

END USER LICENSE AGREEMENT
FOR DTX Studio™ Clinic
Version 3.* (2022-07-22)

THIS IS A CONTRACT. PLEASE READ THIS LICENSE AGREEMENT CAREFULLY BEFORE PRESSING THE "AGREE" BUTTON BELOW. BY PRESSING "AGREE", YOU AGREE TO BE BOUND BY THE TERMS OF THIS LICENSE AGREEMENT AND ANY TERM INCORPORATED HEREIN. IF YOU DO NOT AGREE TO THE TERMS OF THIS LICENSE AGREEMENT, PRESS "DISAGREE" AND PROMPTLY RETURN THE SOFTWARE TO COMPANY; YOUR LICENSE FEE WILL THEN BE REFUNDED, IF ALREADY PAID.

1. LICENSE, RIGHT TO INSTALL AND USE OF THE SOFTWARE

This end user license agreement (the "**Agreement**") is concluded between you and Medicim NV, Stationsstraat 102 b6, B-2800 Mechelen, Belgium and/or any other affiliated company of our group from which you received DTX Studio Clinic ("**Company**") and governs the use of DTX Studio Clinic software products including related data and libraries that are part of the DTX Studio Clinic product, driver software for image acquisition devices that are part of the installer, and related written materials (the "**Software**"). This Agreement also governs the support and maintenance relating to the Software. The Company grants you as the end user a non-exclusive and limited license to use this copy of the Software (the "**License**"). The Software is licensed, not sold, to you. The License is non-transferable except for transfers of the Software to another computer or another operating system of the same user, practice location or Institution, subject to your specific license terms. The License is subject to further terms and conditions depending on the license type you have concluded with the Company as defined in section 2 below, and as defined and communicated to you by the Company prior to the conclusion of this Agreement.

2. LICENSE AND DEFINITIONS

2.1 General license terms

Use of the Software: The copyright and other proprietary notices that appear on or in the Software must be reproduced on any permitted copy. You shall comply with all applicable laws and regulations in connection with the use of the Software. You may use the Software only for the intended purposes as defined in the Instructions for Use ("**IFU**") and/or in the Software User's Guide at each point in time, or for personal or internal training, education or demonstration. Any right to use the Software for external training, education or demonstration of the Software is subject to prior written approval by the Company. The Company may control the number and type of Licenses and the use of the Software by key codes or by other means.

Authorized Users: The Software is only available to authorized users, defined as dentists (including, but not limited to, periodontists, prosthodontists, orthodontists, endodontists), oral and maxillofacial surgeons, dental technicians, dental students under supervision, Universities or similar institutions, and dental laboratories (to the extent permitted by local applicable legislation), or authorized employees, auxiliary persons, contractors, representatives or agents thereof ("**Authorized Users**"). By installing, copying or by using the Software, you represent being an Authorized User. If you cannot adhere to the above representation, the Company is unwilling to license the Software and the installation and/or use of the Software is a violation of national and international copyright laws and conventions. If you accept the terms of this Agreement on behalf of a person or entity which is an Authorized User and on whose behalf you are authorized to act, you may only use the Software on behalf of such person or entity. In this case you are jointly and severally bound under this Agreement together with such person or entity.

Connectivity: The Software may require regular connection with our servers to maintain proper functionality. You agree that the Company may temporarily, without notice to you, suspend your access to the Software in case We do not detect a connection of your computer device to our servers for more than fourteen (14) consecutive days. This suspension shall last until said computer device is connected again to our servers, provided that the License is still valid at that time.

Cloud Functionality: refers to functionality in the Software, which enables either one of transmitting, receiving or storing data via or on a cloud platform managed by Company. For avoidance of doubt, depending on the nature of the Software, the type of license or the user account, the Cloud Functionality may be limited to one of transmitting, receiving or storing data.

Dongle: Certain modules of the Software may be dongle controlled and may only be run on the machines where a dongle is attached.

Maintenance Package: refers to a subscription-based service for maintaining functionality of the Software. Unless otherwise specified by Company in the specific license terms as referred to in Section 2.2, said the Maintenance Package service comprises:

- providing of Updates of the Software at such time and in such way as Company at its own discretion deem appropriate.
- other services, which Company communicated to be included in the Maintenance Package.

The Maintenance Package shall not include the provision of Upgrades and other modified versions of the Software.

Service Provider: a third-party service provider, from which certain services can be requested through the Software. Such services may include diagnostic, prosthetic design and surgery planning services, clinical tools, including custom tools, such as surgical guides, dental products, including implants and custom dental prosthetics based on data representing the patient's oral anatomy, ordered products, and CAD information.

Update: shall mean minor extensions to the supplied functionality and/or replacement of the manner of functioning of a supplied functionality by a newer functionality which has improved characteristics, but which does essentially retain the original functional scope and/or implements it differently.

Upgrade: shall mean extension of the Software feature set.

User Account: each Authorized User will receive a username and a password to create an account. It is the responsibility of each Authorized User to maintain the confidentiality of such credentials and to update them regularly to prevent unauthorized access. You agree to have a secure and strong password and to apply and maintain appropriate security measures to protect it. It is recommended that you have an active and up-to-date antivirus and anti-malware software with a correctly configured firewall on the computer on which you are using the Software. You are solely responsible for the access to your user account and any use of the Software through your user account. Any changes of records made by using your user account will be traced and assigned to you as the owner of such a user account.

