APPENDIX A

Contract with

Supplier

relating to the Supply of

An filling machine for GMP production of intravenous fluids

For the

Capital Region of Denmark, Pharmacy

Capital Region of Denmark

REGH13010275

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# Schedules

1. Contracting authority's complete tender documents EU Tender REGH13010275 including points of clarification/responses no. 1-X.

1. Contract configuration (configuration based on information stipulated in the Supplier’s response to the tender conditions in Schedule C).
2. Qualification (attached).

1. Paradigms for site acceptance test and two year trial (attached).
2. Bank guarantee for advance payment (attached).
3. Performance guarantee during remedial period (attached).

1. Supplier's bid no. XX, date XX.

# Purchaser

Capital Region of Denmark Pharmacy

Marielundsvej 25

DK-2730 Herlev

Denmark

Represented by

Corporate Procurement

Capital Region of Denmark

Kongens Vænge 2

DK-3400 Hillerød

Denmark

# Supplier

ORG. NO.

# Contact persons

## Supplier’s contact persons

## Purchaser’s contact persons

Pharmaceutical contact persons:

Technical contact persons:

Responsible Commercial/judicial contact persons:

Tom Knøfler

Direct phone: +45 3866 5824

E-mail: [tom.knoefler@regionh.dk](mailto:tom.knoefler@regionh.dk)

# Purchaser’s reservations

In the event of changes in legislation or structural changes in the organisation of the Regions’ hospitals and/or institutions that come into force after the contract has been entered into, and which entail substantial changes to the Purchaser’s needs for equipment and deliveries in regard to this contract, the Purchaser reserves the right to demand that the contract be adjusted/amended/extended proportionally in accordance with this, and/or to cancel deliveries and obligations within the affected areas with a written notice appropriate to the actual circumstances, containing documentation of the circumstance(s) that has/have come about.

Any change to the contract as a result of the above could lead to a claim for compensation; cf. clause 30.

The contract’s other provisions will continue to apply after any change as a result of the above.

Changes that are so extensive that they cannot be contained within the legal framework of the tender, and thus necessitate a new tender, could similarly lead to a claim for compensation; cf. clause 30.

If the tender relating to the equipment covered by the present contract is brought before the Complaints Board for Public Procurement or the Courts, and the Purchaser’s decision to award the contract to the Supplier is annulled or the contract is declared null and void, or the Purchaser is ordered to terminate the contract, the Purchaser is entitled to cancel the contract with appropriate notice as defined by the Complaints Board for Public Procurement or by the Courts, or in lack of such definition, with a notice period appropriate for the actual circumstance against payment only of the Supplier’s actual expenses caused by the termination (negative contract interest).

# Contract documentation

The contract comprises the present document and schedules as defined in the schedule overview; cf. clause 1.

In the event of any discrepancy between the present contract and associated schedules, the contract takes precedence. In the event of any discrepancy between the schedules, these take precedence in the order in which they are listed in the schedule overview.

# Scope of the contract

This contract covers delivery and installation of (PRODUCT, TYPE, + ACCESSORIES)

## Contract configuration

The configuration of the delivery is specified in the contract configuration Schedule 2 with reference to the Supplier’s item no. and product text. The contract configuration covers the basic configuration and equipment options in accordance with the Supplier’s tender as well as those equipment options chosen by the Purchaser.

### Equipment options

The Purchaser may purchase the equipment options at a fixed price in accordance with Schedule 2 to supplement the contract configuration throughout the entire remedial period; cf. clause 21.

### Option for an additional solution/equipment

The Purchaser may purchase an additional solution/equipment in the same configuration at a fixed price in accordance with Schedule 2 to supplement the contract configuration up to two (2) years from approved site acceptance test; cf. clause 20.

## Removal of existing installation

Not relevant in this contract

## Special installation-related services

This contract also covers the special installation-related services listed below:

XX

## Additional options

The present contract also covers:

* Service options; cf. clauses 23 and 25.
* Options for consumables; cf. clause 24.

## Technical and functional specifications

The detailed technical and functional specifications are stipulated in the Purchaser’s requirements specification (Schedule 1) and the Supplier’s tender (Schedule 7). The Purchaser’s A requirements shall always be met. The Supplier’s equipment meets the Purchaser’s B requirements to the extent to which this is confirmed by the Supplier in its tender (Schedule 7).

## Compliance with directives, standards and GMP rules

Equipment covered by this contract shall be in compliance with Directive Machinery Directive 98/37/EC and its amendments and supplements, including 2006/42/EC, including the requirement for CE marking, and shall comply with all relevant standards as passed by The European Committee for Standardization (CEN), The European Committee for Electrotechnical Standardization (CENELEC) or The International Organisation for Standardization (ISO).

The Supplier must be able document this with appropriate conformance statements etc.

The robot and its computer systems must comply with EU GMP. The robot must be able to to be validated according to Eudralex, vol. 4 Annex 1 and DS/EN ISO 14644, cf. the requirements specification in Schedule 1 and requirements for qualification in Schedule 3.

## Other services associated with the delivery

In addition to the equipment specified above, all services and incidental services covered by this contract with schedules are included in the delivery. Thus, the total price (cf. clause 9) covers:

* Delivery to the Purchaser’s address at the specified user site DDP (Incoterms 2010); cf. clause 17.1.
* Removal of packaging; cf. clause 18.
* Assembly, installation/connection; cf. clause 18.
* Trial run and test of equipment and installation, including interface to and function with existing installations and systems; cf. clause 18.3.
* Acceptance test and notification in accordance with current Danish legislation for the equipment; cf. clause 18.4.
* Test of software functionality, as well as network configuration; cf. clause 18.5.
* Complete documentation for the delivery including quality assurance of the installation, etc.; cf. clause 15.3.
* Delivery of Danish user instructions/user manuals; cf. clause 15.3.2.
* Delivery of technical documentation, including specifications, diagrams and service manuals, etc.; cf. clause 15.3.4 and clause 15.3.5.
* Delivery of software, software manuals and licenses; cf. clause 15.3 and clause 25.
* Basic instruction in correct operation and safe use of the equipment for the Purchaser’s users and technicians; cf. clause 19.1.
* 2-year guarantee and remedial period equivalent to full service, incl. spare parts; cf. clause 21.
* Telephone support; cf. clause 23.3
* Updating and upgrading software; cf. clause 25.

# Deadlines and timetable(s)

## Factory acceptance test (FAT)

Taking in to account the qualification requirements in Schedule 3 the Supplier must be ready for factory acceptance test (FAT) no later than the xxst of xxxxxxxx 2013.

The Purchaser will participate in the factory acceptance test at a convenient time as soon as possible after the Supplier has notified the Purchaser that the delivery is ready for factory acceptance test, cf. clause 16.

## Delivery and start of assembly

The Purchaser is ready to receive the equipment at the stipulated user site around 1st of November 2013.

Delivery shall be in accordance with the Supplier’s detailed timetable and as agreed, but between 8 a.m. and 4 p.m. on weekdays. Delivery shall take place in time for the deadline below for site acceptance test to be met.

## Site acceptance test (SAT)

Site acceptance test must be possible no later than two (2) weeks after successful conclusion of the factory acceptance test.

The Purchaser will perform the site acceptance test at a convenient time as soon as possible after the Supplier has notified the Purchaser that the delivery is ready for site acceptance test, cf. clause 20.

