

# FIN-CERAMICA FAENZA S.P.A. - GENERAL CONDITIONS OF SALE

The following General Conditions of sale (hereafter "General Conditions") apply to all contractual relationships between Fin-Ceramica Faenza S.p.A., with registered office at Via Granarolo, 177/3 - 48018 FAENZA (RA), Italy, Tax Code and VAT No.IT 01025400399 (hereafter the "SUPPLIER"), and its **customer residing outside Italy** (hereafter the "CUSTOMER") relating to the supply of goods, wherever this is not regulated by a specific contract or distribution agreement, but by a Financial Proposal.

## 1. DEFINITIONS

The words and expressions below have the following meanings:

- **Financial Proposal:** Financial Proposal means the document sent by the SUPPLIER to the CUSTOMER containing product descriptions, quantities, prices, discounts, methods of payment, any related services, and any other information required to uniquely and completely identify each element of the Financial Proposal. The annexes and any additional documents form an integral part of the Financial Proposal, provided they are referenced in the Financial Proposal itself.
- **Order:** an Order is the completed and signed order form sent by the CUSTOMER to the SUPPLIER. The annexes and any additional documents form an integral part of the Order, provided they are referenced in the Order itself.
- **Order Confirmation:** an Order Confirmation means the form sent by the SUPPLIER that includes all the terms and conditions agreed between the Parties.
- **Party or Parties:** Party or Parties refer to the SUPPLIER, the CUSTOMER and their successors and assignees.
- **Product or Products:** Product or Products means any goods that can be supplied by the SUPPLIER to the CUSTOMER, both directly manufactured by the SUPPLIER or manufactured by third parties and only distributed by the SUPPLIER.

## 2. OBJECT AND SCOPE OF APPLICATION

- 2.1 The Object of these General Conditions is the supply of Products by the SUPPLIER to the CUSTOMER as specifically identified in the Financial Proposal.
- 2.2 These General Conditions apply any time the SUPPLIER sends a Financial Proposal to the CUSTOMER, starting from the accepting date of the General Conditions by the CUSTOMER.
- 2.3 The Parties agree that, independently of what is set out in the CUSTOMER's general conditions of purchase, these General Conditions replace and prevail over the CUSTOMER's general conditions of purchase.
- 2.4 These General Conditions, together with the Financial Proposal, the Purchase Order and the Order Confirmation, represent the entire agreement regulating the relationship between the SUPPLIER and CUSTOMER in relation to a specific supply of Products, and replace and supersede any previous verbal or written communication between the Parties.

## 3. FINANCIAL PROPOSAL, ORDER AND ORDER CONFIRMATION

- 3.1 Any Financial Proposal sent by the SUPPLIER to the CUSTOMER represents a contractual offer to the CUSTOMER, and remains in force for a period of 60 (sixty) days from the date of issue, unless otherwise specified in writing by the SUPPLIER in the Financial Proposal itself.
- 3.2 The CUSTOMER, if it intends to accept, shall send the related Order to the SUPPLIER, within the period of validity of the Proposal. The Order shall be sent to the SUPPLIER in writing, by fax (+39 0546 607312) or by e-mail ([customercare@finceramica.it](mailto:customercare@finceramica.it)), on headed notepaper with the following information:
  - a) details of the Financial Proposal (number and date);
  - b) product code and related quantity required;
  - c) unit price for each code and total price for the quantity requested;
  - d) delivery address;
  - e) terms and conditions of payment according to the conditions set out in the Financial Proposal.

Product codes, description and unit prices to be used as a reference in the Order shall match those specified in the Financial Proposal.

The SUPPLIER is free to accept or refuse the Order at its sole discretion.

- 3.3 Where the Financial Proposal contains a specific indication of the quantity of Products offered, the SUPPLIER is free to accept, notwithstanding article 3.2, the Financial Proposal duly stamped and signed for acceptance by the CUSTOMER.
- 3.4 After receiving the Order, The SUPPLIER will send the Order Confirmation to the CUSTOMER to summarize definitively all terms and sales conditions agreed between the Parties.
- 3.5 What stated above is not applicable in case of goods on consignment.

## 4. DELIVERY TERMS

- 4.1 The delivery of the Products shall be carried out according to the delivery terms specified in the Order Confirmation.
- 4.2 The Product shipment date will be communicated by the SUPPLIER to the CUSTOMER by sending the Order Confirmation. If the CUSTOMER does not agree with the shipment date, he will have the right to withdraw acceptance and cancel the Order, informing the SUPPLIER within 5 (five) working days from the receipt.

In relation to "Custom Devices", the delivery time will be agreed between the Parties as required.