2.2 Specific license terms

Within the license offer provided to you at the moment of the granting of a license to the Software, Company may specify further terms and conditions of the specific license granted, including but not limited to number of Authorized Users and the number of computers on which the Software can be installed under the license.

2.3 Duration of the License

This License is granted to you for a period of one (1) year from the activation date of your first License and includes the Maintenance Package (see 3.2) for the duration of said one-year period. After this initial one-year period, the payment of an annual Maintenance Fee in accordance with Section 3 will be required. If you decide not to pay the Maintenance Fee, you will retain the right to use the version of the Software as installed on your system at that time. However, without payment of the Maintenance Fee you shall no longer benefit from the services of the Maintenance Package and you may eventually lose access to basic technical support (see 3.1 iii).

3. TECHNICAL SUPPORT

3.1 Basic Technical Support

The Company may provide limited basic technical support related to the usage of the Software, which may include internet-based support during business hours, and access to certain information online. The Company collects and links data about your software usage to your license so that the company can improve the technical support it provides to you. This software usage data is used by our support teams to troubleshoot support issues that you raise. For more information about the information the Company collects and how to opt out please refer to Clause 5 Data Privacy.

Basic technical support **does not** include

- (i) training and educational support;
- (ii) the free providing of updates, upgrades or modified versions of the Software;
- (iii) support for versions which are either (i) older than the two (2) most recent versions of the Software or (ii) older than three (3) years, of which the Company does not guarantee the functionality;
- (iv) support in connection with third party software. You acknowledge that additional third-party software not approved by Company for use in connection with the Software may affect the performance of the Software.

3.2 Maintenance

Maintaining of performance of the Software requires the subscription to a Maintenance Package. The Maintenance Package is included in your License during the first year from the date of your first conclusion of the License with us. After this first year, Company will charge an annual maintenance fee as consideration for the services according to the Maintenance Package (the “**Maintenance Fee**”). The amount and currency of the Maintenance Fee shall be communicated by Company prior to the conclusion of this Agreement and will thereafter be defined by Company for any further annual payment of the Maintenance Fee. The Maintenance Fee will be invoiced by Company at the beginning of every year of usage of the Software and shall be paid within thirty (30) days upon receipt of the invoice. The Maintenance Package is not transferable. The Maintenance Package will be automatically renewed after every year of usage. You can terminate the Maintenance Package by written termination note delivered to Company at least three (3) months prior to the yearly renewal date. If you decide to again subscribe to the Maintenance Package after termination of the same, Company will charge an extra reactivation fee in addition to the Maintenance Fee. In case of a termination of this Agreement by Company in accordance with section 9 below prior to the end of a year of usage, the respective amount of the Maintenance Fee will be reimbursed on a pro rata temporis basis.

In addition, Company may offer you a variety of reduced, enhanced or otherwise modified adaptations of the Maintenance Package with different features and services (the “**Additional Maintenance Package**”). The Additional Maintenance Packages each include the features or services as communicated from time to time. Except for the included features and services, all terms and

conditions for the Maintenance Package as defined in this Agreement shall also apply to the respective Additional Maintenance Packages.

4. ORDERING THROUGH THE SOFTWARE

The Software may allow you to order certain services, including diagnostic, prosthetic design and surgery planning services, clinical tools, including custom tools, such as surgical guides, dental products, including implants and custom dental prosthetics based on data representing the patient's oral anatomy, ordered products, and CAD information. Any information on products provided in the Software does not constitute an offer of or solicitation for sale or other transaction. Some products shown or described in the Software may not be available or not be regulatory cleared, released or licensed for sale in all markets. For current product assortment and availability of the Company products, please contact your local Company office or dealer. Orders for dental products or services are binding for you and become binding for the Company or Service Provider upon acceptance of the order. The Company or Service Provider may reject such orders in case the provided data or information are not in line with required specifications expectations or for other legitimate reasons.

By sending an order for custom tools or dental products you represent that: (i) You have complied with the specific technical constraints that govern the manufacturing of the specific product, (ii) you are satisfied with and approve the design of the ordered product, (iii) you acknowledge that the Company or Service Provider does not make any medical or clinical review of your design, and (iv) you agree that the Company or Service Provider therefore does not assume any liability for damages or injuries resulting from your design and produced product. In addition to the provisions of this Agreement, such orders will be governed by the terms and condition of the entity you are ordering from; whereas in case of conflicts the provisions of this Agreement shall prevail.

5. DATA PRIVACY

5.1 Transmission of Data through the Software

As an Authorized User, you may be subject to the laws and regulations of one or more jurisdictions, including but not limited to, laws and regulations that may apply to your use, collection, disclosure, transmission or retention of personally identifiable information, including health information. It is the Authorized User's sole responsibility to comply fully with all such applicable laws and regulations.