## Adjustment of the timetable

The Purchaser reserves the right to effect adjustments to the timetable. Adjustments of deadlines that do not involve stricter time requirements for the Supplier will not provide grounds for extension of deadlines and/or compensation; however, see clause 30.

## Detailed timetable

No later than 14 days after entering into the contract, the Supplier shall submit a detailed timetable for the installation for the Purchaser’s approval, specifying the following milestones as a minimum. The stipulated deadlines (cf. clauses 8.1 and 8.3) shall be met.

* Status meeting (video- or telephone-conference) every week
* Design qualification (DQ)
* Production (final technical rectification deadline)
* Factory acceptance test
* Delivery
* Assembly/installation/connection
* Installation qualification (IQ)
* Basic instruction of the Purchaser’s users in correct operation and safe use of the equipment as well as basic instruction of the Purchaser’s technical personnel in operation and maintenance of the equipment
* Additional training of the Purchaser’s users
* Delivery of complete handover documentation and notification of the delivery
* The Purchaser’s compliance test of the equipment
* Site acceptance test
* Operational qualification (OQ) and validation.

# Price

The total cost of the delivery incl. discounts amounts to      .

The agreed price is fixed and listed exclusive of VAT, but includes other duties (customs duties, etc.).

Options are priced separately. The prices of options are fixed, unless an option for price regulation is explicitly stated in this contract.

# Contract number

The Purchaser’s case number is: 13010275

The Purchaser’s contract number shall be listed as a reference on all documents and correspondence relating to this contract.

# Invoicing

The invoices shall be submitted electronically to GTIN/EAN location no.: XX stating the date, product designation, quantity, price and the purchaser's contract number as well as the installation site and contact reference for the delivery that the invoice relates to.

# Payment terms and conditions and instalment plan

Payment terms and conditions are thirty (30) days net after receipt of an appropriate invoice.

## Instalment plan 30 % - 40 % - 30 %

The invoice for the first instalment, corresponding to 30 % of the agreed sum, may be submitted after the contract is signed. Payment is conditional on the Purchaser receiving a bank guarantee no later than at the time of receipt of the invoice; cf. clause 13.

The invoice for the second instalment, corresponding to 40 % of the contracted total, may be submitted after the successful site acceptance test (SAT); cf. clause 20.

The invoice for the third instalment, corresponding to 30 % of the contracted total, may be submitted after a trial period, in which the Purchaser has been able to ensure that the equipment meets the desired operating stability and GMP requirements and validate the production; cf. clause 21.2.

Payment is conditional on the Purchaser receiving a bank guarantee no later than at the time of receipt of the invoice; cf. clause 14.

# Bank guarantee for advance payment

The Supplier shall, no later than at the same time as forwarding the invoice, provide a full bank guarantee for advance payment of the first instalment each of 30 % exclusive of VAT.

The bank guarantee shall be issued by a recognised bank or bonding company acceptable to the Purchaser and shall be drawn up as an obligation payable on demand in compliance with Schedule 5.

The bank guarantee shall be marked: Contract relating to Contract no./Case no.

The bank guarantee for the amount of XX shall be composed in such a way that, upon presentation thereof and without legal process, the Purchaser may demand payment of the bank guarantee if the Supplier, in the opinion of the Purchaser, is in breach of its obligations.

The bank guarantee may not be time-limited but shall apply until the provider of the bank guarantee receives written notification from the Purchaser that the bank guarantee may be rescinded.

The Purchaser will rescind the bank guarantee at the Supplier’s written request immediately after acceptance of the Site acceptance test.

# Performance guarantee during the remedial period

As security for the Supplier’s obligations during the remedial period, the Supplier shall furnish a guarantee payable on demand for 10 % of the contracted total excluding VAT.

The guarantee shall be issued by a recognised bank, bonding company, insurance company or similar acceptable to the Purchaser, and is to be drawn up as a bank guarantee or insurance bond in compliance with Schedule 6.

The performance guarantee for the amount of XX shall be forwarded to the Purchaser no later than at the time of the invoice for the third and last instalment, and shall be drawn up so that it is paid to the Purchaser on request and without legal process if, in the opinion of the Purchaser, the Supplier is in breach of the contract. The performance guarantee shall not be time-limited but shall apply until the provider of the performance guarantee receives written notification from the Purchaser that the guarantee may be rescinded.

The performance guarantee shall be finally rescinded when the remedial period expires at the written request of the Supplier, on the condition that there are no persisting non-remedied deficiencies. In this event, the performance guarantee will be rescinded when the deficiencies have been remedied.

The provision of security and provision of performance guarantee mentioned in clause 13 and the present clause confer no restriction on the Purchaser’s option to invoke non-performance rights against the Supplier, including claiming compensation for any losses.

# Quality assurance and documentation

All deliveries shall be subject to quality assurance, and shall be tested and documented in accordance with applicable legislation and all relevant standards.

Specifically the Supplier commits to qualification as specified in Schedule 3.

In so far as it has not already been covered by Schedule 3, the requirements specification or elsewhere in the tender material in Schedule 1 the following terms shall also apply.

## Quality assurance, test and documentation of the delivery

Quality assurance and test of the delivery shall be effected and documented in such a scope and manner that all installations and all equipment are duly documented as required by law/standards, and in such a way that all test procedures and measurements are unequivocally reproducible at the Purchaser’s premises. All equipment necessary for implementation and post-testing of the quality assurance and tests shall be made available to the Purchaser after the tests have been carried out.

All documentation, including final site acceptance documentation, shall be transferred to the Purchaser electronically no later than at notification of the delivery.

All units shall be stated as SI units.

## Access to ongoing documentation

It can be expected that the Purchaser, or its representative, will oversee and audit the production, installation and testing.

Upon request, the Supplier shall make all necessary data available and provide opportunity for the Purchaser or its representative to closely monitor the project's progress.

## Handover documentation

Before site acceptance test can take place, the materials mentioned in the present clause 15.3 shall be available. All materials shall be in Danish or English.

All handover documentation shall be transferred to the Purchaser no later than at notification of the delivery; cf. clause 15.1.

### Installation report

At conclusion of the installation, all quality assurance and all required tests (cf. items 15.1, 18.3, 18.4 and 18.5) shall be documented in an installation report. This report shall also contain details of the measuring equipment and procedures used, with copies of the most recent calibration certificates, etc.

### User instructions

User instructions shall be drawn up in Danish or English and shall be designed and prepared so that they:

* Ensure correct and optimal operation, as well as safe use of the equipment.
* Prevent incorrect use that could damage the equipment.
* Optimally take into account users, patients and third parties.
* Facilitate the functioning of otherwise faultless equipment in accordance with the intended use.

### Daily operating and maintenance manual

The daily operating and maintenance manual shall be compiled in Danish or English and shall provide instruction on daily cleaning, maintenance and service so that, through implementation of the described routines, the equipment retains its full functionality and can be operated correctly and safely for both users and patients.

The daily operating and maintenance manual may be incorporated into the user instructions.

### Service manual

Service manuals shall be compiled in Danish or English and shall contain all control measurement procedures, service instructions and adjustment and maintenance instructions necessary to conduct a full service of the equipment.

The scope and content of the Service manual shall reflect the information provided by the manufacturer for the Supplier’s own service engineers.

### Technical manuals and software manuals

The technical manuals shall be compiled in Danish or English and shall include specifications at component level, including diagrams, etc.

