

GENERAL TERMS AND CONDITIONS

Last Update: 02-07-2015

§1 Scope

1. SICAT GmbH & Co. KG (hereinafter referred to as SICAT) renders its services exclusively on the basis of the following general terms and conditions of business. Business relationships apply in particular to the sale of SICAT products and the creation of surgical guides by SICAT from scan guides or electronic data sent in by customers.
2. These general terms and conditions of business apply exclusively; SICAT will not recognize any of the customer's conditions which contradict or deviate from these general terms and conditions of business unless SICAT has expressly agreed in writing that they are valid. These general terms and conditions of business apply even if SICAT supplies the customer without reservation in the knowledge that the customer has contradictory or deviating conditions from those of SICAT's general terms and conditions of business.
3. All agreements made between SICAT and the customer for the purposes of executing this contract are set out in this contract in writing.
4. If SICAT amends these general terms and conditions of business, these amended conditions will become a constituent part of this contract if SICAT sends the amended conditions to the customer for information and the customer does not raise any objection to their inclusion in the contract within six weeks. SICAT will advise the customer separately of the consequences of not responding when it sends the amended conditions.

§2 Conclusion of contract / withdrawal

1. The contract in question comes into being when SICAT accepts the order by means of an order confirmation; SICAT will send the order confirmation by e-mail. If the customer has not given an e-mail address when ordering or this cannot be reached for technical reasons, the customer hereby relinquishes the statement of order confirmation.
2. Conditions for the acceptance of orders for SICAT surgical guides of the **CLASSICGUIDE** type are receipt of
 - a. the planned work on CD or by electronic means,
 - b. the scan guide with bite plate in addition to the required model,
 - c. the surgical guide order and
 - d. payment information.
3. Conditions for the acceptance of orders for SICAT surgical guides of the **OPTIGUIDE** type are receipt of
 - a. the planned work on CD or by electronic means,
 - b. the surgical guide order,
 - c. payment information and
 - d. the optical impression or stone model.
4. Conditions for the acceptance of orders for SICAT surgical guides of the **DIGITALGUIDE** type are receipt of
 - a. the planned work on CD or by electronic means,
 - b. the surgical guide order,
 - c. payment information and
 - d. the optical impression.
5. Conditions for the acceptance of orders for SICAT therapeutic appliance of the **OPTIMOTION** type are receipt of
 - a. the planned work by electronic means,
 - b. therapeutic appliance order,
 - c. payment information ,
 - d. therapeutic position and
 - e. the optical impression or stone model.
6. SICAT reserves the right to withdraw in the following cases:
 - a. the product is not available from SICAT's supplier for a period of at least four weeks.
 - b. there are errors in the data which mean the order cannot be completed.
 - c. SICAT reserves the right to perform a credit check following agreement of the contract and if the outcome of this is negative, to withdraw from the contract. In the event of poor creditworthiness, withdrawal can be prevented by payment in advance.

§3 Qualifications and duties of the customer

1. The customer is responsible for the circumstances and conditions in which the product made by SICAT is prepared, ordered and used for treatment.
2. The customer confirms that he has the qualifications required to use the product. The customer accepts full medical responsibility for implant planning / the design and use of the surgical guides. These services are not a subject of the contract.
3. The surgical guides customer undertakes to take precise note of the specifications for using the SICAT surgical guide, in particular before ordering and before using the surgical guides in order to avoid incorrect usage. This includes, for example, reports from SICAT Support and the report supplied with every surgical guide, as well as any drill report sup- plied.
4. If the customer does not have the qualifications necessary to use the product, he must inform SICAT of this without delay unless he or she is placing the order on behalf of an end-user who is qualified in accordance with this stipulation and the end-user who has the qualifications required to use the product undertakes fitting and has knowledge of the specifications for using SICAT surgical guides.
5. In the aforementioned case, the customer undertakes to inform the end-user of any relevant communication from SICAT which relates to implant planning and use of the surgical guides.