When sending data or information to the Company you expressly agree that the Company does not desire or require access to any of your patients' personally identifiable information, including health information, and that you will not submit any patients' personally identifiable information, including health information, to the Company, or refer to any particular patient, any particular patient's medical condition, or otherwise disclose to the Company any other information which could identify a particular patient, in connection with your use of the Software or the Company's provision of technical support or maintenance of the Software. The Company reserves the right to delete without prior notice the content or parts of the content of any transmission in relation to the Software sent to the Company that the Company believes is in violation of applicable laws. The Company is entitled to log and store all data pertaining to any such transmission. To the extent any such transmission contains patient data or other personal and/or confidential data, you have the full responsibility for the processing of such data and you should comply with all applicable laws and regulations, including, but not limited to, laws and regulations that require that you obtain and maintain the prior express consent of the patient before transmitting the patient's data to third parties. In exceptional circumstances we may inform you that we are unable to resolve a support request without access to patient personally

identifiable information. If it is necessary for the Company to access patient personally identifiable information in order to resolve a support request we will request your approval to do so and the information will be processed in accordance with the Data Processing Agreement or Business Associate Agreement (as applicable set out at Annex 1 and Annex 2). You agree to indemnify and hold the Company harmless with respect to any claim based upon the content of your transmissions or the sharing of patient records.

The Software may enable you to store and transmit records through Company's Cloud functionality. Records that you store or transmit using the Cloud Functionality may contain patient personally identifiable information, including health information. The information will be processed in accordance with the Data Processing Agreement or Business Associate Agreement (as applicable set out at Annex 1 and Annex 2). Company has put in place adequate technical and organizational measures in place in order to ensure an adequate security of your data. The servers we use are based in the European Economic Area. We may transfer, upon your instructions (for example if you decide to share a record with a third party), such data to another jurisdiction. It is your entire responsibility to ensure that you have the right to instruct us for such transfer such data to another jurisdiction and you agree to indemnify and hold the Company harmless against any claim arising out of or related to such cross-border transfer of data that would originate from your instructions.

If you are practicing in the United States, by accepting these terms, you agree to be bound by our business associate agreement that you can find as Annex 1 to this Agreement (HIPAA Business Associate Agreement). This business associate agreement covers our relationship to you with regards to certain protected health information, in accordance with the Health Insurance Portability and Accountability Act (HIPAA).

If you are practicing in a country of the European Union, UK, Norway, Lichtenstein, Iceland or Switzerland, by accepting these terms, you agree to be bound by our data processing agreement that you can find under Annex 2 to this Agreement (EU Data Processing Addendum). This agreement covers our relationship when Company acts as a processor to the personal data you control, in accordance with the EU General Data Protection Regulation (and for the UK, the UK GDPR & DPA 2018) or other applicable data protection law.

Patient records may contain patient data. Please note, that you alone decide with whom you want to share your patient records and it is your responsibility to determine whether you require the respective patient's consent for sharing patient data with third parties (which may include Software users of your clinic, group practice or similar institution), and to obtain all required consents. It is also your responsibility to ensure that you are allowed to transfer such records to a particular jurisdiction. By sharing patient records using the Software via the Cloud Functionality or otherwise you represent and warrant that (i) you have obtained all contained patient data lawfully and with the patient's consent, if necessary (ii) you have obtained the prior approval, as required, of every patient for sharing the respective patient data, (iii) you use such patient records only for lawful purposes and within the course of dental practice, and (iv) you are compliant with applicable patient rights regulation and legislation, and data protection laws. Please note that it may be possible for you to anonymize the data prior to sharing it with others by deleting the relevant patient data or by using the anonymization function in the Software. Notwithstanding anything to the contrary, it is your sole responsibility to ensure that your deletion of data or use of the anonymization function in the Software is in compliance with laws and regulations, including requirements for anonymization or de-identification of personally identifiable health information, that are applicable to you.

5.2 Your privacy

The Company is committed to protecting your privacy.

Type of data collected and purpose of collection: Company may collect your e-mail address, name, address, telephone number, profession or other information in relation to purchases (e.g. credit card number, user name/ user ID, IP address, MAC address or other device identifier or other information that you provide us. Such personal data may be used to improve and operate the Software including product ordering, customer service and other services including marketing (e.g. sending product information), for software enhancement, commercial business analysis and evaluation or other similar reason and to communicate with you. In some instances, such as during the installation of the Software or as part of a customer service enquiry, you may be obliged to provide us with some information in order for us to perform our services. In other instances, we may use your contact details in order to send you product information, or Company information that we believe are of interest to you.

If you do not want to receive such marketing communication from the Company, you may inform us by sending an email at privacy@dtxstudio.com

Company may also collect certain information on the use of the Software such as technical information (e.g. CPU speed and operating system), general usability information (e.g. usage of workspaces or shortcuts), actual usage information (e.g. scanner and operating system used) and commercial information (e.g. design and ordering pattern). Company may use this information to help us troubleshoot issues and to improve the Software and customer experience. Company may also use actual usage and commercial information to help us understand the use of the Software for the purposes of improving the Software in relation to the needs of our customers and for commercial business analysis and evaluation .

You may opt out of the collection of this information by sending an email to privacy@dtxstudio.com.

