medartis®

CMX TERMS & CONDITIONS

Please read the following Terms & Conditions carefully before using the CMX Portal operated by Medartis AG ("Medartis").

These Terms & Conditions apply to and govern the registration for, access to and use of the CMX Portal and the sale of custom-made devices or services ("Product") by Medartis to Customers (as defined below). All terms and conditions are subject to change.

Therefore, the service of the CMX Portal is conditioned on User's acceptance of and compliance with these Terms & Conditions.

By Accessing the CMX Portal you agree to be bound by these Terms & Conditions.

No other terms and conditions shall have force or effect. Any additional or deviating general terms and conditions contained in the Customer's order or response to Medartis' confirmation or otherwise submitted to Medartis in connection with the CMX Portal shall be deemed to be rejected by Medartis and are non-binding on Medartis, even if these general terms and conditions are not expressly rejected by Medartis.

1. DEFINITIONS

For the purpose of these Terms & Conditions:

- "**Access**" or "**Accessing**" means the registering for, accessing, logging in on or on to and/or uploading data on to the CMX Portal, or otherwise accessing services through the CMX Portal.
- "**Contributor**" means a registered and authorized User, who has been invited by another User through the respective feature on the CMX platform to contribute to such other user's case.
- "**Customer**" means a medical professional, qualified prescriber, clinic or surgery center which orders and purchases Product from Medartis.
- "**GDPR**" means the General Data Protection Regulation (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27th April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC).
- "**Material**" means the software and/or user documentation related to the CMX Portal.
- "**MDD**" means the Medical Device Directive (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices).
- "**MDR**" means the Medical Device Regulation (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC).
- "**Medartis**" means Medartis AG and, where applicable, its affiliates.
- "**Patient Data**" means Personal Data relating to the Patient, necessary for the design, manufacture and supply of the Product, including without limitation name (plain or acronymized), age, gender, summary of the relevant medical records, diagnosis, planned treatment and relevant images (e.g. CT, MRI, Cone-Beam-CT, 3D-Scans, etc.).
- "**Patient**" means the person for which the Product is ordered.
- "**Personal Data**" means any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.
- "**Physician**" **means any person authorized by national law by virtue of that person's professional qualification to issue a prescription or use or apply a medical product.**
- "**Product**" means a medical device or service for use in connection with an orthopedic treatment as offered by Medartis on the CMX Portal (including without limitation custom-made implants, anatomic plates, surgery planning tools, cutting and drilling templates, bone models, etc.).
- "**Technical Data**" means all designs, 3D-models, drawings and/or any other technical data used in connection with the development, manufacture and/or sale of the Product.
- "**User**" means the Customer or any other person, which is authorized and qualified to use the CMX Portal and to order a Product for and on behalf of Customer. This also includes guest users, who are granted only temporary and restricted access to the CMX Portal.

2. PERMITTED USES

The User may Access and use the CMX Portal solely for the purpose of ordering a Product from Medartis for and on behalf of the Customer, making Patient Data available to Medartis as may be necessary for the design, manufacture, sale and delivery of such Product, to facilitate the communication between the User and Medartis and for using any other features made available on the CMX Portal (together, the "Permitted Use").

All Technical Data used in connection with the development, manufacture and/or sale of the Product are and shall remain the exclusive property of Medartis. Technical Data shall not be extracted, decompiled, reverse engineered, modified, edited or otherwise processed.

3. SOFTWARE LICENSE

Medartis hereby grants the User, which accepts, a personal, non-exclusive, revocable license to use the CMX Portal for the Permitted Use, as authorized in these Terms & Conditions.

The User acknowledges and agrees that all software, software documentation, user documentation and/or instructions for use related to the CMX Portal (“Material”) are proprietary products of Medartis protected under copyright law and that all right, title and interest in and to such Material, associated intellectual property rights (including, but not limited to, trademarks), are and shall remain with Medartis. The User agrees that the software of the CMX Portal or any part thereof may not in any event be reverse assembled, reverse compiled or otherwise translated. The User agrees that s/he is not entitled to the right to assign, sublicense, transfer, pledge, lease, rent or share his rights granted under this Article 3, nor sell or share any software and/or user documentation or any part or copy thereof.