- 4.3 In cases of force majeure, meaning those outside the reasonable control of the SUPPLIER (e.g. strikes, fire, mobilization, requisition, embargoes, currency restrictions, riots, attacks, lack of means of transport, general lack of raw materials and energy usage restrictions), the SUPPLIER will communicate new delivery terms. If an agreement is not reached, the CUSTOMER shall have the right to withdraw acceptance or cancel the Order within 5 (five) working days from the receipt of the communication.
- 4.4 The CUSTOMER authorizes and accepts partial deliveries.
- 4.5 The delivery terms communicated by the SUPPLIER pursuant to art. 4.2 will automatically be suspended when the following occur and extended once they cease:
  - a) if the CUSTOMER requests changes during the processing stages or replies late to project approval requests;
  - b) if the financial situation of the CUSTOMER and/or the total credit provided by the SUPPLIER to the CUSTOMER may, at the sole discretion of the SUPPLIER, put the payment for the supply at risk.

## 5. PRICES

- 5.1 The Product prices (hereafter "Prices") specified in the Financial Proposal are in Euro (€) and net of VAT, unless otherwise specified in writing by the SUPPLIER in the Financial Proposal itself.
- 5.2 If a different currency is used, reference is made to the exchange rate on the day on which the SUPPLIER receives the Financial Proposal signed in acceptance by the CUSTOMER.

## 6. PAYMENTS

- 6.1 Invoices payment terms are strict, fundamental, and cannot be extended except where provided for in article 6.3 below. If invoices are past due, the SUPPLIER shall be authorized to apply an interest rate equal to the official Euribor rate plus 7%, starting from the due date of the invoice.
- 6.2 Unless otherwise agreed in writing, the payment shall be made according to the terms and methods indicated in the Financial Proposal. Where the Parties have reached an agreement on payment deferral, notwithstanding what is established in article 6.1, and the CUSTOMER fails to pay any instalment within the agreed timescale, the SUPPLIER can demand payment of the entire residual amount it is owed in a single instalment, and shall be authorized to apply a default interest rate to this amount as set out in the previous art. 6.1., with no additional notice, starting from the date on which the CUSTOMER was due to pay the outstanding instalment.

6.3 The SUPPLIER shall be authorized to interrupt the shipment of the Products if the financial situation of the CUSTOMER and/or the total credit provided by the SUPPLIER to the CUSTOMER may, at the sole discretion of the SUPPLIER, put the Products payment at risk.

## 7. WARRANTY

7.1 The SUPPLIER guarantees the CUSTOMER that the Products comply with all applicable standard to the European market, Directive 2007/47/EC amending Directive 93/42/EEC and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

7.2 The SUPPLIER guarantees that its Quality Management System (QMS) complies with the ISO 9001 and ISO 13485 standards in force.

7.3 Within 8 (eight) days of receiving the Products, the CUSTOMER must inform the SUPPLIER of any defects relating to the quality of the Product units received (by way of example and not limited thereto, damaged product or packaging, missing parts/components, inconsistency between the number of packages delivered compared to those specified on the delivery note) provided that such defects cannot be attributed to transport. In this case, the CUSTOMER will be required to document (through photographs, videos, documents, etc.) the anomaly. Within 8 (eight) days of the notification, the SUPPLIER shall inform the CUSTOMER if it is necessary to return the Products to the SUPPLIER in order to check them.

7.4 If the Products are defective, the SUPPLIER shall, at its sole discretion, replace them at its own expense, issue a credit note to reverse the invoice, or, where payment has already been made, reimburse the amount paid.

7.5 Independently of its validity, the notification referred to in art. 7.3 does not release the CUSTOMER from its obligation to pay the price of the Products within the agreed contractual terms.

## 8. RESPONSIBILITIES

8.1 The SUPPLIER shall hold the CUSTOMER harmless from any claim or request by third parties in relation to the Products if, and to the extent of any damage suffered by the third party, it is due to a defect in the Products. The SUPPLIER shall bear all costs and expenses in this regard, including the costs of any legal action.

8.2 It is understood that the SUPPLIER shall be responsible only for its own Products and not for the applications, accessories or systems within which its Products are assembled, used or connected by the CUSTOMER.

## 9. FURTHER CUSTOMER'S OBLIGATIONS

9.1 By purchasing the Products, the CUSTOMER explicitly accepts that it shall comply with the following conditions:

- the CUSTOMER shall store the Products as specified on the packaging, and in particular shall not store expired Products;
- the CUSTOMER shall put in place a suitable storage system for medical devices;
- the CUSTOMER shall guarantee the identification and traceability of each purchased Product for at least 15 (fifteen) years;
- the CUSTOMER shall notify the SUPPLIER in writing as soon as possible and in any case, not later than 2 (two) weeks of each identified nonconformity;
- the CUSTOMER shall immediately, and in any case no later than 2 (two) days after becoming aware of any each adverse event and/or complaint received from its customers in relation to the Products;
- the CUSTOMER undertakes to immediately recall all Products at the request of the SUPPLIER or the Competent Authorities;
- *the CUSTOMER undertakes to comply with current European Regulations with particular reference to Article 14 and Article 16 of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.*

9.2 If the CUSTOMER does not comply with the conditions established in section 9.1 above, the SUPPLIER shall not be responsible under any circumstances for claims for compensation or responsibilities made by the CUSTOMER or third parties. Furthermore, CUSTOMER's failure to comply with the obligations set out shall void any right of warranty referred to in article 7.3.