§4 Description of services

1. Surgical Guides
A SICAT **CLASSICGUIDE** is made by converting a scan guide prepared by the customer into a surgical guide. In this process, SICAT puts the sleeves the customer requires in a defined position by extending the axis of the implant planned by the customer. SICAT guarantees and documents manufacturing deviation accuracy as outlined below: the drill sleeve axis will not deviate by more than 500 µm from the planned implant at the location of the implant. To be more precise: related to the detected marker balls, the intersections of the drill sleeve axis in question and a plane which intersects the planned implant apically or occlusally and is perpendicular to the planned implant axis will be no more than 500 µm from the apical/occlusal end of the planned implant.
A SICAT **OPTIGUIDE** is produced by superimposing an optical scan (surface scan) on the corresponding 3D X-ray. In this process, SICAT puts the sleeves the customer requires in a defined position by extending the axis of the implant planned by the customer. SICAT guarantees and documents manufacturing deviation accuracy as outlined below: the drill sleeve axis will not deviate by more than 500 µm from the planned implant at the location of the implant. To be more precise: related to the position of the surface scan found in the course of superimposition, the intersections of the drill sleeve axis in ques-

tion and a plane which intersects the planned implant apically or occlusally and is perpendicular to the planned implant axis will be no more than 500 µm from the apical/occlusal end of the planned implant.

For SICAT **DIGITALGUIDE**, SICAT designs and exports for you the STL model of the surgical guides. You receive these online and they can be printed in a laboratory of your choice. Prerequisite for this is an available already superimposed (registered) optical impression. The optical impression shall comprise at least half a dental arch and shall be superimposed with the x-ray volume with sufficient accuracy. Movement or metal artefacts may affect the accuracy of the superimposition and thus also the accuracy of the surgical guide. Place your SICAT order online. SICAT assumes no liabilities for the production of a SICAT **DIGITALGUIDE** on the basis of the SICAT designed STL model with regard to the production by a third party.

The following applies to SICAT **CLASSICGUIDE**, SICAT **OPTIGUIDE** and SICAT **DIGITALGUIDE**: SICAT has no influence over the quality of the scan guide, the quality of the X-ray, the quality of the stone model and the quality of the surface scan provided by the customer, the quality of implant planning, intra-operative handling of the surgical guide and the accuracy of fit in the interaction of drills and sleeves. The aforementioned issues are therefore not constituents of the SICAT's services. Any deficiencies in these constituents provided by the customer are therefore their responsibility. As these factors may have an impact on any implantation carried out and are the sole responsibility of the customer, the accuracy with which an implant is inserted is not a subject of the contract and SICAT accepts no liability for this unless there is evidence in accordance with the definition above of erroneous positioning of sleeves by SICAT.