The software may be accessed or used exclusively with the original user interfaces provided by Medartis.

The software is provided “AS-IS”. Medartis disclaims all representations and warranties, express or implied, with respect to the software, including, without limitation, warranties of fitness for a particular use or purpose, merchantability and non-infringement. Medartis makes no warranties that the software will operate without interruption or be error-free.

Medartis may suspend or terminate the license at any time for any or no reason. In the event of license termination, the User shall cease all use of the application and uninstall the application.

4. PASSWORD

Access to the CMX Portal and software is granted by the use of a password associated with the User on a strictly personal basis (“Password”), together with a two-factor authentication to a trusted phone number designated by the User. Under no circumstances shall the User share the Password or allow third parties to use the Password to access the software.

5. USER QUALIFICATIONS AND AUTHORIZATIONS

By registering to the CMX Portal, the User confirms that s/he is a medical professional with sufficient expert knowledge in the field of medical devices and qualified to use the CMX Portal. Medartis does not provide any medical advice and/or recommendations. During the design process of the Product, Medartis may give input from an engineering perspective, provided however that the final decision and responsibility remains with the User. By Accessing the CMX Portal on behalf of a Customer, the User confirms and warrants that s/he is authorized by the Customer to place an order for the Product and to accept these Terms & Conditions on behalf of the Customer.

The User understands and acknowledges that the ordering process is safety-critical for the Patient. Since this CMX Portal is only available in English and German, the User must be fluent in German or English and must be able to reliably communicate verbally and in writing and to use the CMX Portal in German or English.

Guest Users are granted temporary access to individual case files through other Users and may view and comment on such data. The Guest User confirms to treat all information provided on the CMX portal, in particular (but not limited to) information concerning patients and their medical and treatment history, as well as information related to Medartis and/or its products and systems, as strictly confidential, unless such information is already in the public domain at the time of access.

Contributors are granted temporary access to individual case files through other Users and may view and edit such data. The Contributor confirms to treat all information provided on the CMX portal, in particular (but not limited to) information concerning patients and their medical and treatment history, as well as information related to Medartis and/or its products and systems, as strictly confidential, unless such information is already in the public domain at the time of access.

6. DESIGN VALIDATION – DESIGN FREEZE

Before Medartis can start manufacturing or providing a Product, the Physician is required to review and validate the proposed design and confirm that it is in accordance with the respective prescription. If in the Physician's professional judgment, the design has been deemed to conform to and be suitable for the specific case for which it was designed, the Physician shall validate the proposed design by electronic signature of the Case Specific Design Freeze document ("Validation"). Such Validation is the sole responsibility of the Physician and is final and binding.

The Design and all other information associated with the Product will remain uploaded and accessible to the User on the CMX Portal for a period of twelve (12) months from the Validation date. After such period, these information will be archived, but may be requested in justified cases, for as long as they are subject to the legal retention period.

7. CONCLUSION OF THE AGREEMENT

Unless mutually agreed otherwise, Medartis, or, where applicable, one of its subsidiaries will submit an offer to the Customer, at the beginning of the design process (the "Offer"). The Offer contains a description of the desired Product and an estimated price. The estimated price for the Product quoted in the Offer is non-binding and indicative. The final price for the Product invoiced to the Customer may vary from the estimate. If the Offer is not accepted within ten (10) calendar days, it is no longer binding for Medartis.

With the order or the acceptance of the Offer respectively, a contract as defined by the Swiss Code of Obligations is concluded. This contract may be revoked by the Customer without giving any reason until the Validation pursuant to section 6 of these Terms & Conditions. If the Customer exercises this right of revocation, Medartis has the right to invoice the Customer for the expenses so far incurred up to a maximum amount equivalent to 20% of the Offer price.

The Products are individually manufactured goods which are specifically designed for a Patient which cannot be returned. The Customer has no right of withdrawal from the purchase after Validation.