Further information on how we handle personal data can be found in our Privacy Notice: <https://envistaco.com/en/privacy-policy>

Transfer of data to third parties: Company does not sell or disclose your Personal Data to third parties without your consent, except:

- To affiliates and third-party service providers to provide services (including support services) and information on our Software and related products, including marketing and advertising, and to support our business operations. We require these parties to handle Personal Data in accordance with our Privacy Notice.
- To affiliates to offer and provide information about related products and services. We do not share Personal Data from countries that require consent, unless consent has been obtain in advance to sharing with related affiliates. We require these parties to handle Personal Data in accordance with our Privacy Notice.
- To another company in connection with the sale or transfer of one of our product lines or divisions, which includes the services provided through one or more of the Company's affiliates.
- To governing regulatory authorities, including the US Food and Drug Administration, or as may otherwise be necessary for Company to comply with a legal obligation or demand.
- To authorities or third parties in order to enforce this Agreement or protect the rights, property or safety of the Company, its affiliates, employees, users of the Software or the public

In the event Company decides to reorganize or divest our business through sale, merger, or acquisition, Company may share Personal Data about you with actual or prospective purchasers. We will require any actual or prospective purchasers to treat this Personal Data in a manner consistent with this notice.

You can find all related affiliates here: <https://www.envistaco.com>

Data Transfers: Company may transfer your personal data to, or store it at, a destination outside the European Economic Area (“EEA”) Switzerland or UK. It may also be processed by staff operating outside the EEA, Switzerland or UK, who work for us or for one of our suppliers. Such staff may be engaged in, among other things, the fulfilment of your order, the processing of your payment details and the provision of support services. Where the Company has to transfer your personal data to other third countries, we will use appropriate approved safeguards or we will seek your explicit consent. For further information, please do not hesitate to contact us using the details below: Medicim NV, Stationsstraat 102, 2800 Mechelen, Belgium, or contact us at privacy@dtxstudio.com

Your rights: You have the right to see and get a copy of Personal Data about you that we maintain as well as to ask us to make corrections to inaccurate or incomplete Personal Data about you. You have the right to receive data you have provided to us in a machine-readable format and to transmit that data to another controller. You may also request the erasure of your Personal Data or the restriction of its processing, object to the processing of Personal Data about you or withdraw your consent. To seek access to Personal Data about you, to file a concern, complaint, or request for correction, or to opt-out of particular programs, please contact our Privacy Office by emailing us at privacy@dtxstudio.com.

Your Local Data Protection Authority is responsible for making sure that privacy law is followed in the relevant countries. For more information about your privacy rights, or if you are not able to resolve a problem directly with us and wish to make a complaint, contact your local Data Protection Authority: http://ec.europa.eu/justice/data-protection/bodies/authorities/index_en.htm.

Security Measures: The Company will implement appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access by unauthorized third parties and against other unlawful forms of processing. However, we cannot guarantee that unauthorized third parties will not thwart our security systems and gain unlawful access to your personal data.

Our privacy policy, which is incorporated to this Agreement by reference, is available in full here: <https://envistaco.com/en/privacy-policy>

6. COPYRIGHT AND OTHER INTELLECTUAL PROPERTY

The Company and its affiliates own or have the right to license the Software and the Software is protected by national copyright law and international treaty provisions. You may not modify, adapt, translate, reverse engineer, decompile, disassemble, or otherwise attempt to discover the source code of the Software (except to the extent required to obtain interoperability with other independently created computer programs or as permitted by compulsory law). The Software may also be covered by one or more patents.

The Software comprises references to third-party products. These products are referred to using the tradenames and trademarks owned by such third parties.

7. RESTRICTIONS

Except as expressly permitted by this Agreement or by the applicable mandatory law, you are not entitled to lease, rent, loan, timeshare, resell, assign, transfer, license or sublicense, or otherwise

distribute or grant any rights of use (such as usufruct) to the License or the Software to any third party without the explicit written consent of the Company.

You agree that the Software will not be shipped, transferred or exported into any country or used in any manner prohibited by the United States Export Administration Act, or any other export laws, restrictions or regulations.

These items are controlled and authorized by the U.S. Government for export only to the specified country of ultimate destination for use by the end-user herein identified. They may not be resold, transferred, or otherwise disposed of, to any other country or to any person other than the authorized end-user or consignee(s), either in their original form or after being incorporated into other items, without first obtaining approval from the U.S. government or as otherwise authorized by U.S. law and regulations.

8. WARRANTY AND LIABILITY

The Company warrants, for a period of six (6) months from delivery, that the Software as made available to you by the company will perform in accordance with the Company's then current product description when operated according to its instructions. The Company's liability for any damages caused by the use of the Software is excluded to the extent permitted by law, if you have omitted to Update/Upgrade your installed copy of the Software for six (6) months or more with such Update/Upgrade as the Company has made available in accordance with section 3 above. Further Company's liability under this Agreement is limited to an obligation of the Company to correct, or in its sole discretion, to replace the Software with software of equivalent functionality. Correction and replacement, as specified in this section 8, are the sole remedies available for you in case of any defects in the Software.

By installing and/or using the software, you confirm that you have the full knowledge how to use the software safely and effectively. The software is no replacement of the adequate and careful dental diagnostics and treatment in accordance with the medical duty of care. You are using the software at your own risk. The company therefore specifically denies any liability for indirect, incidental, special or consequential damages resulting from the sale or use of the software, except if such damage is caused by a gross negligent or wilful misconduct of the company to the extent permitted by applicable law.