2. If certain drill sleeves cannot be incorporated in the surgical guide due to planning and space available in the jaw, SICAT will instead automatically insert pilot sleeves, assuming there is adequate space in the jaw. The customer agrees to the corresponding amend- ment to the order they originally placed.
3. Therapeutic appliances
A SICAT **OPTIMOTION** is produced by superimposing an optical scan (surface scan) on the corresponding 3D X-ray, the selected therapeutic position and the chosen parameters by the customer.
The following applies to SICAT **OPTIMOTION**: SICAT has no influence over the quality of the provided X-ray, the quality of the stone model, the quality of the surface scan provided by the customer, the quality of the traces of movement and the quality of the static position. The aforementioned issues are therefore not constituents of SICAT's services. Any deficiencies with regard to the data and the stone model provided by the customer are therefore their responsibility. As far as these factors may have an impact on the result of the therapeutic appliance, the accuracy with which the therapeutic appliance is produced is not subject of the contract..
4. GALILEOS Implant
GALILEOS Implant is intended for use as planning and simulation software to aid qualified dental professionals in the placement of dental implants and the planning of surgical im- plant treatments. GALILEOS Implant is based on medical imaging information presented by the Sirona GALAXIS 3D viewer and produced by Sirona GALILEOS medical cone beam scanners. The dental professionals' input information may be exported from GALILEOS Implant and used as input data for CAD or Rapid Prototyping Systems.
5. SICAT Implant
SICAT Implant is a software application for the visualization of imaging information of the oral-maxillofacial region. The imaging data originates from medical scanners such as CT or DVT scanners. SICAT Implant is intended for use as planning and simulation software to aid qualified dental professionals in the placement of dental implants and the planning of surgical treatments. The dental professionals' planning data may be exported from SICAT Implant and used as input data for CAD or Rapid Prototyping Systems.
6. SICAT Function
SICAT Function is a software application for the visualization and segmentation of the imaging information of the oral-maxillofacial region. The imaging information originates from medical scanners such as CT or CBCT scanners. SICAT Function supports qualified dental professionals during diagnosis, diagnostics and therapy planning in the oral-maxillofacial region as well as during therapy planning with regard to problems related to the chewing mechanisms. The planning data can be exported from SICAT Function and will be used to realize the therapy.
7. SICAT JMT⁺
The SICAT JMT⁺ system (software and hardware) calculates from registered movements of the patient's mandible all necessary parameters with the aim to support the diagnosis with regard to the following indicators:
 - Supporting diagnosis for the treatment of a diseased jaw
 - Supporting diagnosis for the production of an occlusal bite splint
 - Supporting diagnosis for the production of tooth replacement
 - Supporting diagnosis for esthetic functional reconstruction with or without dental implants
 - Supporting diagnosis for the treatment of craniomandibular dysfunction (CMD)The measuring system also allows an export of the data collected for the further use in CAD/CAM or PACS systems. The measuring system shall only be used by qualified dental professionals. The operation environment is restricted to the premises of dentists. Measurements are taken within 15 minutes and shall not be performed with regard to open wounds in the mouth or on the head and it shall only be carried out on patients that are 10 years of age or older and on patients that are mentally fit to exactly follow the instructions by the operator.

§5 License agreement for SICAT Implant and GALILEOS Implant, SICAT Function and SICAT JMT⁺ System

1. The SICAT Implant, GALILEOS Implant, SICAT Function and das SICAT JMT⁺ System are the property of SICAT and are protected by both copyright law and international copyright agreements, as well as by other laws and agreements relating to intellectual property rights. With the conclusion of this license agreement, SICAT grants the customer a non-exclusive license to use SICAT Implant / GALILEOS Implant / SICAT Function / SICAT JMT⁺ System. The customer has no right to sublicense the software / hardware. Reproduction is permitted only to the extent that such reproduction is necessary to use the program. Copyright notices, serial numbers or any other features serving to identify the program may under no circumstances be removed or modified. SICAT Implant / GALILEOS Implant / SICAT Function/ SICAT JMT⁺ System may be used by more than one user. The customer may save or install a copy of SICAT Implant / GALILEOS Implant on a storage medium which is used solely within an internal network. The customer may not modify SICAT Implant, GALILEOS Implant, SICAT Function and the SICAT JMT⁺ System or use them in any other form. Modification, reverse engineering, decompilation or disassembling of SICAT Implant, GALILEOS Implant, SICAT Function and the SICAT JMT⁺ System is prohibited. Apart from the limited license for use within the terms of this agreement, SICAT retains exclusive ownership of all rights (including all ownership rights, entitlements and interests) in and in connection with SICAT Implant, GALILEOS Implant, SICAT Function and the SICAT JMT⁺ System. This also applies to the rights of SICAT's suppliers.

2. Minimum system requirements for SICAT Implant, GALILEOS Implant, SICAT Function & SICAT JMT⁺. The minimum system requirements for SICAT Implant, GALILEOS Implant and SICAT Function can be seen on the packaging, in the instructions for use and during installation. The minimum system requirements for SICAT JMT⁺ can be seen in the instructions for use.
3. The full scope of the contractual features of the programs is included in the user manual.