Software manuals shall similarly be compiled in Danish or English.

The scope and content of the technical manuals and software manuals shall reflect the information provided by the manufacturer for the Supplier’s in-house technicians.

## Updating the documentation

The Supplier is obliged to keep manuals and other documentation updated by unsolicited and systematically forwarding all service notifications and updates for this material to the Purchaser immediately upon release.

Furthermore, the Supplier undertakes to amend the documentation immediately in the event that the Supplier is made aware of any errors or omissions.

In the event of updates or upgrades of the equipment or the installed software, full documentation for this shall be supplied.

Technical documentation shall be available for the Purchaser throughout the lifetime of the equipment up to a maximum of ten (10) years.

## Rights to the manuals

The documentation required above is considered to be an integral part of the delivery, notwithstanding that the Supplier retains the copyrights, etc. associated with the documentation. The Purchaser shall have full right to dispose of the documentation that is available at the Purchaser's address.

# Factory acceptance test

The Supplier’s production of the equipment is concluded with a factory acceptance test (FAT), including, but not limited to, a complete test of all tests that are to document that machine and system programmes are ready and comply with specifications.

The factory acceptance test shall be documented, and in general be designed such that it facilities the Purchaser’s subsequent compliance checks and in general comply with and meet the quality assurance and test principles that are stated in Schedule 3.

Factory acceptance test is concluded when the Purchaser’s responsible person together with the Supplier, have signed for this on an appropriate written document.

No review, comments or approval of any type by the Purchaser may be taken as an indication of a change in the requirements that have been set in accordance with the requirements specification. A deviation from the requirements specification will only be accepted if the Purchaser has submitted a written request to this effect and has subsequently accepted in writing and by signature the Supplier's terms and conditions for executing this change.

The Supplier is responsible for holding the factory acceptance test, including any costs associated herewith except travel and accommodation for the Purchaser’s personnel.

## Notification of factory acceptance test

When the equipment has been produced and assembled and is ready for factory acceptance test the Supplier shall notify the Purchaser and submit any required documentation, cf. Schedule 3.

After this, within the following 15 working days, the Purchaser shall give notification to the Supplier when factory acceptance test is to take place. The Supplier is obliged to attend. The time for the factory acceptance test must be within three months from the Suppliers notification.

# Delivery

Delivery shall take place as instructed by the Purchaser’s technical/clinical contact person at the stipulated installation site.

## Delivery terms and conditions

DDP, Delivered Duty Paid in accordance with Incoterms 2010, to the Purchaser’s address at the stipulated installation site.

Risk for the equipment is only considered to be transferred to the Purchaser after the Site acceptance test has been conducted; cf. clause 20.

Liability and risk in connection with theft, fire, water damage and any other unforeseen contingency will be borne by the Purchaser from the time of physical delivery at the Purchaser’s stipulated site.

## Delivery address/Installation site

Capital Region of Denmark Pharmacy, Room 1.501

Marielundsvej 25

DK-2730 Herlev

Denmark

## Internal transport routes

The Supplier has had opportunity to be shown the internal transport route by the Purchaser’s technical contact person at the delivery address.

## Installation site

The Supplier has had opportunity to inspect the installation site advised by the Purchaser’s technical contact person and/or has received sufficient drawings of the installation site, technical installations and any planned structural changes.

## Structural changes to the installation site

The installation site is to be handed over by the Purchaser in a prepared condition, including provision of the agreed technical facilities.

Delivery and installation of the equipment requires the following modifications to installations and/or building structures at the installation site, as listed in clause XX of the Supplier’s tender:

These works are to be undertaken and paid for by the Purchaser, with the exception of modifications to building structures, which are included in clause XX of the Supplier’s tender:

## Lack of knowledge of the actual conditions

By signing the present contract, the Supplier declares that it has been made acquainted with the actual physical frameworks for the delivery, including access conditions to, and installation conditions at, the installation site, and that these have been found to be satisfactory with the modifications listed in clause 17.5.

The Supplier’s lack of knowledge of the actual physical framework and conditions, including access conditions and installations, may not therefore constitute grounds for deviation from the conditions stipulated in the present contract with schedules, and similarly the Supplier may not claim additional payment, extension of deadlines or anything else on these grounds.

## Supplier’s acceptance of the installation site

Fourteen (14 days) prior to the delivery the Supplier is obliged to check and approve in writing that the installation site is in compliance with the contracted conditions for delivery and installation of the equipment.

In the event that the Supplier does not find the installation site in compliance with the contractual conditions, the Supplier shall immediately notify the Purchaser in writing, specifying those conditions that are not in compliance with the contractual conditions.

## Supplier’s refusal to deliver

In the event that, by the contracted delivery date, the Purchaser has not remedied the conditions that the Supplier has pointed out (cf. clause 8.1), the Supplier is entitled to refuse to carry out the delivery.

Should the Supplier nevertheless decide to carry out the delivery, this shall be at the Supplier’s own risk.

In the event that, on legitimate grounds, the Supplier may refuse to carry out the delivery, the Supplier may cancel the contract on the conditions stated in clause 30.

# Assembly, installation and Supplier’s tests

Assembly and installation of the equipment shall be the responsibility of the Supplier and shall be carried out by professionally trained personnel, in a professionally correct manner in accordance with the contract, with first-class professional quality, and in such a way that a high standard of hygiene can be maintained.

In addition to being in compliance with the contract, assembly and installation shall satisfy current legislation, and all regulations and statutory instruments for the relevant trade areas and the equipment delivered.

The Supplier will be compensated for direct costs that arise because stricter legislation is introduced in the period from the time of entering into the contract to the accepted Site acceptance test.

If the assembly, installation and connection to power otherwise require special certification, the Supplier shall notify the Purchaser of this prior to delivery, and on request shall forward the required documentation for the relevant certification to the Purchaser. In the event that special safety matters are to be taken into consideration, the Purchaser is entitled to demand special marking/labelling.

Installation and connection to power includes all cabling from the equipment to the connection point(s) for the allocated technical installations at the installation site.

## Packaging and waste management

The Supplier is responsible for disposal of packaging in an environmentally sustainable manner immediately after delivery and unpacking of the equipment.

## Executing tasks at the Purchaser’s delivery address

The Supplier shall ensure that delivery, assembly and installation as well as disposal of packaging and other waste management is carried out with minimum disturbance to patients, personnel and daily operations at the delivery address.

In particular this applies to the daily production of pharmaceuticals at the Purchaser’s delivery address.

Execution of tasks at the Purchaser’s delivery address shall in principle be carried out during the Purchaser’s normal business hours.

In the event that the Purchaser deems that the above has not reasonably been met, the Purchaser reserves the right to reduce the time during which these tasks can be executed, without this conferring an opportunity on the Supplier to extend deadlines and/or demand compensation.

## Supplier’s checks and test of the installation

The Supplier’s installation of the equipment is concluded with an installation test, including, but not limited to, a complete test of all factory tests that are to document that machine and system programmes are ready for the start of the Purchaser’s compliance test. The installation test shall be documented in an Installation Report, and in general be designed such that it facilities the Purchaser’s subsequent compliance checks.

The Supplier’s checks and test of the equipment shall follow the manufacturer’s requirements and recommendations as well as the associated procedures, and in general comply with and meet the quality assurance and test principles that are stated in Schedule 3.