9. INDEMNIFICATION

The Company will defend, indemnify, save and hold you harmless from any money judgment, costs, and attorney fees awarded or in settlement to the extent such are due to a claim that the Software, as provided by the Company, infringes a copyright or protected trade secret of any third party. This indemnity is subject to the Company being provided prompt notice of such claim and being granted full control of the defence or settlement thereof. The Company specifically disclaims any liability for patent infringement. The indemnity of this section 9 is the sole remedy available for you for infringement of any rights.

You shall indemnify and hold harmless the Company from any damages and any money judgment, costs, and attorney fees awarded or in settlement to the extent such are due to a claim from a third party based on the unlawful disclosure, use, sharing or transmission of patient data or the infringement or breach of applicable patient rights regulation and legislation, and data protection laws, or for any breach of this Agreement by you.

10. TERM AND TERMINATION

This Agreement and the herewith agreed upon License are effective from the date of your acceptance (which is submitted by pressing the "AGREE" button below) until its termination in accordance with this section 10.

Right to terminate: Company or You may terminate the Agreement and the License unilaterally at any time by prior written notice to the other Party, including e-mail or other electronic communication in connection with the Software.

Automatic termination: The License shall automatically terminate upon failure by You to comply with any term of this Agreement.

Upon termination: You agree to immediately destroy the Software and all copies, modifications and merged portions in any form and promptly return the Software to the Company. Your User Account will be deleted promptly. The Company shall block any Authorized User from accessing the Software under the same License by any appropriate technical means. The Company will store records received from You for ninety (90) days from the termination in which period you shall be entitled to obtain a copy of any such data or records. After this period, the Company will delete such records, unless required otherwise.

11. GENERAL PROVISIONS, GOVERNING LAW AND JURISDICTION

If any part of this Agreement is found void and unenforceable, the remaining of the Agreement shall remain valid and enforceable according to its terms. The Company is entitled to change the terms of this Agreement; any and all changes shall become effective the earliest of You accepting them (e.g. at installation of an Update/Upgrade), or thirty (30) days after the communication of such change (by notice to you or by update of these terms). This Agreement shall be governed by the substantive laws of Belgium. The exclusive place of jurisdiction shall be at the registered office of Company.

Annex 1: HIPAA Business Associate Agreement

This Business Associate Agreement (“BAA”) is entered into by and between the authorized users (as defined in the End User License Agreement) (“Covered Entity”) and Medicim NV, Stationsstraat 102 b6, B-2800 Mechelen, Belgium and/or any other affiliated company of our group from which you received DTX Studio Clinic (collectively “Business Associate”) (collectively referred to herein as the “Parties”), effective as of the date the End User License Agreement is agreed upon by the Covered Entity.

WHEREAS, the Parties have entered into one or more services agreements (“Services Agreement”) whereby Business Associate performs certain functions, activities, or services for or on behalf of Covered Entity that involve the use or disclosure of Protected Health Information (as defined herein) and Electronic Protected Health Information (as defined herein); and

WHEREAS, this BAA is intended to comply with the requirements of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and implementing regulations, the Standards for Privacy of Individually Identifiable Health Information (the “Privacy Rule”) the Security Standards for the Protection of Electronic Protected Health Information (the “Security Rule”), and the privacy, security and Breach Notification regulations of the Health Information Technology for Economic and Clinical Health (“HITECH”) Act and the HIPAA Omnibus final rule (collectively, the “HIPAA Rules”), as amended from time to time.

NOW, THEREFORE, in consideration of the Parties’ continuing obligations under the Services Agreement between the Parties, the agreements herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

1. Definitions

Except as otherwise defined herein, any and all capitalized terms in this BAA shall have the definitions set forth in the Privacy Rule or the Security Rule.

- (A) “Breach” has the meaning given to such term in 45 C.F.R. § 164.402.
- (B) “Business Associate” has the meaning set forth above.
- (C) “Covered Entity” has the meaning set forth above.
- (D) “Designated Record Set” has the same meaning as the term “designated record set” in 45 C.F.R. § 164.501 of the Privacy Rule.
- (E) “Electronic Protected Health Information” (“E PHI”) has the same meaning as the term “electronic protected health information” in 45 C.F.R. § 160.103 of the Security Rule, limited to the information created or received by Business Associate from or on behalf of Covered Entity.
- (F) “Health Information Technology for Economic and Clinical Health (“HITECH”) Act” has the meaning set forth above.
- (G) “HIPAA” has the meaning set forth above
- (H) “Individual” has the same meaning as the term “individual” in 45 C.F.R. § 160.103 of the Privacy Rule.

- (I) “Privacy Rule” has the meaning set forth above.
- (J) “Protected Health Information (“PHI”)” has the same meaning as the term “protected health information” in 45 C.F.R. § 160.103 of the Privacy Rule (including, without limitation, Electronic Protected Health Information), limited to the information created or received by Business Associate from or on behalf of Covered Entity.
- (K) “Required by Law” has the same meaning as the term “required by law” in 45 C.F.R. § 164.103 of the Privacy Rule.
- (L) “Secretary” means the Secretary of the Department of Health and Human Services or his or her designee.
- (M) “Security Incident” has the same meaning as the term “security incident” in 45 C.F.R. § 164.304 of the Security Rule.
- (N) “Security Rule” has the meaning set forth above.
- (O) “Unsecured PHI” has the meaning given to such phrase in the Breach Notification Rule at 45 C.F.R. § 164.402.

