

AS SISTĒMU INOVĀCIJAS
Registration No. 40003946311
Address: Mazcenu aleja 6a, Jaunmārupe, Mārupes nov., LV-2166

Riga, 8 February 2024
No. AK-02/2024

Procurement regulations and technical specification

1. General information about the beneficiary:

Name: AS SISTĒMU INOVĀCIJAS.

Unified registration No.: 40003946311.

Address: Mazcenu aleja 6a, Jaunmārupe, Mārupes nov., LV-2166.

Contact person: Ēriks Jakobsons, tel. No. 27034544, e-mail address:
eriks@sibiotech.com.

The procurement tender is organised within the scope of the activity "Investment in aquaculture" organised by the Rural Support Service.

The procurement tender is organised pursuant to Cabinet of Ministers Regulations No. 104 of 28 February 2017 "Regulations on the procurement procedure and the procedure of its application for projects funded by the contracting authority".

2. Object of the procurement: Soft shell capsule manufacturing line.

3. Place of delivery of the object of procurement: Ķengaraga iela 10A, Riga, LV-1063.

4. Delivery term: 30.12.2024.

5. Tender validity period: 01.07.2024.

6. Description and specification of the object of the procurement:

a. General description of the object of the procurement

Softshell capsule-producing machine with auxiliary equipment for R&D and pilot production of sealed soft shell (gelatine) capsules for nutraceutical and pharmaceutical applications.

Full line, including auxiliary equipment.

Production capacity for up to 5000 capsules per hour.

b. Technical specification

1.	Rotary die soft shell (gelatine) capsule manufacturing line:	A set of equipment dedicated to manufacturing soft shell (gelatine) capsules suitable for nutraceutical and pharmaceutical applications.
	1.1. Soft shell capsule manufacturing machine.	Rotary die soft shell (gelatine) capsule-producing machine: - two sets of aluminium die rolls, appropriate filling wedges, change parts and special casing for capsule sizes – 20 Oblong and 10 Oval;

		- operation speed should be variable in the range 1.5–5.0 RPM; - the medicine pump; - the spreader box should provide an adaptable gel ribbon width; - casting drum construction should ensure gel ribbon transfers directly to rolls; - the cooling control of casting drums should be provided; - the gel ribbon lubrication should be provided; - the capsule transfer conveyor should be provided; - at least one die roll alignment gauge; - at least one gel ribbon thickness monitoring gauge; - the control of all production and process parameters should be done by an industrial-grade PLC; - process control software should provide automatic execution of chosen process setpoints (recipes), selective access to process control and compliance with GMP requirements; - CFR 21 Part 11 compliance software; - the construction of the capsule-producing machine should prevent any possible rust occurrence and allow easy cleaning and maintenance; - the outside covers of the machine should be completely made from stainless steel and designed according to the cGMP requirements; - the machine must be suitable to produce capsules with animal, fish and vegetable shell material.
	2.1. Capsule shell (gelatine) preparation system.	Capsule shell (gelatine) preparation tank (stainless steel): - working capacity not less than 80 L; - total tank capacity up to 250 L; - designed pressure -1/+1 bar; - operating temperature at least +5°C to +100°C; - heating/cooling jacket – water/steam; - suitable for plant-based capsule shell preparation; - tank should be equipped with appropriate ports, connectors for material inlet/outlet, heating, pressure/vacuum, temperature control and mixing; - temperature sensor; - a vacuum gauge; - a frame stirrer with scraper; - a sight glass; - material feed hose with integrated heating; - all parts made of stainless-steel compatible with GMP. Gel preparation tank control system: - based on industrial grade PLC and operator panel; - process control software. Heating system for capsule shell (gelatine) melting tank should be based on standalone, electric, water heater and cold exchanger module. The circulation pump, appropriate fittings, water lines and control elements should be included in offer.
	3.1. Medicine tank.	Pressurized medicine tank (stainless steel):