§6 Prices

1. All price information in catalogs or price lists is subject to change without notice. The prices prevailing on the day the contract is concluded apply. All prices should be understood to be without prompt payment discount or other reductions. Statutory value-added tax is not included in the prices; this will be shown separately on the invoice at the statutory rate on the day the invoice is issued.
2. Costs of postage, packing, carriage and any consignment or insurance costs will all be borne by the customer. If goods are shipped without duty paid, the fees levied by customs officials and any costs associated with this shall be borne by the customer.

§7 Payment conditions

3. The purchase price becomes due when the contract is concluded.
4. Payment is made by direct debit or credit card except as otherwise expressly agreed. Payments on account or advance payment require the express consent of SICAT. If the customer's registered office is outside Germany, payment is possible exclusively by credit card or in advance except as otherwise agreed.
5. In the case of the advance payment method, goods will only be dispatched to the customer on receipt of payment.
6. The customer only has set-off rights if his or her counter-claims are established in law, undisputed or recognized. He or she is authorized to exercise the right of retention only if his or her counter-claim is based on the same contractual relationship. In this case, the contractual relationship is the specific individual order.

§8 Delivery / delivery time

1. SICAT is entitled to make part-deliveries (in particular if one part of the goods ordered is temporarily unavailable). In this case, SICAT will bear any additional carriage costs.
2. SICAT surgical guides are generally dispatched within six working days (Monday-Friday) of order confirmation. Should SICAT be unable to dispatch the goods ordered within this time – perhaps due to high demand – SICAT will immediately inform the customer of any such delay. Delivery periods are country-specific and may vary. The start of the delivery time quoted by SICAT presupposes the presence of all the documentation and materials required for production as outlined in these general terms and conditions of business, as well as clarification of all technical issues.
3. Compliance with the duty to deliver and the delivery time furthermore assumes that the customer fulfills all his obligations properly and in good time. The right to object to a contract which has not been fulfilled is reserved.
4. Regardless of further terms in these general terms and conditions of business, in the event of delivery being delayed, SICAT will accept liability for lump sum compensation for delay of 3% of the value of the supply for each complete week's delay, up to a maximum of 15% of the value of the supply.

§9 Transfer of risk - packing costs

1. SICAT dispatches SICAT products to the delivery address named by the customer when ordering / in the order documentation. The risk of the goods being lost is transferred to the customer when the goods are handed over to the carriers working on behalf of SICAT.
2. If the customer so desires, SICAT will cover the consignment with transport insurance; the costs incurred will be borne by the customer.

§10 Warranty / remedy or replacement

1. The warranty period (period when defects can be remedied or a replacement provided) is one year. It begins when the goods are transferred to the customer.
2. SICAT will not be held liable for defects which impair conventional or contractually-assumed use to only an insignificant extent.
3. In the event of a defect, SICAT is entitled at its own discretion either to remedy the defect or make a replacement delivery at no charge. The costs of remedy or replacement incurred as a result of the subject of purchase having been taken to a location other than the one at which it is located in accordance with the contract will be borne by the customer. Defects will be remedied or a replacement supplied only if the customer has previously paid the purchase price less a deduction for the defect. If the defect cannot be rectified or no replacement can be made or the customer cannot be expected to await further attempts to remedy or replace, then the customer can either withdraw from the contract or demand a rebate (reduction in remuneration) instead of remedy or replacement.

§ 11 Special arrangements for SICAT surgical guides regarding remedy/replacement and liability

1. The customer undertakes to check the surgical guide within no more than 14 days of its arrival at their premises and to report any defects found to SICAT by fax or e-mail within this period. This check must in any event be made before the operation. The customer should use this check to ensure that the surgical guide has been produced in accordance with their specifications. The surgical guide is considered in accordance with contract if it is used on the patient or the customer does not report any defect within 14 days of receiving the relevant surgical guide at their premises. If the purchaser neglects to check compliance with the order or uses a non-conforming surgical guide, he takes sole responsibility for this and thereby releases SICAT from any liability which could have been avoided by doing so.
2. If there are defects which prevent the surgical guide from being used during surgery, SICAT undertakes to supply the customer with a free bite plate for a new surgical guide to be made.
3. SICAT is not obliged to provide remedy or replacement if the product, especially with reference to surgical guides, is interfered with or modified without SICAT's consent, unless the customer can prove that the defect was not caused by this interference or these modifications