9.3 The CUSTOMER must not add, create or modify the Product labelling without prior written authorization from the SUPPLIER's Quality Assurance department. Wherever the CUSTOMER does not comply with this clause, the SUPPLIER shall have the right to claim compensation for any damage suffered.

9.4 If it is necessary to register with the Competent Authorities, the CUSTOMER cannot open any type of procedure without the prior written authorization of the SUPPLIER.

9.5 During the consignment period, CUSTOMERS will be liable in case of deterioration, subtraction, loss, destruction or alteration of the products received in view. CUSTOMERS will also be liable for any damages caused to third parties for causes not attributable to the SUPPLIER.

9.6 If Finceramica grants to the Customer the use of MaioRegen Mini-Arthro Kitfree of charge, the Customer accepts the application of the provisions of Annex 1, attached to these General Conditions.

## 10. MISCELLANEOUS

10.1 In order to ensure shared ethics and compliance with the principles of legality, correctness and transparency in carrying out the company activities, the SUPPLIER has adopted a Code of Ethics. The CUSTOMER acknowledges and confirms that it has read the SUPPLIER's Code of Ethics, published on the website [www.finceramica.it](http://www.finceramica.it), and undertakes to behave in a way that complies with the provisions contained therein. The non-compliance with any of the provisions in the aforementioned Code of Ethics constitutes a serious breach of the obligations referred to in these General Conditions, and gives the SUPPLIER the right to terminate the existing relationship with the CUSTOMER with immediate effect by simply giving written notice, without prejudice to compensation for any damage suffered by the SUPPLIER.

10.2 In any case, the SUPPLIER shall not be responsible for any unlawful behaviour of the CUSTOMER.

10.3 The total or partial invalidity or unenforceability of one of more clauses of the General Conditions shall not affect the validity or enforceability of the remaining clauses or parts not affected by invalidity or unenforceability, which shall remain completely valid and effective.

10.4 Any relinquishment by the SUPPLIER to exercise a right arising from these General Conditions cannot be understood as a waiver of the right or of any other right in relation to this provision or other provision of the General Conditions.

## 11. GOVERNING LAW AND JURISDICTION

11.1 These General Conditions shall be governed by and construed in accordance with Italian laws.

11.2 Any disputes arising from these General Conditions, from the Financial Proposal or from the Order or connected to them shall be under the exclusive jurisdiction of the Court of Ravenna, with the express exclusion of any other or alternative court.

## 12. PROTECTION OF PERSONAL DATA

The SUPPLIER recognizes that all the information acquired during its business operations are to be considered confidential in compliance with the current legislation Regulation (EU) 2016/679.

The CUSTOMER declares that it clearly understands and agrees with every clause in these General Conditions.

DATE \_\_\_\_\_ THE CUSTOMER \_\_\_\_\_

Pursuant to articles 1341 and 1342 of the Italian Civil Code, the CUSTOMER expressly approves the content of the following articles: 7.3; 8; 9.2; 11.  
THE CUSTOMER \_\_\_\_\_

**GENERAL TERMS AND CONDITIONS OF LOAN FOR USE**

These General Terms and Conditions of Loan for use (hereinafter the "**General Terms and Conditions of Loan for use**") regulate, except for possible exceptions specifically agreed in writing between the parties, all the loan for use contracts concluded between Fin-Ceramica Faenza S.p.A., with registered office in Faenza (RA), Via Granarolo 177/3, VAT no. 01025400399 (hereinafter the "**Bailor**") and any subject (hereinafter the "**Bailee**") who, under the terms of pre-existing commercial relations such as the distribution of the products of the Bailor or the sale of the products by this last to the Bailee, uses the instrumentation (Surgical instruments supplied non-sterile; re-usable, after washing and sterilization) and/or assets of any kind owned by the Bailor (hereinafter the "**Assets**" or, individually, the "**Asset**"), which will be considered granted in loan for use.

