

13/2019

Request for information on prices and quality of:

Clinical Cryostats

Information on the quality, usability, technical characteristics, delivery time and the price shall be submitted to the email address verdfyrirspurnir@landspitali.is no later than the 14th of June 2019.

Queries should be sent to the email address <u>verdfyrirspurnir@landspitali.is</u> no later than the 7th of June 2019 and will be answered on the website on the 12th of June 2019 at the latest.

A contract will be signed with one (1) supplier for the equipment.

Landspítali University Hospital is requesting information on one type of clinical cryostats, which will be used by the department of pathology, this cryostats will replace current Leica CM1900 device. This Cryostats must be suitable for and support the medical service and the clinical environment in Landspitali.

General requirements for goods and services

- All products offered must comply with all regulations and international standards applicable in the European Economic Area regarding relevant products, such as EN ISO 13485: 2012, GMP, ISO 9000 or 9002, CE standards and other European standards for medical devices such as EN-60601-01, CENELEC HD 472 S1. Sellers must demonstrate these standards and regulations.
- The requested device shall have a minimum of two years warranty period.
- Details on technical information, as well as price, is requested for the products.
- Upon delivery, the products must be in unopened and undamaged packages.
- The seller must have professional knowledge of the product in question, or have on their behalf a person with professional knowledge, who will be able to advise the users on product use as well as any major innovation in this field.

Product requirements:

The following requirements are made for the clinical cryostats:

- The device shall be currently available on the market
- The device shall provide the highest clinical standard and performance, flexibility, reliability, user friendliness and efficiency.
- The device shall be robust, easy to use and simple to maintain; capable of delivering the same results over an extended period of time.
- The device shall have motorized sectioning
- The device shall have UVC disinfection

- The device shall have thickness range from 1µm to 100µm
- The maximum speciman size shall be 50mm*80mm
- The cryochamber shall have temperature range from 0°C to -35°C at ambient temperature of 20°C
- The speciman cooling shall have temperature range from -10°C to -50°C
- The price for all hardware and software necessary for the proper functioning of the device shall be included.

Other:

- Training for staff shall be included.
- The price for service of the system shall be included.

Delivery:

Device:

The seller is obliged to deliver the device to the purchaser, ready for clinical use, and within 8 weeks of the order. If, upon delivery, it is revealed that the shipment, or part of the shipment, is significantly defective, the purchaser is entitled to reject the defective product, and shall then disclose in writing to the seller the reason for the rejection. The rejected shipment is thereby considered as undelivered.

In the event of a problem or a delay in the delivery, the seller shall immediately inform the purchaser of the expected arrival time of the product and indicate the reasons for delay/ problems. If the purchaser is required to purchase a similar product from another party, due to a breach in the contract, the seller shall pay the additional costs incurred. Delivery from the seller's warehouse to the site of operation, as well as device installation and instruction shall be included in the price.

The seller is responsible for the packing, transport, insurance and delivery to the site of operation. The seller is responsible for the equipment until the equipment has been completely installed, accepted and delivered to the purchaser according to the contract, fully operational and ready for clinical use.

Prices shall include all costs and taxes related to this project, excluding VAT.

Payments:

An invoice shall be issued in ISK or Euro (€) for the total value of the equipment purchased, with payment arrangements as follows:

- 70% of the equipment value will be paid after acceptance testing and ready for clinical use.
- 30% of the equipment value will be paid after final acceptance of the system unit.

The invoice must state the contract number and name of contact person placing the order.

The invoice must state where it will be paid, that is, the name of the bank, number of the operation, and account number. To be valid the invoice must show the contract prices.

General terms of payment, if not otherwise agreed, is 30 days end of month of delivery.

The invoices must be sent to the location stated in the contract.

If the conditions above are not met, the invoice will be considered as invalid. The purchaser will not be obliged to pay until a valid invoice has been presented.

Price Changes:

Equipment:

An invoice is made based on the EUR average for the month before delivery of the device.

Delivery of information:

Information sheets are attached to this price query and information must fill in the requested information in the form (Excel). Additional information must be supplied in electronic format. Information should be sent to the email address: verdfyrirspurnir@landspitali.is.

3 (3)