No review, comments or approval of any type by the Purchaser may be taken as an indication of a change in the requirements that have been set in accordance with the requirements specification. A deviation from the requirements specification will only be accepted if the Purchaser has submitted a written request to this effect and has subsequently accepted in writing and by signature the Supplier's terms and conditions for executing this change.

The Supplier is responsible for holding the installation test, including any costs associated herewith.

## Safety test

It is assumed that the Supplier will complete approved safety test on behalf of the Purchaser as a prerequisite for any subsequent Site acceptance test.

The safety test shall deal with all safety aspects that the Purchaser deems to be important, including, but not limited to, mechanical and electrical safety checks in accordance with current legislation.

The safety test shall be undertaken by the Supplier in close collaboration with the Purchaser’s technical contact person, or a person so authorised by the Purchaser, and in accordance with the guidelines established by the Purchaser.

If the acceptance test do not satisfy the requirements and tolerances stipulated, this is deemed a material deficiency.

The Supplier shall pay all costs for safety rest, including any and all fees to authorities and similar.

## Tests in regard to software functionality, remote access and network configuration

The Supplier shall carry out (in collaboration with the Purchaser) tests in regard to software functionality, as well as tests in regard to network configuration and remote access.

For tests in regard to software functionality, network configuration and remote access, refer to the Purchaser’s tender documentation and Schedule 3.

# Instruction and training

The delivery includes basic instruction of the Purchaser’s users and technicians (cf. clause 19.1), as well as training of the Purchaser’s users and technical personnel in accordance with the Supplier’s tender.

In connection with the Site acceptance test, a list shall be drawn up of the training/instruction that has been completed, any training/instruction that is outstanding and a progress plan for completion of the outstanding training/instruction.

Furthermore, it is expected that the Supplier will provide the necessary training for all future updates and upgrades of software and hardware that are supplied in accordance with clause 25.4-25.6 as well as undertake in-depth instruction of users in the quality assurance programs and tests.

## Basic instruction of the Purchaser’s users and technicians

To the extent necessary and without reimbursement, the Supplier shall undertake instruction of the Purchaser’s users in correct operation and safe use of the equipment, including a review of the topics in the user instructions (cf. clause 15.3.2).

To the extent necessary and without reimbursement, the Supplier shall undertake instruction of the Purchaser’s technicians in daily operation and maintenance of the equipment, including, but not limited to:

* Review of the delivered equipment’s design and construction.
* Review of which parts should/must be cleaned and maintained, and relevant procedures for this purpose.
* Review of the instructions in the daily operating and maintenance manual (cf. clause 15.3.3).
* Review of the instructions in the service manual (cf. clause 15.3.4).
* Review of the procedure for service call-outs and the procedure for ordering spare parts.

Instruction of the Purchaser’s users and technicians shall be held at the Purchaser’s premises, as agreed from time to time.

## Further instruction

Additional courses and their terms and conditions shall be in accordance with Schedule 7 of the Supplier’s tender.

Courses will be held in accordance with the Purchaser’s wishes.

# Site acceptance test

Site acceptance test (SAT) of the delivery shall take place when the equipment has been assembled, installed and tested at the correct installation site and the Purchaser’s technical/pharmaceutical responsible person at the delivery address, together with the Supplier, have signed for this on the enclosed site acceptance document (Schedule 4) after conducting the following site acceptance test.

At completed site acceptance test, the Purchaser assumes all responsibility for the delivery.

## Best available technology

It is required that the vendor will live up to BAT (Best Available technology). BAT requirement means that when the system is ready for site acceptance test - best available technology will be delivered by Supplier with out any extra cost.

## Notification of Site acceptance test

When the equipment has been assembled, installed and tested, the Supplier shall transfer complete documentation for the delivery to the Purchaser, with subsequent notification.

After this, within the following 15 working days, the Purchaser shall give notification of the Site acceptance test, which the Supplier is obliged to attend.

If the Supplier does not attend the Site acceptance test, he shall accept the Purchaser’s conclusions and assessments as valid.

## The Purchaser’s compliance checks

In the interim period from notification of the delivery to completion of the Site acceptance test, the Purchaser has an opportunity to use the equipment to check compliance with the Purchaser’s requirements and the Supplier’s documentation and specifications, including (but not limited to):

* Check that the safety regulations have been met.
* Execute performance tests including demonstration of the Supplier’s equipment specifications.
* Inspect the equipment in order to determine that other technical and quality specifications have been met.
* Check that the delivery is in compliance with requirements specifications.
* Check that the delivery and quality assurance documentation otherwise comply.
* Production testing (not production).

The compliance checks are facilitated as a test in which the equipment and programme functions are checked individually and integrated in relation to the requirements specification, system description and documentation.

The precision of the individual components will be estimated using a validation protocol and compared with the Supplier’s methods specifications.

The Supplier will provide measuring equipment, phantoms, and skilled operators to the extent necessary and at no extra cost.

Any faults and deficiencies found by the Purchaser during this check shall be rectified by the Supplier without undue delay.

After the Supplier has documented that all deficiencies have been remedied, the Purchaser has an additional 15 days in which to conduct renewed compliance checks.

The Purchaser’s use of the equipment to carry out testing and check compliance with the Purchaser’s requirements and the Supplier’s documentation and specifications does not confer liability and risk for the equipment to the Purchaser; cf. clause 20.4.

## Conducting the Site acceptance test

At the Site acceptance test, the enclosed handover and acceptance document with a list of any deficiencies will be drawn up. The document is to be signed by the Purchaser and Supplier who each retain one copy.

The delivery is considered to be handed over and the risk transferred to the Purchaser when the Site acceptance test has taken place, unless material deficiencies of the delivery are demonstrated at the Site acceptance test. Material deficiencies are present if the following conditions are not satisfied:

* The entire delivery shall be correctly delivered, assembled and connected.
* Approved acceptance test in accordance with current legislation shall be available.
* Mechanical and electrical safety checks shall have been carried out in accordance with current legislation.
* Function tests in regard to, and with, interfaces to other installations and systems, including software, network, and remote access, shall be executed with completely satisfactory results.
* Testing and test of the delivery in accordance with the requirements specifications in the tender material and the Supplier’s tender shall be performed and duly documented with completely satisfactory results.
* The complete handover documentation for the delivery, including quality assurance of the installation, documentation of test and testing, etc. shall be transferred to the Purchaser no later than at the time of notification of the delivery.
* The Purchaser’s users shall have received the necessary basic instruction in correct operation and safe use of the equipment.
* The Purchaser’s compliance checks shall be completed with completely satisfactory results.
* The Purchaser’s technical personnel shall have received basic instruction in daily operation and maintenance of the equipment (may be deviated from if agreed).
* Successful test production has been demonstrated.

If the delivery is subject to material deficiencies, or if the sum of non-material deficiencies is considered by the Purchaser to be material in total, the Purchaser has the right to reject the delivery until these matters have been remedied.

If material deficiencies are demonstrated, a new Site acceptance test shall be held after the Supplier has notified the Purchaser in writing that the deficiencies have been remedied.

The Supplier shall meet its own costs in connection with the Site acceptance test and the associated tests; cf. clause 18.3 and clause 20.3.

If the Purchaser puts the whole delivery or parts thereof into use ***for production*** prior to the handover time without prior agreement with the Supplier, the liability for the delivery or those parts that have been put to use is transferred to the Purchaser from the time of putting into use. The remedial period is likewise calculated from this time point.