		- working capacity not less than 50 L; - designed pressure not less than 1 bar; - operating temperature at least +5°C to +100°C; - heating/cooling jacket; - tank should be equipped with appropriate ports, connectors for inlet/outlet, heating/cooling, pressure and temperature control; - temperature sensor; - all parts made of stainless-steel compatible with GMP.
	4.1. Capsule drying unit.	Offer should include: - capsule drying unit with batch volume not less than 50 kg; - electrical box with control of drying process; - all parts made of stainless-steel compatible with GMP.
		Offer should include: - sorting table; - capsule storage trays; - storage tray dollies.
		Offer should include following services: - Factory acceptance tests (FAT); - Installation and operation qualification documentation; - Installation of the softshell capsule producing line at customer premises; - Technical training of soft shell capsule production at the customer premises (minimum 5 days).
		Supplier should provide following documentation: - electrical diagrams of all components of capsule production line; - functional description; - design description; - user manuals.
	EU declaration of conformity and Latvian standards.	EU declaration of conformity.
	Warranty:	at least 12 months from the date of installation

The supplier may replace all the references to specific standards, products or manufacturers used in the procurement documentation with equivalent or analogue products meeting the specification requirements

7. **Winner selection criteria:** – a tender for the lowest price, which meets the requirements of the technical specification.
8. **Draft contract:** the draft procurement contract is attached in Annex 1.
9. **Requirements to the tenderer's capacity and quality:** – the Tenderer has at least one year experience in the field of the procurement.
10. **Tender preparation requirements:**
 - a fully developed and final tender should be prepared;

- the form attached in Annex 2 is recommended for preparing the tender;
- the tenderer may use its own form to prepare the tender, but should include all the information referred to in Annex 2, incl.:
 - a. **technical specification of the object of the procurement indicating the manufacturer (make) and model (if applicable) of each unit (component/additional equipment);**
 - b. information about the supplier (company details) should be specified in the tender;
 - c. the estimated delivery time of the equipment should be specified in the tender;
 - d. the period of validity of the tender should be specified in the tender;
 - e. the price of the tender in EUR, excluding VAT should be specified in the tender;
 - f. the date of the tender, the name, position, signature and contact details of the person who prepared it should be specified in the tender;
 - g. the tender should be prepared in computer form, including all the required information.
- The tenderer should also submit together with the tender a completed form attached in Annex 3.

11. Tender submission requirements:

- fully developed and final tenders may be submitted by suppliers from the date of notification of the procurement procedure until **11.03.2024** 17:00 by sending a tender signed with a secure electronic signature to the email address eriks@sibiotech.com.
- any tenders submitted after the specified deadline will not be assessed and shall be considered invalid.

AS SISTĒMU INOVĀCIJAS
Member of the Board

Dace Rudāja

to PROCUREMENT REGULATIONS AND TECHNICAL SPECIFICATION
“Soft shell capsule manufacturing line”
(Procurement identification No. AK-02/2024).

“DRAFT PROCUREMENT CONTRACT”

This contract was concluded in Riga on ____ 20__ between

SIA _____, unified reg. No. _____, hereinafter referred to as the Seller, represented by its Member of the Board _____, acting on the basis of the Articles of Association, on the one hand, and AS SISTĒMU INOVĀCIJAS, unified registration No. 40003946311, hereinafter referred to as the Buyer, represented by its Member of the Board Dace Rudāja, acting on the basis of the Articles of Association, on the other hand, hereinafter jointly referred to as the parties, but severally as the party, enter into the following Purchase and Sale Contract (hereinafter referred to as the Contract), which is binding on the parties, their successors in title and liabilities:

1. Subject-matter of the Contract.

1.1. The Seller shall sell and deliver, but the Buyer shall buy and accept from the Seller in accordance with the terms of the contract the **“Soft shell capsule manufacturing line”**, hereinafter referred to as the Equipment, the price, technical data, manufacturing, delivery deadlines and payment for which are defined in the technical specification developed by the Buyer and the tender submitted by the Seller to the Buyer, which is Annex No.1 to this Agreement.