2. **Obligations and Activities of Business Associate**

- (A) Business Associate acknowledges and agrees that all PHI that is created or received by Covered Entity and used by or disclosed to Business Associate or created or received by Business Associate on Covered Entity’s behalf shall be subject to this BAA.
- (B) Business Associate agrees to not use or disclose PHI other than as permitted or required by this BAA or as Required by Law.
- (C) Business Associate agrees to use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this BAA.
- (D) Business Associate agrees to notify Covered Entity promptly following discovery of any Breach of Unsecured PHI. Business Associate will provide such information to Covered Entity as required in the Breach Notification Rule.
- (E) Business Associate agrees to report to Covered Entity any use or disclosure of PHI not provided for by this BAA or any Security Incident of which it becomes aware.
- (F) Business Associate agrees to ensure that any agent, including a subcontractor, to whom it provides PHI received from, or created or received by Business Associate for, or on behalf of, Covered Entity agrees in writing to substantially similar restrictions and conditions that apply through this BAA to Business Associate with respect to such information.
- (G) To the extent Business Associate maintains PHI in a Designated Record Set, Business Associate will make such PHI available to Covered Entity within thirty (30) business days of a request by Covered Entity for access to such PHI. For avoidance of doubt, Covered Entity understands and agrees that Business Associate does not maintain any PHI in a Designated Record Set. If an Individual makes a request for access directly to Business Associate, Business Associate will within thirty (30) business days forward

such request in writing to Covered Entity. Covered Entity will be responsible for making all determinations regarding the grant or denial of an Individual's request for PHI and Business Associate will make no such determinations. Only Covered Entity will release PHI to an Individual pursuant to such a request, unless Covered Entity directs Business Associate to do so.

- (H) To the extent Business Associate maintains PHI in a Designated Record Set, Business Associate will provide such PHI to Covered Entity for amendment within thirty (30) business days of receiving a request from Covered Entity to amend an Individual's PHI. For avoidance of doubt, Covered Entity understands and agrees that Business Associate does not maintain any PHI in a Designated Record Set. If an Individual makes a request for amendment directly to Business Associate, Business Associate will within thirty (30) business days forward such request in writing to Covered Entity. Covered Entity will be responsible for making all determinations regarding amendments to PHI and Business Associate will make no such determinations unless Covered Entity directs Business Associate to do so.
- (I) Within thirty (30) days of receiving a written request from Covered Entity, Business Associate shall provide to Covered Entity an accounting of the disclosures of the Individual's PHI in accordance with 45 C.F.R. § 164.528. If an Individual requests an accounting of Disclosures directly from Business Associate, Business Associate will forward the request and its record of Disclosures to Covered Entity within thirty (30) business days of Business Associate's receipt of the Individual's request. Covered Entity will be responsible for preparing and delivering the accounting to the Individual. Business Associate will not provide an accounting of its Disclosures directly to any Individual, unless directed by Covered Entity to do so.
- (J) Business Associate agrees to make internal practices, books, and records, including policies and procedures and PHI, relating to the use and disclosure of PHI received from, or created or received by Business Associate on behalf of, Covered Entity, available to the Secretary, in a time and manner designated by the Secretary, for purposes of the Secretary determining Covered Entity's compliance with the Privacy Rule.

3. Permitted Uses and Disclosures by Business Associate

- (A) Except as otherwise limited by this BAA, Business Associate may use or disclose PHI to perform functions, activities or services for or on behalf of Covered Entity as contemplated in the Services BAA, provided that such use or disclosure does not violate the Privacy Rule or the HITECH Act if done by Covered Entity.
- (B) Except as otherwise limited by this BAA, Business Associate may use PHI for the proper management and administration of Business Associate or to carry out the present and/or future legal responsibilities of Business Associate.
- (C) Except as otherwise limited by this BAA, Business Associate may disclose PHI for the proper management and administration of Business Associate, provided that disclosures are Required by Law, or Business Associate obtains reasonable assurances from the person to whom the PHI is disclosed that it will remain confidential and be used or further disclosed only as Required by Law or for the purpose for which it was disclosed to the person, and the person notifies Business Associate of any breaches in the confidentiality of the PHI.

- (D) Business Associate may use PHI to report violations of law or other conduct to appropriate federal and state authorities or other designated officials, consistent with 45 C.F.R. § 164.502(j)(1).
- (E) Business Associate may use PHI to aggregate data as permitted by 45 C.F.R. § 164.504(e)(2)(i)(B).
- (F) Business Associate may use PHI to create de-identified information in accordance with 45 CFR § 164.514.

4. Obligations of Covered Entity on Behalf of Business Associate

- (A) Covered Entity shall notify Business Associate of any limitation(s) in its notice of privacy practices within fifteen (15) business days of Covered Entity's receipt of the Individual's request in accordance with 45 C.F.R. § 164.520, to the extent that such limitation(s) may affect Business Associate's use or disclosure of PHI.
- (B) Covered Entity shall notify Business Associate of any changes in, or revocation of, permission by an Individual to use or disclose PHI within fifteen (15) business days of Covered Entity's receipt of the Individual's request, to the extent that such changes may affect Business Associate's use or disclosure of PHI.
- (C) Covered Entity shall notify Business Associate of any restriction to the use or disclosure of PHI that it has agreed to within fifteen (15) business days of Covered Entity agreeing to such restriction in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.
- (D) Covered Entity shall not request that Business Associate use or disclose PHI in any manner that would not be permissible under HIPAA if done by a Covered Entity (unless permitted by HIPAA for a business associate).
- (E) Covered Entity is responsible for implementing appropriate privacy and security safeguards to protect its PHI in compliance with HIPAA.