## Disputes concerning delivery

If the Purchaser and Supplier cannot reach agreement on the Purchaser’s right to reject the delivery, the Parties agree to let an impartial arbitrator appointed by the Danish Institute of Arbitration in Copenhagen make a final decision on the dispute. Costs arising in this respect will be met by the Party against whom the decision is made.

Disputes relating to understanding of and interpretation of the contract and other legal matters cannot be decided by the appointed expert.

## Delayed delivery

The Purchaser considers each and every delay to be material. If the Supplier anticipates a delay in the delivery, the Supplier shall immediately notify the Purchaser in writing with a description of both the cause of the delay and the expected duration/scope of the delay.

In the event of a delayed delivery resulting in non-compliance with the deadline for site acceptance test (cf. clause 8.3) the Supplier will be subject to a daily fine. However, this does not apply if the delay is due to force majeure such as an industrial dispute, government intervention, war or natural catastrophe unless the Supplier could or should have been able to foresee the situation.

If the Purchaser is solely responsible for non-implementation of the Site acceptance test within the agreed deadline after notification of the delivery by the Supplier at the correct time (cf. clause 20.2), the Supplier may, after the deadline for site acceptance test, demand payment of the second instalment (cf. clause 12.1) against a full bank guarantee (cf. clause 13). The Purchaser shall pay the Supplier’s documented costs associated herewith.

## Calculation of the daily fine in the event of delayed delivery

If the Supplier can be made accountable for the delayed delivery (cf. clause 20.6), the size of the fine will be calculated proportionally to the Supplier’s estimated share of the delay in accordance with the following:

For the first thirty (30) week days that the desired deadline for site acceptance test (cf. clause 8.3) is overrun, the daily fine will be calculated in accordance with the following:

(0.2 percent of the contracted total) x (the number of days’ delay)

For further delays that the desired deadline for site acceptance test (cf. clause 8.3 is overrun, the daily fine will be calculated in accordance with the following:

(0.4 percent of the contracted total) x (the number of week days’ delay beyond thirty (30))

# Supplier’s remedial obligation and responsibility for operating stability during the remedial period

The remedial period is set as 24 months calculated from the accepted Site acceptance test (but cf. clause 21.2, clause 21.3, clause 21.5 and clause 21.6).

If faults or deficiencies arise or are discovered during the remedial period, the Supplier is obliged to immediately rectify all faults and deficiencies at no cost to the Purchaser. Exempt from this is rectification of all faults and deficiencies that are due to conditions for which the Purchaser bears the risk.

A deficiency is present if the Supplier or the Supplier’s services do not meet the requirements stipulated in the contract or the guarantees given by the Supplier. A deficiency is also present if the delivered documentation does not meet the provisions of the contract.

Remedy includes identification of the deficiency submitting information to the Purchaser on any option to bypass the fault so that there is minimal disturbance to operations, and rectification of the fault/repair without undue delay.

Part of remedying a deficiency comprises documenting the remedy in writing. This documentation shall subsequently be incorporated as part of the total documentation for the delivery.

During the remedial period, fault rectification and repairs shall be carried out at the Purchaser’s premises unless otherwise agreed, and shall be started within the guaranteed response time; cf. clause 22.5.

In the event that the Supplier cannot remedy the fault and/or deficiencies of the delivered equipment so that this meets the stipulated specifications of the equipment, the Purchaser has the right to have the faulty and/or deficient products replaced with corresponding brand new products.

All equipment, spare parts and sub-components replaced during the remedial period are covered by a 24-month guarantee from the time of replacement.

If, despite a written request concerning this, the Supplier omits to meet its remedial obligations in accordance with the present provisions, the Purchaser has the right, after advance or simultaneous notification to the Supplier, to arrange for the necessary rectifications to be carried out at the Supplier's expense.

## Operating stability during the remedial period

Throughout the remedial period, the Purchaser's operating terms and conditions, including operating stability and guaranteed response time, shall be met; cf. clause 22.

Furthermore, it is a prerequisite that throughout the remedial period the Purchaser shall not be in a weaker position than if a fully comprehensive service contract with preventive maintenance and no-cost remedy and including spare parts had been signed.

## Trial and period and validation

The first six (6) months after the accepted Site acceptance test are considered to be a trial period to enable the Purchaser to ensure that the desired operating conditions have been met and achieved validated production. If the operating conditions are not met (cf. clause 22) during this trial period, or the production can not be validated at the end of the remedial period will be extended by six (6) months and a new trial period will commence.

If the operating stability is not met during the trial period, the Purchaser may furthermore demand a fine as compensation for operating loss; cf. clause 21.3.

If the operating stability is met during the first six (6) months, and the production is validated by the end of the trial period these months shall comprise part of the remedial period.

## Operating loss

The Purchaser’s operating loss is set at DKK 7,500 per day

One (1) percentage point operating loss aggregated over a one (1) month period is set at 0.50 days.

## Operating stability/uptime during the remedial period (excluding the trial period)

If the operating stability at any time during the remedial period falls below the guaranteed operating stability aggregated over a one (1) month period (cf. clause 22.2), the free remedial period shall be extended by 30 days for each percentage point the accumulated operating stability is less than the guaranteed operating stability.

Furthermore, the Purchaser may demand a fine as compensation for operating loss for each percentage point the aggregated operating stability over one (1) month period is less than the guaranteed operating stability; cf. clause 21.3, clause 22.2 and clause 22.3.

## Two (2) year trial and review of the equipment

The Supplier is obliged to notify the Purchaser of a two (2) year trial and deficiency review for the equipment at expiry of the remedial period. A trial and deficiency review shall be notified in reasonable time and shall be held no later than one (1) month before expiry of the remedial period.

The scope of the trial and deficiency review shall reflect all tests and checks in connection with the handover and acceptance procedures. In connection with the trial and deficiency review, the paradigms for the handover and acceptance documents (Schedule 4) may be used.

The technical requirements and the results of the trial and deficiency review shall be in compliance with the results attained in connection with the acceptance test. The Supplier will provide measuring equipment, phantoms and skilled operators to the extent that these are necessary.

If faults or deficiencies are demonstrated during the trial and review, the Supplier is obliged to remedy the problems promptly and at no cost to the Purchaser.

When the deficiencies have been remedied for the Purchaser and documented in writing, the Supplier shall call a new trial and deficiencies review.

The remedial period ceases only after the trial and deficiencies review has been conducted without any deficiencies, and both Parties have signed to this effect.

If the Supplier omits to call a two (2) year review of the equipment, the remedial period shall continue even though the 24-month period has expired.

## Supplier’s remedial obligation after 24 months

If the equipment or parts thereof are shown to be defective due to construction faults, the Supplier’s remedial obligation shall be extended to that time in which the equipment has user value for the Purchaser – but not more than ten (10) years after delivery/accepted Site acceptance test for the equipment.

Throughout the lifetime of the equipment, but not exceeding a maximum of ten (10) years, the Supplier is obliged to carry out the modifications and updates that are necessary to mitigate safety concerns and/or required by the authorities, at no cost to the Purchaser.

The Supplier is likewise obliged, at no cost to the Purchaser, to carry out modifications and updates that may be required by the manufacturer during the lifetime of the equipment but not exceeding a maximum of ten (10) years.

# Operating conditions

## Purchaser’s production/business hours

The equipment shall be operational throughout the Purchaser’s normal production/business hours which are Monday to Friday, 06:00 to 22:00, excl. public holidays.