2. Prices and total Contract value.

2.1. The total amount of the Contract (purchase price) for the purchase, delivery and installation of the Equipment is EUR _____ (____ EUR, 00 cents), plus VAT (21%) EUR _____ (____ EUR, 00 cents).

3. Payment and delivery conditions.

3.1. The Buyer undertakes to make an advance payment of **60%** of the total Contract amount specified in Cl.2.1, i.e., EUR _____ (____ EUR, 00 cents) plus VAT (21%) EUR ____ (____ EUR, 00 cents) within 10 (ten) business days of signing this contract and receiving an invoice from the Seller.

3.2. The Buyer undertakes to make the final payment of **40%** of the total Contract amount specified in Cl.2.1, i.e., EUR ____ (____ EUR, 00 cents) plus VAT (21%) EUR ____ (____ EUR, 00 cents) within seven business days of the factory acceptance test of the Equipment.

3.3. The Seller shall ensure the delivery and installation of the Equipment, as well as staff training.

3.4. The place of delivery and installation of the Equipment: Kengaraga iela 10A, Riga, LV-1063

3.5. The ownership of the Equipment shall be transferred from the Seller to the Buyer after the bill of lading/invoice has been paid in full. The Buyer's authorised representative shall confirm compliance of the product with the information provided in the bill of lading/invoice with his/her signature in the bill of lading/invoice. After the bill of lading/invoice is signed,

the Buyer is no longer entitled to make claims regarding the composition of the Equipment, non-compliant labelling and packaging, except for claims regarding damage of the Equipment during transportation if transport services are provided by the Seller.

4. Quality and warranty.

4.1. The Seller guarantees that the quality and composition of the Equipment meet the standards set by the manufacturing company.

4.2. The Seller undertakes to ensure maintenance and service during and after the warranty period based on a mutually concluded agreement.

5. Dispute resolution and responsibility

5.1. All disputes and disagreements related to the fulfilment of this Contract shall be resolved by the parties through negotiations.

5.2. If it is not possible to reach an agreement through negotiations, then disputes and disagreements shall be resolved in the courts of the Republic of Latvia in accordance with the laws of the Republic of Latvia.

5.3. The Parties shall be responsible for the default of contractual liabilities according to the applicable laws and regulations of the Republic of Latvia.

5.4. If the deadline specified in Cl.3.4 of this Contract is not met, the Buyer shall pay the Seller a contractual penalty of 0.1% of the relevant amount for each day of delay. The amounts paid by the Buyer shall first cover the penalties. Payment of penalties shall not relieve the Buyer of the performance of its contractual obligations.

5.5. If the Product is not delivered and installed within the deadline specified in this contract/annex, the Seller shall pay the Buyer a contractual penalty of 0.1% of the amount referred to in Cl.3.4 for each day of delay. Payment of the contractual penalty shall not relieve the Seller of the full performance of the obligations under this Contract.

5.6. In the event of a breach of the Contract, each Party shall have the right to submit to the other Party a claim to which the other Party is required to respond immediately, but no later than within 7 calendar days from the date of receipt of the claim.

5.7. The Parties undertake not to disclose any technical, financial and commercial information or other data obtained or known during the duration of the Contract which may be used for competition purposes.

6. Other provisions.

6.1. The Parties undertake to inform each other in writing in advance of any changes to its address, name, other details and legal status specified in this Contract.

6.2. The reorganisation or change of the form of property of the Parties cannot give rise to unilateral amendment or termination of the Contract, since the obligation to fulfil the Contract shall be transferred to the successors in title of the Parties.

6.3. All the amendments and supplements to this Contract shall be made only by written agreement of the Parties and shall become an integral part of this Contract as soon as they are signed.

6.4. All disputes and disagreements between the Parties shall be resolved through negotiations, but if no agreement is reached, it will be transferred for resolution to a court in accordance with regulatory enactments of the Republic of Latvia.

6.5. In the matters which are not specified in this Contract, the Parties shall be guided by applicable laws and regulations of the Republic of Latvia.

6.6. All the amendments and supplements to this Contract shall be made only by written agreement of the Parties and shall become an integral part of this Contract as soon as they are signed.