8. DATA PROTECTION

Medartis is Processing Personal Data of the User for the purpose of providing and managing the CMX Portal and the Access to the CMX Portal. For the purpose of these Terms & Conditions the term "Processing" shall have the meaning set forth by the GDPR. By Accessing the CMX Portal, the User agrees to such use of Personal Data by Medartis in accordance with the Privacy Notice of Medartis and the following provisions on the protection of Personal Data.

Patient Data is Processed by Medartis on behalf of the Customer for the design, manufacture and supply of the Product and in order to comply with all applicable regulatory and legal requirements, including without limitation the traceability and record keeping requirements applicable under the MDD and/or MDR (the "Purposes"). Patient Data may be stored by Medartis for a period of twenty (20) years after the sale of the Product to the Customer. In Processing Patient Data on behalf of the Customer, Medartis agrees to comply with and be bound to the provisions set forth in these Terms & Conditions as well as all applicable legal requirements, including without limitation the GDPR. The Physician acknowledges that Patient Data is "sensitive data" and that for the Processing of Patient Data all obligations and requirements for the Processing of special categories of personal data under the GDPR have to be taken into account. The Physician confirms that the Patient has been informed of and expressly agreed to the Processing of his or her Patient Data by Medartis, subsidiaries and / or distributors in the form required by law. A form that complies with the legal requirements (incl. GDPR) is available for download at LINK.

Medartis may use Patient Data in pseudonymised form for statistical, analytical, scientific or research and development purposes.

By uploading Patient Data on the CMX Portal, sharing such data with other Users via the share tool on the CMX Portal and/or ordering the Product, the User expressly confirms and warrants that the Customer has fulfilled all its obligations as a controller pursuant to the GDPR, including without limitation that the Patient has been fully and transparently informed of the Purpose for which Patient Data is Processed hereunder, as well as his/her rights with regard to such Processing and that the Patient Data will be transferred to Medartis AG in Switzerland as a processor for the above mentioned Purposes. The CMX Portal is hosted on servers of Microsoft Inc.'s Azure Cloudservice. Patient Data will be stored on these servers in encrypted form. The servers are located within the European Union. Medartis has entered into a contract with Microsoft Inc. to ensure compliance with the above-mentioned terms. In addition, Microsoft Inc. is ISO/IEC 27001 certified.

Without the prior consent of the Customer, Medartis will not provide any information to third parties or to the Patient and agrees to immediately forward to the Customer any inquires of third parties or Patients addressed to Medartis.

The Processing by Medartis of Patient Data on behalf of the customer starts with the upload thereof in the CMX Portal and ends with the regular completion of all contractual and statutory obligations in connection with the Product and/or these Terms & Conditions. Medartis agrees to Process Personal Data only as long as required for the respective purpose.

Medartis will process Patient Data only as set forth in these Terms & Conditions or following an instruction of the Customer, except when necessary to fulfil legal or statutory requirements. Medartis will notify the Customer if such legal requirements exist, unless there is a legal obligation that prohibits such notification. Medartis will not use any Patient Data provided by the Customer hereunder for any purpose other than the Purposes.

Medartis confirms that all Medartis employees, affiliates and subcontractors, which are concerned with the Processing of Patient Data under these Terms & Conditions are known to Medartis and are bound in writing to be under a strict confidentiality obligation.

Medartis confirms to have appointed a data protection officer in accordance with the GDPR. The data protection officer can be contacted under the following email: dataprotection@medartis.com.

Medartis confirms to adhere to the provisions set forth in Chapter V of the GDPR concerning the processing of personal data outside of the EU.

In case any Patient Data is Processed by a subcontractor of Medartis, Medartis ensures that all data protection laws and regulations as well as the provisions set forth in these Terms & Conditions are adhered to.

Medartis will always follow any reasonable and lawful instructions of the Customer relating to the processing of Patient Data, unless there is a legal obligation impeding this.