## Operating stability/uptime

Operating stability is important to the Purchaser. During the remedial period, and for as long as the Purchaser subsequently desires to maintain a service contract, the Supplier shall guarantee an operating stability of at least 98%*,* aggregated over a one (1) month period twelve (12) times a year (once a month).

## Calculation of operating stability/uptime

Operating stability is measured in relation to production of cytotoxic preparations with a less than 2 % rejections rate:

actual operating time

Operating stability = --------------------------- x 100

agreed operating time

Agreed operating time is defined as: the Purchaser’s production hours after deduction of planned maintenance and service.

Actual operating time is defined as: agreed operating time after deduction of repair time.

Repair time is the time within the agreed operating time during which the equipment cannot be used for fault-free operation (production of cytotoxic preparations with a less than 2 % rejections rate) due to faults with the equipment and/or programs.

Operating impediments that are due to the Purchaser's circumstances, legal industrial disputes, or other circumstances which are not under the control of either of the Parties (including power outage, fault in the public data networks, and similar) are not included in repair time.

Calculation of repair time commences when the Supplier is notified of the operating stoppage and ends when the equipment is handed over to the Purchaser in a fully functional condition. If a partnership contract has been entered into by which the hospital’s in-house personnel are involved in fault-finding and any fault rectification, calculation of repair time commences similarly from the time at which the Supplier is notified of the operating stoppage.

Repair time only covers idle time due to faults in equipment covered by this contract.

The operating stability shall be calculated by the Supplier for each installation immediately after each operating quarter, and shall be submitted to the Purchaser's technical/clinical contact person; cf. clause 4.2. Service reports are used as documentation and shall be completed and signed by the Purchaser and Supplier at each operating stoppage; cf. clause 23.6.

## Supplier’s cancellation of scheduled maintenance and service

The Supplier shall give the Purchaser written notification of any cancellation in good time and no later than one (1) week prior to the scheduled maintenance and scheduled service.

If the Supplier omits to provide notification in due time, the Purchaser shall be compensated for operating loss (cf. clause 21.3) during the downtime that was scheduled in connection with the maintenance and service.

## Guaranteed response time

The Supplier guarantees a maximum response time for remedy through remote access of **1 hour** during the remedial period.

The Supplier guarantees a maximum on-site response time of **24 hours** during the remedial period.

In this context, guaranteed response time is understood to mean the maximum time within the business hours (refer to clause 22.1) from service call-out until remedy by qualified service technicians has commenced either remotely or on site.

If remedy can be performed by phone or remote access, a physical on-site presence will not be necessary.

If remedy cannot be performed by phone or remote access, the time used for non-effective fault rectification shall be included in the response time.

After the remedial period, the guaranteed response time may be included as an option in the service contract.

# Service

Service contracts and terms and conditions are specified in the Supplier’s tender. If the Purchaser elects to enter into a service contract, this shall be in accordance with the provisions stipulated in this contract.

## Entering into a service contract

The Purchaser is not obliged to enter into the service contract that is offered after expiry of the remedial period, but may freely elect to carry out service itself.

The service contracts offered by the Supplier may be signed at any time desired by the Purchaser, but no later than six months after expiry of the remedial period.

If, at a later time, the Purchaser wishes to enter a service contract at a higher or lower level, the Purchaser is entitled to do so. If the Purchaser wishes to enter a higher service level, the Purchaser is entitled to do this after the Supplier has carried out a service inspection and the equipment has been brought up-to-date.

The Purchaser thus has the opportunity to enter into a service contract at a higher level (including from no service contract to a service contract) when the Supplier has had an opportunity to review the equipment for test and replacement of any components, etc. that are not covered by the lower service level. Any necessary replacement of components shall be paid for by the Purchaser.

The service terms and conditions that are offered shall apply for up to ten (10) years and the agreed prices may be index-adjusted once a year in accordance with the annual developments in the Statistics Denmark “net price index” and “wage index for the private sector” by 50% of each index. The first adjustment may take place at expiry of the remedial period based on month, 201X (THE MONTH OF THE TENDER).

## Operating stability/uptime after the remedial period

If a service contract with an uptime guarantee has been entered into and operating stability is lacking, the Purchaser may demand payment of a fine.

Fines for compensation for operating loss may be demanded for each percentage point that the aggregated operating stability over a one (1) month period is less than the guaranteed operating stability; cf. clause 21.3, clause 22.2 and clause 22.3.

## Telephone support

The Supplier shall provide telephone support at no cost for basic operation and preliminary detection and identification of a fault for as long as the procured equipment has user value for the Purchaser, but for a maximum of ten (10) years.

Support for fault finding and support for applications is calculated as time taken, if it is not covered by a service agreement taken up by the Purchaser.

## Remote access

The Supplier shall be provided opportunity for Remote Access; cf. terms and conditions in Schedule 1 and Schedule 7.

## Service organisation and service on call

The Supplier undertakes throughout the lifetime of the equipment (not exceeding a maximum of ten (10) years) to be able to provide a service at specialist level, even in the event of resignation, illness or other long-term absence among the specialists included in the Supplier’s service set-up.

In cases where a service agreement has not been entered into, the Supplier shall respond to a service call-out on all weekdays within the stated business hours. The Supplier guarantees a maximum on-site response time of **three days or less.**

More detailed terms and conditions are presented in the Supplier’s tender.

## Service report

For all service, repair and maintenance, whether called out or as a result of the service contract, the Supplier shall complete a service report that clearly describes the notified fault(s), repairs, replacements, spare part usage, and control measurements.

Service reports shall as a minimum contain the date and time of the fault notification to the Supplier, the date and time when remote and/or on-site rectification commenced, a description of the fault, the cause of the fault, a description of the remedy of the fault, and the date and time completion was notified to the Purchaser.

The service report shall provide documentation for the hospital’s equipment log system, and shall be promptly handed over and/or submitted electronically in its entirety to the Purchaser’s technical contact person or their appointed deputy when completion has been notified after each fault.

The Supplier shall ensure that the Purchaser signs for receipt of the service report.

The above regulations also apply during the remedial period.

## Service information

The Purchaser shall have comprehensive and unrestricted access to all service information at all times to the same extent as the Supplier’s own service organisation, including (but not limited to) any service information generated by the Supplier’s use of service software.

# Spare parts and consumables

The Supplier guarantees to be able to deliver spare parts or replacement parts and consumables for a ten (10) year period calculated from the completion of the accepted Site acceptance test.

The Supplier guarantees to be able to deliver critical spare parts within one (1) working day to the Purchaser’s address unless otherwise agreed for the order in question.

The Supplier guarantees to be able to deliver other spare and replacement parts as well as consumables within three (3) working days to the Purchaser’s address unless otherwise agreed for the order in question.

The Supplier shall provide a 12-month guarantee on new factory spare parts that are replaced after expiry of the remedial period.

For the procedure for ordering spare parts and consumables, including business hours, see Supplier’s tender Schedule 7.

## Prices

Prices of spare parts and consumables and conditions are specified in Schedule 2 and the Supplier’s tender.

Assembly shall be covered in the prices of spare parts. Spare parts shall be delivered and assembly commenced within the guaranteed deadline.

Consumables are delivered DDP (Delivered Duty Paid in accordance with Incoterms 2010), to the Purchaser’s address at the stipulated installation site.