6.7. This Contract is drawn up in Latvian on 3 (three) pages in 2 (two) identical counterparts; one counterpart for each Party. The Contract can be signed with an electronic signature containing a time stamp. Such a Contract shall supersede signing of any paper counterparts.

6.5. All disputes and disagreements between the Parties shall be resolved through negotiations, but if no agreement is reached, it will be transferred for resolution to a court in accordance with regulatory enactments of the Republic of Latvia.

6.6. In the matters which are not specified in this Contract, the Parties shall be guided by applicable laws and regulations of the Republic of Latvia.

7. Procedures for the entry into force.

7.1. The Contract shall enter into force when signed by both Parties and shall be in effect under the parties fulfil their liabilities towards each other unless it is terminated in accordance with the procedure defined in the Contract or laws and regulations of the Republic of Latvia.

8. Registered addresses and details of the Parties:

Seller:

Buyer:

9. Signatures of the Parties:

Seller

Buyer

L.S.

L.S.

Annex 2
to PROCUREMENT REGULATIONS AND TECHNICAL SPECIFICATION
“Soft shell capsule manufacturing line”
(Procurement identification No. AK-02/2024).

Procurement tender (form)

For “**Soft shell capsule manufacturing line**” Procurement procedure No. AK-02/2024.

____.____.____ 2024

Contracting Authority:	AS SISTĒMU INOVĀCIJAS
Registration No.:	40003946311.
Address:	Mazcenu aleja 6A, Jaunmārupe, Mārupes nov., LV-2166.
Contact person:	Ēriks Jakobsons, tel. No. 27034544, e-mail address: eriks@sibiotech.com.
Tenderer:	
Registration No.:	
Address:	
Telephone:	
E-mail:	
Contact person:	

OBJECT OF THE ORDER (specifying manufacturer and model):	
Tender validity period:	01.07.2024.
Equipment delivery deadline:	30.12.2024.
Place of provision of the service:	Kengaraga iela 10A, Rīga, LV-1063.
Technical specification:	
“Rotary die soft shell (gelatine) capsule manufacturing line.	A set of equipment dedicated to manufacturing soft shell (gelatine) capsules suitable for nutraceutical and pharmaceutical applications.
1. Soft shell capsule manufacturing machine.	Rotary die soft shell (gelatine) capsule-producing machine: - two sets of aluminium die rolls, appropriate filling wedges, change parts and special casing for capsule sizes – 20 Oblong and 10 Oval;

	- operation speed should be variable in the range 1.5–5.0 RPM; - the medicine pump; - the spreader box should provide an adaptable gel ribbon width; - casting drum construction should ensure gel ribbon transfers directly to rolls. - the cooling control of casting drums should be provided; - the gel ribbon lubrication should be provided; - the capsule transfer conveyor should be provided; - at least one die roll alignment gauge; - at least one gel ribbon thickness monitoring gauge; - the control of all production and process parameters should be done by an industrial-grade PLC; - process control software should provide automatic execution of chosen process setpoints (recipes), selective access to process control and compliance with GMP requirements; - CFR 21 Part 11 compliance software - the construction of the capsule-producing machine should prevent any possible rust occurrence and allow easy cleaning and maintenance; - the outside covers of the machine should be completely made from stainless steel and	
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	designed according to the cGMP requirements. The machine must be suitable to produce capsules with animal, fish and vegetable shell material.	
2. Capsule shell (gelatine) preparation system.	Capsule shell (gelatine) preparation tank (stainless steel): - working capacity not less than 80 L; - total tank capacity up to 250 L; - designed pressure -1/+1 bar; - operating temperature at least +5°C to +100°C - heating/cooling jacket – water/steam; - suitable for plant-based capsule shell preparation; - tank should be equipped with appropriate ports, connectors for material inlet/outlet, heating, pressure/vacuum, temperature control and mixing; - temperature sensor; - a vacuum gauge; - a frame stirrer with scraper; - a sight glass; - material feed hose with integrated heating; - all parts made of stainless-steel compatible with GMP. Gel preparation tank control system: - based on industrial grade PLC and operator panel; - process control software. Heating system for capsule shell (gelatine) melting tank should be based on standalone, electric, water heater and cold exchanger module. The circulation pump, appropriate fittings, water lines and control elements should be included in offer.	

