach or terminate such written agreement with such subsupplier.

6.3 The Customer has the right to receive a copy of the Supplier's agreement with the subsupplier as regards the provisions related to data protection obligations. The Supplier shall remain fully liable to the Customer for the performance of the subsupplier's obligations. The fact that the Customer has given consent to the Supplier's use of a subsupplier is without prejudice for the Supplier's duty to comply with the Agreement.

7 CONFIDENTIALITY

7.1 The Supplier shall keep the Data confidential.

7.2 The Supplier shall not Disclose the Data to third parties or take copies of Data unless strictly necessary for the performance of the Supplier's obligations towards the Customer according to the Agreement and in accordance with the terms of this Agreement, and on condition that whoever Data is Disclosed to is familiar with the confidential nature of the Data and has accepted to keep the Data confidential in accordance with this Agreement, as required by appropriate laws and regulations.

7.3 The Supplier is a legal entity, thus all terms of the Agreement apply to any of the Supplier's employees and the Supplier must ensure that its employees comply with the Agreement, including their commitment to confidentiality.

7.4 The Supplier must limit the access to Data to employees and other personnel for whom access to said Data is necessary to fulfil the Supplier's obligations towards the Customer.

7.5 The obligations of the Supplier under Clause 4 persist without time limitation and regardless of whether the cooperation of the Parties has been terminated.

7.6 The Customer shall treat confidential information received from the Supplier confidentially and may not unlawfully Use or Disclose the confidential information.

8 AMENDMENTS AND ASSIGNMENTS

8.1 The Parties may at any time agree to amend this Agreement. Amendments must be in writing.

8.2 The Supplier may not assign or transfer any of its rights or obligations arising from this Agreement without the Customer's prior, written consent.

9 TERM AND TERMINATION OF THE AGREEMENT

9.1 The Agreement enters into force when the General License Terms and Conditions are accepted and remains in force as long as the Supplier Processes the Data. Termination of the Agreement shall follow termination of the General License Terms and Conditions.

9.2 In case of termination of the Agreement, regardless of the legal grounds therefore, the Supplier must provide the necessary transition services to the Customer. The Supplier is obliged to assist in a loyal way and as fast as possible with Disclosing the Data to another supplier, if conditions set forth in Clause 5.2 are met, or to return them to the Customer.

9.3 On the Customer's request the Supplier shall immediately transfer or delete (including duly anonymize) Data, which the Supplier is Processing for the Customer, and shall retain no copies of such information, unless Union, member state law or other applicable law or regulation requires storage of the Data. In the event that transfer or deletion is not feasible, the Supplier shall extend the protections of this Agreement to the Data and limit further Processing, Use, and Disclosure of such Data to those purposes that make the return or transfer of the information infeasible, for so long as Supplier maintains such Data and shall return or transfer any Data when it is no longer necessary for such purposes.

9.4 Supplier is under no circumstances entitled to condition the full and unlimited compliance with the Customer's instructions on the Customer's payment of outstanding invoices etc., and the Supplier has no right of retention of the Data.

10 MISCELLANEOUS

10.1 If any of the provisions of the Agreement conflict with the provisions of any other written or oral agreement concluded between the Parties, then the provisions of this Agreement shall prevail. However, the requirements in Clause 4 do not apply to the extent that the Parties in another agreement have set out stricter obligations for the Supplier. Furthermore, the Agreement shall not apply if and to the extend the EU Commission's Standard Contractual Clauses for the transfer of Personal Data to third countries are concluded and such clauses set out stricter obligations for the Supplier and/or for sub-suppliers.

10.2 This Agreement does not, other than as expressly provided for herein, determine the Customer's remuneration of the Supplier for the Supplier's services according to the Agreement.

10.3 If HIPAA and/or HITECH are amended (including, without limitation, by way of anticipated regulations yet to be promulgated as provided in HITECH), or if new laws and/or regulations affecting the terms required to be included in business associate agreements between covered entities and business associates are promulgated, and either Party determines that modifications to the terms of this Agreement are required as a result, then promptly following a Party's request, the Parties shall engage in good faith negotiations in an effort to arrive at mutually acceptable changes to the terms set forth in this Agreement that address such amended or new law and/or regulation. If the Parties are unable to agree on such modifications following a reasonable period of such good faith negotiations, which shall in no case extend beyond the effective date of such amended or new law and/or regulations, then any Party that would become non-compliant in the absence of such modifications shall have the right to terminate this Agreement, and the provisions of Clause 9.3 shall then apply.

10.4 Notices. Any notice required or permitted under this Agreement shall be given in writing to Customer and to Supplier at: DPO@3shape.com.

10.5 Notices will be deemed to have been received upon actual receipt, one (1) business day after being sent by overnight courier service or facsimile, or three (3) business days after mailing by first-class mail, whichever occurs first.

10.6 Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of Denmark.

10.7 Interpretation. Any ambiguity in this Agreement with respect to PHI shall be resolved to permit compliance by the Parties with HIPAA and HITECH.

10.8 No Third Party Beneficiary. Nothing in this Agreement is intended, nor shall be deemed, to confer any benefits on any third party.

ANNEX 1

This Annex constitutes the Customer's instruction to the Supplier in connection with the Supplier's Data Processing for the Customer, and is an integrated part of the Agreement.

***The Processing of* Data**

a) Purpose and nature of the Processing operations

To facilitate the functionality and use of the Software as well as for the purpose of storage

To anonymize data for further use for development and improvement purposes.

To facilitate support if requested

To analyze performance and usage in order to understand the usage of the software for statistical purposes and for the purpose of improving the software.

b) Categories of Data Subjects

1) Patients treated by the Customer

2) Dentists or employees of the Customer

3) Customer's of the (3Shape) Customer

c) Categories of Personal Data and Individually Identifiable Health Information

1) Name, personal identification number, age, sex, address

2) Name, IP address, product use.

d) Special categories of Data

Ethnicity, information on condition in mouth and teeth, ears

e) Location(s), including the country of the Processing operations

European Economic Area, Ukraine and the United States

ANNEX 2

Subsuppliers

3Shape TRIOS A/S and 3Shape Medical A/S both use the following subsupplier:

3Shape A/S
Holmens Kanal 7
1060 København K

3Shape A/S uses the following subsupplier, which is also sub-subsupplier for 3Shape TRIOS A/S and 3Shape Medical A/S:

Microsoft Ireland Operations, Ltd.
Carmenhall Road
Sandyford, Dublin 18, Ireland

3Shape Poland Sp. z o.o.
Zapadła 8d
70-033 Szczecin, Poland