Medartis is obligated to notify the Customer of any breach of data protection concerning Patient Data processed by Medartis on behalf of the Customer, considerable disruptions in data processing as well as any controls conducted or measures taken by the competent supervisory authority. The notification contains the description of the breach, the approximate number and categories of affected Patient Data, name and contact information of the data protection officer and the measures taken.

In processing Patient Data on behalf of the Customer, Medartis undertakes the following technical and organizational measures for data processing safety:

- All the employees of Medartis having access to Patient Data are obliged to confidentiality.
- Medartis has implemented data protection policies and guidelines and all employees participate in training on data protection and information security when hired.
- Medartis has appointed a data protection officer which can be contacted by e-mail to: dataprotection@medartis.com.
- All Patient Data are stored in a data centre which can be accessed by authorized persons involved in the Processing or use of Patient Data.
- Measures which ensure that the persons authorized to access Patient Data can access exclusively the Patient Data assigned to their individual access rights.
- All computers are equipped with anti-virus software, significantly reducing the risk of malware.
- The user rights are limited to the minimum level required for the performance of activities (need-to-know principle).
- Each Medartis employee involved in the Processing of Patient Data has a personal user account for all relevant systems they have access to.
- All user accounts are secured by individual passwords, each password is known only by the account holder and may not be communicated to other persons, not even within the organization.

- User passwords follow a state-of-the-art policy including length and complexity requirements.
- User accounts are automatically locked after several consecutive unsuccessful authentication attempts.
- Access to systems providing access to Patient Data is secured using additional security measures, such as two-factor authentication (2FA) mechanism.
- Administrative access to server systems is reserved to authorized persons. The connection is performed via encrypted connections, and authentication is performed using nominative accesses.
- All the production server systems are secured via firewalls that allow only for the intended (incoming and outgoing) transfer protocols (default deny).
- Patient Data are only transmitted over encrypted channels (HTTPS).
- Access to Patient Data is limited to the minimum level required for the performance of activities (need-to-know principle).

There is a standardized process for the identification and handling of security incidents. The data protection and security measures described above are binding. They constitute the minimum standard owed by Medartis.

The data protection measures may be adapted for the purpose of technical and organizational further development if the level of protection and security does not fall below the minimum standard herein defined.

If Patient Data in connection with these Terms and Conditions is stored on hard drives and other data carriers, they shall be marked as such and tracked. They are to be stored appropriately and must not be accessible to unauthorized persons. Their creation and use shall be documented.

9. CONFIDENTIALITY

The User acknowledges that in Accessing the CMX Portal s/he may get access to Confidential Information of Medartis and/or Information provided to him/her by another User. The User acknowledges that such Confidential Information shall be and remain the sole property of Medartis and the other User or his/her patient respectively and hereby undertakes to treat all such Confidential Information as strictly confidential and not to disclose it to any third party. “Confidential Information“ shall mean any confidential or proprietary information and/or trade secrets to which the User may have got access, directly or indirectly, in oral, written, electronic or other form, including but not limited to information on Medartis and/or Medartis’ products and systems, the research, methods, processes and techniques, marketing materials, cost or pricing information, as well as data shared by other Users.

10. LIMITED WARRANTIES AND LIABILITY

Medartis warrants for twenty four (24) months that the Product, at the date of delivery to the Customer will be free from defects in manufacture, materials, and workmanship, provided the Product is used for the specific purpose intended and in accordance with the relevant instruction of use (IFU), and is maintained, handled (including without limitation sterilized), operated, implanted and/or used in accordance with Medartis’ instructions, manuals and recommendations. Medartis does not assume any liability for defects in connection with the Validation, including (but not limited to) defects which occur as a result of or in connection with the validated design.

If a warranty defect arises, Medartis will, at its option, replace the defective Product or refund the purchase price thereof. Such replacement or refund shall be the sole liability of Medartis and the sole remedy of the Customer with respect to the defective Product. Medartis shall have no responsibility to replace or issue refunds for Products damaged as a result of (i) inadequate implantation, handling, operation or maintenance of the Product, (including without limitation, the implantation, handling, operation, maintenance or sterilization of Products contrary to the instructions and/or recommendations of Medartis), use of inappropriate operating or substitute materials, deficient implantation measures, or chemical, electro-chemical or electrical influence, to the extent that such circumstances are not due to any fault on the part of Medartis, or (ii) acts of the Customer or third parties, acts of God or nature, modification, misapplication, abuse or other similar events.