3. Medicine tank.	Pressurized medicine tank (stainless steel): - working capacity not less than 50 L; - designed pressure not less than 1 bar; - operating temperature at least +5°C to +100°C; - heating/cooling jacket; - tank should be equipped with appropriate ports, connectors for inlet/outlet, heating/cooling, pressure and temperature control; - temperature sensor; All parts made of stainless-steel compatible with GMP.	
4. Capsule drying unit.	Offer should include: - capsule drying unit with batch volume not less than 50 kg; - electrical box with control of drying process; All parts made of stainless-steel compatible with GMP.	
Offer should include: - sorting table; - capsule storage trays; - storage tray dollies.		
Offer should include following services: - factory acceptance tests (FAT); - installation and operation qualification documentation; - installation of the softshell capsule producing line at customers premises; - technical training of soft shell capsule production at the customer premises (minimum 5 days).		
Supplier should provide following documentation: - electrical diagrams of all components of capsule production line; - functional description; - design description; - user manuals.		
EU declaration of conformity and Latvian standards.		
Warranty:		
Certification	I hereby certify that: - the Tenderer has at least one year experience in the field of the procurement. The tender price is specified:	

	- including the delivery and installation at the specified place of delivery – Kengaraga iela 10A, Riga, LV-1063; - including training of contracting authority's staff on work with the equipment; - including delivery and assembly of the equipment.
	TOTAL TENDER PRICE IN EUR EXCL. VAT
	VAT ____ % EUR
	TOTAL TENDER PRICE IN EUR EXCL. VAT
Other information:	
...	...

- We are not interested in any way in any other tender submitted in this procurement procedure.
- There are no conditions denying us to participate in the procedure and fulfil the requirements specified in the competitive dialogue instruction for tenderer and the technical specification.

(Position name, name, surname, signature of the person preparing the tender)

to PROCUREMENT REGULATIONS AND TECHNICAL SPECIFICATION
“Soft shell capsule manufacturing line”
(Procurement identification No. AK-02/2024).

Declaration that the tender has been developed independently

Hereby, providing comprehensive and truthful information, _____

Tenderer's name, reg. No.

(hereinafter referred to as the Tenderer) with regard to the specific procurement procedure certifies that:

1. the Tenderer has read and agrees to the content of this declaration;
2. the Tenderer is aware of its obligation to provide complete, comprehensive and truthful information in this declaration;
3. the Tenderer's procurement tender has been signed by authorised person/s of the Tenderer;
4. the Tenderer informs that it has submitted the tender independently from competitors¹ and without consultations, contracts or agreements. The Tenderer did not have communication with any competitors regarding:
 - 4.1. prices;
 - 4.2. price calculation methods, factors (conditions) or formulae;
 - 4.3. an intention or decision to participate or not to participate in the procurement (to submit or not to submit a tender); or
 - 4.4. submission of such a tender, which does not meet the requirements of the procurement;
 - 4.5. the quality, scope, specification, performance, delivery or other conditions, which should be resolved independently from competitors, those products or services, this procurement refers to.
5. The Tenderer has not consciously, directly or indirectly disclosed and will not disclose conditions of the tender to any competitor before the date and time of official opening of tenders or awarding of the contract.
6. The Tenderer is aware that the liability under the Competition Law for prohibited agreements, envisaging a fine of up to 10% from the breacher's net turnover of the last financial year, and the tenderer maybe subject to exclusion from participation in the procurement procedure.

/ _____ / Signature

/ _____ / Date

¹ In the context of this certification the term “competitor” means any natural or legal person, which is not the Tenderer and which: 1) submits a tender for this procurement; 2) taking into account its qualification, abilities or experience, as well as offered goods and services, might submit a tender for this procurement.