5. Security Rule and HITECH Act Responsibilities of the Business Associate.

With regard to its use and/or disclosure of ePHI, Business Associate hereby agrees to do the following:

- (A) Comply with the applicable requirements of the Security Rule.
- (B) Require all of its subcontractors and agents that create, receive, maintain, or transmit ePHI on behalf of Business Associate to agree, in writing, to adhere to substantially similar restrictions and conditions concerning ePHI that apply to Business Associate pursuant to Section 5 of this BAA.
- (C) Report to Covered Entity any Security Incident of which it becomes aware. Specifically, Business Associate will report to Covered Entity any successful unauthorized access, Use, Disclosure, modification, or destruction of ePHI or interference with system operations in an information system containing ePHI of which Business Associate becomes aware within thirty (30) business days of Business Associate learning of such Security Incident. The parties agree

that this Section serves as notice by Business Associate to Covered Entity of the ongoing existence of attempted but Unsuccessful Security Incidents (as defined below), for which no additional reporting is required. For purposes of this BAA, "Unsuccessful Security Incidents" include but are not limited to activity such as "pings" and other broadcast attacks on Business Associate's firewall, port scans, unsuccessful log-on attempts, denials of service and any other attempts to penetrate such computer networks or systems that do not result in unauthorized access, use or disclosure of ePHI.

6. Term and Termination

- (A) *Term.* The Term of this BAA shall in effect as of the Effective Date set forth above, and shall terminate when all the PHI provided by Covered Entity to Business Associate, or created or received by Business Associate for or on behalf of Covered Entity, is destroyed or returned to Covered Entity or, if it is infeasible to return or destroy the PHI, protections are extended to such information, in accordance with the termination provisions in this Section 6.
- (B) *Termination for Cause.* If Covered Entity or Business Associate knows of a material breach or violation by the other party of any provision of this BAA, then the non-breaching party shall provide written notice of the breach or violation to the other party that specifies the nature of the breach or violation. The breaching party must cure the breach or end the violation within thirty (30) days after receipt of the written notice. In the absence of a cure reasonably satisfactory to the non-breaching party, then the non-breaching party may terminate this BAA between the parties.
- (C) *Effect of Termination.*
 - (i) Except as provided in paragraph (ii) of this Section, upon termination of this BAA, for any reason, Business Associate shall return or destroy all PHI received from Covered Entity, or created or received by Business Associate for or on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the PHI.
 - (ii) In the event that Business Associate determines that returning or destroying the PHI is infeasible, Business Associate shall extend the protections of this BAA to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI.

7. Notification

With respect to notices pursuant to paragraph 2(D) above, notice shall be made by telephone to the telephone number associated with Covered Entity's account, followed promptly by a written notice as described below.

Any notices required or provided for under this BAA shall be made in writing and shall be either personally delivered, mailed by first class mail or sent via facsimile or electronic mail to the appropriate individual identified below:

For Covered Entity:

Your address

For Business Associate:

Medicim NV, Stationsstraat 102 b6, B-2800 Mechelen, Belgium or contact us at privacy@dtxstudio.com

Either Party may designate a different address in writing to the other.

8. Regulatory References

A reference in this BAA to a section in the Privacy Rule, the Security Rule or the HITECH Act means the section as in effect or as amended.

9. Survival

The respective rights and obligations of the Business Associate under Section 6 of this BAA shall survive the termination of this BAA.

10. Interpretation

Any ambiguity in this BAA shall be resolved to permit compliance with the HIPAA Rules. Any conflict between the terms of this BAA and any other BAA relating to the same subject matter shall be resolved so that the terms of this BAA supersede and replace the relevant terms of any such other BAA.

11. Counterparts

This BAA may be executed in counterparts which, when all signatures are assembled, shall have the same effect as a single, fully-executed agreement. Facsimile and photocopy signatures shall have the same binding effect as manual signatures.

12. Severability

The provisions of this BAA shall be severable, and if any provision of this BAA shall be held or declared to be illegal, invalid or unenforceable, the remainder of this BAA shall continue in full force and effect as though such illegal, invalid or unenforceable provision had not been contained herein.

13. Governing Law

Except to the extent that the HIPAA Rules or other federal law applies, this BAA and the obligations of the Parties hereunder will be governed by interpreted in accordance with the laws of the State of California.

14. Effect

This Agreement amends, restates and replaces in its entirety any prior business associate agreement between the parties. This Agreement supersedes all prior or contemporaneous written or oral contracts or understandings between the parties relating to their compliance with health information confidentiality laws and regulations, including HIPAA and HITECH.