**Article 1. - Conclusion of the contract of loan for use**

- 1.1. The contract of loan for use relative to an Asset (hereinafter the "**Contract of loan for use**") will be considered finalised with the delivery of the Asset to the Bailee and will end with the return of the Asset to the Bailor. The Contract of loan for use will be free of charge and, for anything not specifically regulated, will be subject to the provisions of articles 1803 et seq. of the Italian Civil Code.
- 1.2. The Contract of loan for use will have the term agreed each time between the parties, without prejudice to the Bailor's right to demand the immediate return of the Asset at any time should an urgent need of the Bailor or other company directly or indirectly controlled or affiliated with the Bailor arise. It remains understood that the Contract of loan for use will be considered automatically terminated, and the Bailee will be obliged to immediately return the Asset to the Bailor, should the commercial relations between the Bailor and the Bailee cease for any reason.

**Article 2. - Declarations, obligations and responsibilities of the Bailee**

- 2.1. The Bailee, by receiving the Asset in loan for use, declares:
  - i)* that he has inspected the Asset and verified it is in good condition for use;
  - ii)* that he has verified the suitability of the Asset for the use for which it is intended;
  - iii)* that he has verified the conformity of the Asset with the accident prevention laws and all the safety rules in force;
  - iv)* that he has the necessary abilities to use the Asset correctly and has staff qualified and trained in accordance with the regulations in force;
 He also declares:
  - i)* that he will permit the use of the asset only and exclusively in accordance with the perimeter of use as described in the instructions for use (hereinafter the "Instructions for Use");
  - ii)* that he will provide the training in the use of the Asset to the end user as indicated in the Instructions for Use;
  - iii)* that he will supply the Asset to the end user including always the Instructions for Use (as delivered by the Bailor);
  - iv)* that he will communicate in writing, at the request of the Bailor, and in any case, when returning of the Asset to the Bailor, the number of specific uses for each lot of the Asset;
  - v)* that he will guarantee the identification and traceability of every Asset granted in loan for use for at least 5 (five) years;
  - vi)* that he will inform the Bailor in writing as soon as possible and in any case no later than 2 (two) weeks, of every non-conformity encountered;
  - vii)* that he will immediately notify and in any case no later than 2 (two) days after becoming aware of, every adverse event and/or complaint received from his customers relative to the Products;
  - viii)* that he will immediately recall all the Products following the request of the Bailor or the Competent Authorities.
- 2.2. The Bailee undertakes to keep and preserve the Asset with the maximum care and diligence and to return it at the expiry date agreed with the Bailor, or at the Bailor's request pursuant to the preceding article 1.2, in the conditions in which it was delivered, barring normal wear and tear. No modification, even of improvement, is permitted on any Asset without the prior written consent of the Bailor. It remains understood that the Bailee will be responsible for any damage or loss of the Asset and/or its components, compensating the Bailor for the amount of the damage caused to the Asset.
- 2.3. The Bailor authorises the Bailee to transfer to third parties the possession or use in all or in part of the Asset, provided the Asset is used exclusively by medical personnel specialised in orthopaedic surgery.
- 2.4. The Bailee undertakes not to permit the use of the Asset for purposes and/or uses other than those agreed with the Bailor, than that described in the Instructions for Use and to make use of it in compliance with the accident prevention regulations in force and all the safety rules in force, as well as the provisions of these General Terms and Conditions of loan for use. The Bailee also undertakes to use the Asset in conformity with the rules of good technique and prudence.
- 2.5. The Bailee is required to immediately inform the Bailor of any anomalies or operating defects of the Asset.
- 2.6. Except for any claim or request of third parties relative to the Asset, if and to the extent in which any damage suffered by the third parties, is due to a manufacturing defect of the Asset, the Bailee will be responsible for the use of the Asset and will be liable for the damages caused to persons or things as a result of the use of the Asset. It follows that the Bailor can take recourse against the Bailee for every and any judicial action, appeal, damage, loss, liability or cost that they may incur as a result of the management and use of the Asset.
- 2.7. Should the Asset subsequently be sold to the Bailee, this last guarantees the compliance with the Instructions of Use.

**Article 3. - Express termination clause**

The Contracts of loan for use regulated by these General Terms and Conditions of loan for use can be terminated by the Bailor for just cause and without notice, by simple written communication to the Bailee, should the Bailee not correctly fulfil the obligations provided by the preceding , except for the Bailor's right to act for the compensation of the damage suffered.

**Article 4. - Disputes and Jurisdiction**

Any dispute resulting from the interpretation and/or implementation and/or application of the Contracts of loan for use regulated by these General Terms and Conditions of loan for use will be devolved to the exclusive jurisdiction of the Court of Ravenna, Italy.

Fin-Ceramica Faenza S.p.A.

The Bailee

Pursuant to and in accordance with articles 1341 and 1342 of Italian Civil Code, the Bailee, after having carefully read them, declares that he expressly approves the following clauses: article 2.4 - Ban on transfer to third parties; article 2.6 - Responsibility for the use of the Asset; article 3 - Express termination clause; article 4 - Disputes and Jurisdiction.

The Bailee