If a spare part or consumable which is listed in Schedule 2 (according to the Supplier’s tender) is taken off the market and replaced by another spare part (other item number etc.) the price of the original spare part shall also apply for the new spare part.

The spare parts and consumables, prices, terms and conditions that are offered apply unchanged for up to ten (10) years, and may be price-adjusted once a year in accordance with the annual development in Statistics Denmark “net price index”. The first adjustment may take place after expiry of the remedial period based on XX 201X (THE MONTH OF THE BID).

## Liability and risk if spare parts are not at the Purchaser’s address

If the equipment or parts thereof required in connection with repairs service inspections or similar are located away from the Purchaser’s address, the Supplier shall be liable for the equipment. This applies regardless of whether the repair is carried out under guarantee, as part of a service contract or paid by separate invoice.

# Software and licences

For all deliveries, the Purchaser acquires full access and full user rights to all integrated and supplementary software throughout the lifetime of the equipment. Supplementary software is understood to be software that is supplied with the equipment in order for the equipment to achieve the desired functionality at the Purchaser's premises, but is not necessarily installed on the equipment delivered by the Supplier.

The Supplier guarantees that the Purchaser has perpetual and transferable user rights to the software that is actually delivered, to the associated documents and to later revisions.

The Purchaser is entitled to copy the software, including any back-up and security copies, if necessary for the use, operation and security of the equipment.

Proprietary rights, including copyrights for the delivered software, shall remain with the Supplier.

## Service software, etc.

If so desired, the Purchaser shall have necessary and relevant access to present and future service functionalities, including any service software, passwords and any hardware keys throughout the lifetime of the equipment, corresponding to that of the Supplier’s/manufacturer’s own service technicians.

The Supplier has stipulated in its tender (Schedule 7) the extent to which the access is conditional on the Purchaser signing a non-disclosure agreement, or on one of the Purchaser's technicians attending a technician course in the Supplier’s tender (Schedule 7).

## Operating stability during software updates

The Supplier guarantees the operating stability during ongoing updates to systems (including third-party systems such as Windows).

## Responsibility for software licenses

The responsibility for ongoing updates of licences rests with the Supplier.

## Software updates and upgrades (faults and security)

The Supplier is obliged to implement, at no cost, all updates and upgrades that are released commercially by the manufacturer for the purpose of correcting faults or preventing security problems in the software delivered throughout the lifetime of the equipment, but not exceeding a maximum of ten (10) years.

The Supplier shall offer to implement such updates/upgrades no later than three (3) months after the official release.

## Software updates and upgrades (legislative and manufacturer’s requirements)

The Supplier is obliged to implement, at no cost, all updates and upgrades that might arise from requirements from authorities, legislation and standards within the area of application and/or requirements from the manufacturer or subcontractor, and necessary for the Purchaser’s sustained equipment functionality and/or service guarantee throughout the lifetime of the equipment, but not exceeding ten (10) years.

The Supplier shall offer to implement such updates/upgrades no later than three (3) months after the official release.

## Software upgrades (new functionalities) during the remedial period

The Supplier shall offer to implement, at no cost, all upgrades of the software delivered that are made commercially available during the remedial period.

The Purchaser is not obliged to accept this offer.

Upgrades are understood to be solutions that are released commercially by the manufacturer for the purpose of adding new or improved functionalities to the software delivered.

Upgrades that also contain fault-rectifying elements which have the purpose of preventing security problems in the software delivered, or which are issued as a result of the authorities’ or the manufacturer’s requirements for the software delivered, shall be considered to be updates regardless of the Supplier’s designation in this respect.

The Supplier shall offer to implement such upgrades no later than three (3) months after the official release.

# Third-party rights

The Supplier guarantees that the Supplier’s services do not infringe the rights of others, including patents or copyrights.

If a third party claims infringement of their rights, the infringing Party shall notify the other Party of this in writing. Hereafter, the Supplier shall take over the case and all associated costs, and shall indemnify the Purchaser in all respects.

If there is infringement of a third party’s rights, the Supplier shall, at its own expense, acquire for the Purchaser the continued right to use the product, or to cease the infringement by changing or replacing the product so that it meets the requirements of this contract.

# Product liability and compensation liability

In accordance with the Danish Product Liability Act and the general provisions of Danish law, the Supplier is liable to the Purchaser for any damage that the delivery or the Supplier causes to the Purchaser’s property and its contents and/or personnel. Liability for damage to the Purchaser’s property and contents is nevertheless limited to DKK 10 million per incident. The limitation does **not** apply to personal injury.

The Supplier undertakes to indemnify the Purchaser for any claim, including costs, that might be brought against the Purchaser by a third party which is caused by a fault or deficiency in the delivery, damage caused by the product, or the Supplier’s tortious act.

If a claim is brought against the Purchaser arising from conditions of the delivery, the Supplier is obliged to allow a concomitant claim against the Supplier in the court that is resolving the compensation claim brought against the Purchaser.

# Termination in the event of Supplier's breach of contract

In the event of the Supplier’s material breach of contract, the Purchaser reserves the right to cancel the contract with immediate effect after prior written notice.

The following conditions are considered to be material breach of contract and entitle the Purchaser to cancel the contract with immediate effect:

* The deadline for factory acceptance test or site acceptance test is delayed by more than 15 working days due to the Supplier’s circumstances; cf. clause 16 and 20.6.
* The Supplier and its products, in spite of repeated written complaint from the Purchaser, do not meet the quality requirements stipulated in the contract or current public legislation,
* The delivery does not meet the Supplier’s description of how A requirements and B requirements are to be fulfilled (cf. Schedule 7),
* The delivery has such extensive and serious deficiencies that the Purchaser cannot reasonably use it, and the Supplier either acknowledges that further remedy is useless or has in vain attempted to remedy the deficiencies for more than twenty-one (21) working days after receipt of the first complaint regarding the relevant deficiency. A prerequisite for termination is that the Supplier has received the first claim within the remedial period,
* The Supplier breaches its obligations to remedy in spite of repeated written complaints from the Purchaser,
* The equipment does not meet the required operating stability for a total of six (6) months during the remedial period and the Supplier does not remedy the underlying deficiency within a reasonable deadline set by the Purchaser.
* The remedial period is extended by a total of six (6) months, cf. the provisions on this in clause 21.2 and clause 21.4.
* Despite repeated written complaints from the Purchaser, the Supplier omits to provide sufficient qualified and relevant personnel necessary to fulfil the contract.
* The service contract is breached in such a way that the guaranteed operating stability and response time is not met over a continuous six (6) month period.
* Supplier goes into bankruptcy/liquidation, suspension of payments, enters into an arrangement with creditors, or suffers substantially reduced financial status in general; however, see chapter 7 of the Bankruptcy Act.
* The supplier stops operating in the business covered by the contract or other circumstances arise that bring the correct performance of the contract into serious jeopardy.
* The product and/or occupational liability insurance is/are inadequate.
* The Supplier repeatedly fails to meet guaranteed response times and thus – while inconveniencing the Purchaser’s patients – makes it particularly onerous for the Purchaser to perform production on the equipment in question.

The right to cancel is not affected by the Purchaser’s right to claim daily fines or compensation for operating loss.

If the contract is cancelled, the Supplier shall immediately refund the full purchase sum without deductions for loss of value, use or anything else, and with addition of accrued fines. The Purchaser shall return the equipment that has been received to the extent and in the condition in which it is found at the Purchaser’s. The Supplier shall pay for dismantling and transport.