§12 General liability arrangements

1. SICAT accepts no further liability for compensation beyond the above arrangements; in particular, SICAT will not be liable for loss of profit or other financial loss or consequential damages sustained by the customer unless expressly otherwise arranged below.
2. The above exemption from liability does not apply in the event of fraudulent failure to mention a defect or if the damage is due to deliberate or gross negligence on the part of SICAT or its agents. Furthermore, it does not apply to damages arising from harm to life, limb or health due to negligent or deliberate breach of duty by SICAT or its agents. It also does not apply if SICAT negligently breaches a cardinal duty or a key contractual duty. It also does not apply if there is a breach of product liability law.
3. Liability for loss of data as a consequence of ordinary negligence by SICAT is limited to the typical restoration expenditure which the customer would have incurred with regular production of backup copies appropriate to the risk involved and the performance of virus checks. In any event, the duty to compensate is limited to foreseeable damages.
4. The period of limitation for claims for compensation for damages is 12 months.
5. The period of limitation for claims due to quality defects does not start again as a consequence of remedy or replacement; it continues uninterrupted from the period which commenced with the original delivery.

§13 Data protection

1. The customer agrees to the storage, processing and use of the personal data transmitted by the order for the purposes of executing the order.
2. SICAT processes personal data (e.g. title, name, address, e-mail address, telephone number, bank account details, credit card number) only in accordance with the provisions of German data protection legislation. The terms below provide information about the type, extent and purpose for which personal data are recorded, processed and used. This data protection statement relates only to data recorded by SICAT.
3. Personal data, insofar as they are required for setting up, designing the content of or amending the contractual relationship (user data), are used exclusively for fulfilling the contract. The name and delivery address, for example, have to be passed on to the supplier of the goods in order for the goods to be supplied.
4. Personal data will not be passed to third parties not involved in processing the contract without express consent or unless there is a legal requirement to do so.
5. Insofar as SICAT provides services in advance, e.g. in the event of payment on account, SICAT will obtain information about the customer's creditworthiness, if appropriate. The customer's personal data (e.g. name and address) will be passed on for this purpose. Mathematical/statistical methods will be used to check the level of risk of non-payment. SICAT will make conclusion of the contract to purchase dependent on the result of this credit check.
6. If the customer registers for our newsletter, their e-mail address will be used for our own marketing purposes until the customer unsubscribes from the newsletter. The customer can unsubscribe at any time. The customer expressly provides the consent below separately or, if appropriate, in the course of the ordering process:

„I would like to receive information about SICAT products and services by e-mail. This includes information about new products, events and training sessions. I consent to data provided by me being used by SICAT exclusively in compliance with SICAT's data protection guide-lines. I can revoke this consent at any time with effect for the future.“

The customer can revoke their consent at any time with effect for the future. If the customer no longer wishes to receive the newsletter, he or she can unsubscribe as follows: via an „unsubscribe“ link in the newsletter or by sending an e-mail to info@sicat.com.

§14 Other stipulations

1. Severability clause
If one of the above agreements should be or become ineffective, this will have no impact on the effectiveness of the rest of the contract. The term which comes closest in economic terms to the term which is or has become ineffective will apply instead of the term which is or has become ineffective.
2. Place of fulfillment is SICAT's registered office.
3. To the extent that the customer is a business, SICAT's registered office is the place of jurisdiction for all disputes arising from this agreement; however, SICAT is also entitled to institute legal proceedings at the customer's registered office.

The law of the Federal Republic of Germany applies; the UN Convention on Contracts for the International Sale of Goods [CISG] is excluded.