The Customer shall inspect all Products immediately upon receipt for conformance with the product specifications, to the extent determinable by reasonable visual inspection upon delivery and shall report any defects without any delay. In any event, defects must be reported to Medartis within ten (10) calendar days after delivery. Hidden defects shall be reported to Medartis within ten (10) calendar days after the Customer has become aware thereof.

The Customer shall be obligated, upon consultation with Medartis to give Medartis reasonable time and opportunity to make all replacement deliveries deemed necessary by Medartis. Otherwise, Medartis shall be released from liability for the consequences of any defect which occurs because the Customer has not given the necessary time and opportunity to perform replacement deliveries to Medartis.

Medartis does not give any warranty for the fitness of the Product for any particular purpose, or for the timely delivery of the Product for a time-sensitive surgery. The Customer and Physician are responsible for having a back-up solution ready in case the Product is not available or does not fully work for the intended purpose.

THE WARRANTY SET FORTH IN THIS SECTION 10 IS THE ONLY WARRANTY PROVIDED BY MEDARTIS WITH RESPECT TO THE PRODUCT, AND SUCH WARRANTY IS PROVIDED IN LIEU OF ALL OTHER EXPRESS OR IMPLIED WARRANTIES; AND MEDARTIS SPECIFICALLY DISCLAIMS ANY AND ALL IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. NO PERSON SHALL HAVE ANY AUTHORITY TO MODIFY THE SCOPE OF THIS WARRANTY OR MAKE ANY OTHER REPRESENTATION, PROMISE OR WARRANTY WITH RESPECT TO THE PRODUCT. THIS WARRANTY EXTENDS ONLY TO CUSTOMER AND NOT TO ANY SUBSEQUENT USER, OTHER CUSTOMERS OR TRANSFEREE.

11. REGULATORY COMPLIANCE

The Customer shall retain all records, including without limitation Patient Data, in relation to the Product for a period of fifteen (15) years after delivery. Medartis shall maintain the technical documentation of the Product.

The Customer and Physician shall cooperate with Medartis (including without limitation by permitting governmental inspections and providing access to Medartis) in all regulatory matters and shall comply with all requests and/or procedural requirements of Medartis that Medartis reasonably establishes hereafter in order to safeguard Medartis' compliance with the applicable laws, rules and regulations. The Customer shall, upon reasonable request from Medartis, provide data and information to Medartis in connection with Product returns, recalls, complaints, general feedback and inquiries by a third party or a governmental authority (including without limitation the Swissmedic, or a notified body) without additional cost to Medartis.

The Customer shall immediately and without any justifiable delay report any risks, incidents and adverse events regarding the safety of the Product, User and/or Patient by e-mail to return@medartis.com or to the Medartis' address. Medartis may request the Customer to provide all relevant information and data with respect to any adverse event, incident or feedback provided.

The Customer shall assist Medartis in maintaining proper protocols of third party complaints it becomes aware of, addresses and other materials, and establishing a traceability system, to enable Medartis to act timely and responsibly in the event of product liability occurrences, returns, complaints, inquiries by any third party or governmental authority and product recalls.

12. MISCELLANEOUS PROVISIONS

All agreements based on these Terms & Conditions shall be construed in accordance with **Swiss law** and any disputes that may arise or have arisen from or in connection with these Terms & Conditions and/or the collaborations it governs are subject to the exclusive jurisdiction of **Basel (Switzerland)**.

If any provisions of these Terms & Conditions should be or become invalid or unenforceable, then the rest of these Terms & Conditions remain unaffected.

Medartis may, at any time, and at its sole discretion, modify these Terms & Conditions after notifying the User. Any such modification will be effective immediately upon publication.

In the event of contradictions between the German and the English version of this document the English version shall prevail.

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