15. No Agency Relationship.

It is not intended that an agency relationship (as defined under the federal common law of agency) be established hereby expressly or by implication between Covered Entity and Business Associate under HIPAA or the Privacy Rule, Security Rule, or Breach Notification Rule. No terms or conditions contained in this BAA shall be construed to make or render Business Associate an agent of Covered Entity.

ANNEX 2: EU Data Processing Addendum

This EU Data Processing Addendum (“**Addendum**”) is made by and between **Authorized User to whom the Software is Licensed (“Customer”)** and Medicim NV, Stationsstraat 102, 2800 Mechelen, Belgium, and/or any other affiliated company of our group from which you received the Software (“**Company**”), and amends and is incorporated into the End User License Agreement between Customer and Company (“**Agreement**”). For good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Customer and Company agree as follows:

1. This Addendum shall apply to all Processing of Personal Data under the Agreement. In case of any direct conflict between this Addendum and the Agreement, the terms of this Addendum shall prevail.
2. For the purpose of this Addendum, **Data Processor, Data Subject, Personal Data Breach, and Processing** have the meanings ascribed to them in the European Union (“**EU**”) General Data Protection Regulation 2016/679 (“**GDPR**”). **Applicable Law** means all applicable UK, Swiss, EU or EU Member State laws and regulations relating to the privacy, confidentiality, security or protection of Personal Data, including, without limitation, (i) the GDPR and EU Member State laws supplementing the GDPR, and (ii) the EU Directive 2002/58/EC (e-Privacy Directive), as replaced from time to time, and EU Member State laws implementing the e-Privacy Directive, including laws regulating the use of cookies and other tracking technologies. **Personal Data** means any information relating to an identified or identifiable natural person that is obtained or accessed by Company as contemplated by the Agreement.
3. In circumstances in which Company Processes Personal Data as a Data Processor under the Agreement, Company shall:
 - (a) Process the Personal Data only in accordance with the documented instructions of Customer, unless Company is required to do otherwise by Applicable Law, in which case Company shall inform Customer of the relevant legal requirement before Processing the Personal Data unless informing Customer is prohibited by law on important grounds of public interest;
 - (b) Ensure that Company’s employees or subcontractors authorized to Process the Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality;
 - (c) Take security measures required pursuant to Article 32 of the GDPR;
 - (d) Taking into account the nature of the Processing, assist Customer, by appropriate technical and organizational measures, insofar as this is possible, in fulfilling Customer’s obligation to respond to Data Subjects’ requests for exercising their rights under the GDPR with respect to their Personal Data;
 - (e) Assist Customer in complying with its obligations pursuant to Articles 32 to 36 of the GDPR, taking into account the nature of the Processing and the information available to Company;

- (f) At Customer's choice, delete or return all Personal Data to Customer after the end of the term of the Agreement, and delete existing copies, unless Applicable Law requires storage of the Personal Data;
 - (g) Make available to Customer, for inspection on Company's premises only, the information necessary to demonstrate compliance with the obligations set out in this Addendum and allow for and contribute to audits conducted by Customer or another auditor mandated by Customer and approved by Company, provided that Customer gives Company at least 30 days' prior written notice of its intention to carry out an audit. This notice shall include a detailed work plan for the audit. Any third party involved in the audit must agree to Company's confidentiality undertakings and Customer will bear all costs and expenses incurred by Company in connection with the audit; and
 - (h) Company shall immediately inform Customer if, in Company's opinion, an instruction provided by Customer infringes Applicable Law.
4. Customer agrees that Company may subcontract its Processing operations performed on behalf of Customer under the Agreement. Prior to providing any subcontractor access to Personal Data, Company shall require such subcontractor to enter into a written agreement that imposes the same data protection obligations as set out in this Addendum. Upon Customer's request, Company shall provide Customer with the list of subcontractors authorized to access Personal Data in connection with the Agreement.
5. Customer agrees that Company may transfer Personal Data outside of the EEA or the United Kingdom for the purpose of fulfilling its obligations to Customer under the Agreement and on the condition that Company has implemented appropriate safeguards for the transfer of the Personal Data in accordance with Applicable Law. Customer (as "data exporter") and Company (as "data importer"), with effect from the commencement of any relevant transfer, hereby enter into the Standard Contractual Clauses (processors) for the purposes of Article 26(2) of Directive 95/46/EC set out in Decision 2010/87/EC as the same are revised or updated from time to time by the European Commission ("SCCs") in respect of any transfer to the Company (or onward transfer) where such transfer would otherwise be prohibited by the GDPR in the absence of the SCCs: <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32010D0087>. The SCCs are incorporated by reference as if fully set out within this EULA. Appendix 1 to the SCCs shall be deemed to be prepopulated with the information about the data processing described in this EULA and particularly in Clause 5 Data Privacy. Appendix 2 to the SCCs shall be deemed to be prepopulated with the following: *"Taking into account the state of the art, the costs of implementation and the nature, scope, context and purposes of processing as well as the risk of varying likelihood for the rights and freedoms of natural persons, Company shall ensure a level of security appropriate to the risk, including as appropriate the specific controls described in Article 32(1), (a) to (d) inclusive of GDPR and including any other controls mandated by applicable data protection laws."* If Company subcontracts its Processing operations performed on behalf of Customer under the Agreement, Company may enter into SCCs with subcontractor on behalf of Customer or subcontractor may co-sign SCCs entered into between Customer and Company.