In the event of the Supplier’s breach of service obligations after the remedial period, the Purchaser’s right to cancel applies only to the service contract, and there will only be reimbursement of service for the period of the insurance, and any compensation for operating loss.

Moreover, the Purchaser is entitled to demand compensation for the total operating loss from the desired commissioning date until new replacement equipment has been procured, installed and commissioned. The Purchaser’s operating loss is calculated in accordance with clause 21.3.

Any use-value of the production that the Purchaser may have had from the equipment shall be deducted from the compensation calculated. The use-value is calculated in the same way as the operating loss; cf. clause 21.3.

# Maximisation of liability

The Supplier’s total payment of fines and compensation for operating loss in accordance with this contract may not exceed the total price of the delivery; cf. clause 9. In addition to this, however, in the event that the contract is cancelled, the purchase sum shall be repaid; cf. clause 28.

Other compensation in accordance with this contract is limited to the insurance sum; cf. clause 34.

# Purchaser’s breach of contract

In the event that the Purchaser does not pay the purchase amount or parts thereof in due time, interest will accrue from the due date in accordance with the Danish Interest Act unless otherwise agreed.

If the Purchaser cannot receive the delivery at the agreed time, the Purchaser shall notify the Supplier of this promptly. A new delivery date shall be immediately agreed in writing.

If the Purchaser reports that it cannot receive the delivery as scheduled later than 14 calendar days prior to the fixed date, the Supplier shall be entitled to reimbursement of its direct, documented costs, limited to: additional costs for storage of the equipment, additional transport costs for equipment and personnel, and additional costs for accommodation and food.

If the Purchaser’s circumstances result in postponement of the delivery date by more than 12 months, the Supplier shall be entitled to cancel the contract.

If the Supplier cancels the contract, the Purchaser shall reimburse the Supplier for any direct loss. Indirect loss, including operating loss or lost profit shall not be reimbursed. Compensation may not exceed the total price of the delivery; cf. clause 9. The Supplier shall refund that part of the purchase sum that has been paid with deduction of any compensation. The Purchaser shall return any parts of the equipment that have been received.

# Moving equipment/change to the installation site

The Purchaser may freely move the equipment covered by this contract within Denmark’s national borders without losing the right to service, remedy, etc.

However, the Supplier shall be notified no later than thirty (30) days prior to any move for specification of technical requirements to be met in connection with the move.

Similarly, the Purchaser may change the agreed installation site up to sixty (60) days prior to the delivery date (cf. clause 17.2) within its own Region.

However, the Supplier’s guarantees relating to access and installation conditions stipulated in the tender conditions (section 4.3.1) will lapse and a new timetable shall be agreed.

Any compensation due the Supplier (cf. clause 20.6 and clause 30) shall be calculated for all circumstances in relation to the originally agreed timetable.

# Supplier’s transfer of obligations and outstanding accounts

Only the Supplier shall be liable in respect of the Purchaser. The Supplier shall be liable for all subcontractors and all sub-deliveries.

The Supplier may only appoint another in its place, wholly or in part, with the Purchaser’s written consent. The Supplier is entitled to use sub-suppliers, distributors or subcontractors but the Supplier retains sole responsibility for correct execution of the delivery.

The Supplier may only partially or fully discount or transfer its outstanding accounts to a third party with the Purchaser’s written consent.

Furthermore, the Supplier bears the full responsibility for the subject of the contract up until accepted Site acceptance test of the complete delivery; cf. clause 20.

# Non-disclosure agreement

The Supplier, its personnel and any subcontractors shall maintain unconditional secrecy with regard to information concerning circumstances pertaining to the Purchaser or others with which they become acquainted in connection with the deliveries, provision of services, etc. covered by this contract.

The non-disclosure agreement shall not lapse after cessation of employment or expiry of the contract.

Likewise, the Purchaser shall be bound by a non-disclosure agreement in accordance with current legislation.

The Supplier may include the Purchaser on its list of references, but other than this may not use the Purchaser’s name for marketing purposes without the Purchaser’s consent.

# Insurance

The Supplier is obliged to maintain standard occupational and product liability insurance throughout the expected lifetime of the delivery.

The occupational and product liability insurance shall offer a minimum scope of cover of DKK 10 million per incident per year. At the request of the Purchaser, the Supplier shall demonstrate the existence and scope of the insurance.

# Language

The present contract and all communication on contract matters, including clarification of any subsequent legal matters, shall be in English or Danish unless explicitly stated otherwise in writing by the Purchaser.

# Court of law and disputes

This contract is subject to Danish law.

Any disagreements arising from the signed contract will be settled by negotiation. Any dispute that cannot be settled by negotiation will be decided by the court. The Purchaser shall decide the court venue.

# Other conditions

The delivery shall take place respecting national and international laws and regulations concerning human rights, employee rights, the environment and anti-corruption, i.e.:

* The UN Declaration of Human Rights
* The ILO Declaration on Employee Rights
* The Rio Declaration on Environment and Development
* The UN Convention against Corruption

This means that neither the Supplier nor any subcontractors may use child and adult labour in contravention of conventions. The Purchaser reserves the right to demand documentation in this regard in the event that the Purchaser has reasonable cause for suspicion of breach of a convention.

# Signatures

This contract has been drawn up in two identical copies, one of which is to be retained by the Supplier, and one by the Purchaser.

At XXX, on / 2012

On behalf of the Supplier:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

At XXX, on / 2012 At XXX, on / 2012

On behalf of the Purchaser:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contract Schedule 3

**Qualification**

**(see agreement clause 15)**

1. **Quality system, plan and audit**
   1. The supplier must document its own and possibly used subcontractors' quality management system, for example through ISO certification. If a defective quality management system by a subcontractor is experienced, the supplier must in writing justify the use of this supplier (C-requirement).
   2. The supplier is financially and in terms of activities responsible for preparing a QAP Quality Activity Plan which describes the quality activities and needed documents during the projects. This QAP has to be approved and followed up by The Capital Region Pharmacy, hereafter called RAP (Q-requirement).
   3. The supplier shall establish, continually update and release time schedule for defined activities throughout the project duration (C-requirement).
   4. RAP will perform an audit in connection with the DQ (Q-requirement).
   5. RAP will perform an audit in connection with the FAT (Q-requirement).
   6. The supplier shall take part in a status meeting every 14 day (e.g. by telephone or videoconference) (I-requirement).
2. **Documentation**
   1. All documentation must be supplied in two paper copies and electronically filed on a disc in Word format (C-requirement).
   2. All protocols, test plans, reports and user/maintenance manuals must be in Danish or English language (Q-requirement).
   3. All data sheets, certificates and the like and supplementary manuals must be in Danish or English language (Q-requirement).
   4. All documentation should also be supplied in electronic format in plain manageable format (C-requirement).
   5. All documentation must be archive resistant or actions must be specified to ensure that documentation is made resistant for archivation (Q-requirement).
      1. Use only document pens
      2. Use only laser printing on plain paper of good quality (acid free).
   6. There must be full compliance between actual installation and diagrams / drawings, for example. PI diagram, wiring diagram etc (C-requirement).
   7. It should be easy and fast to get a complete overview of the documentation from the supplier. Tabbed folders, overview documents, contents of documents, etc. must be correct and complete before the requirement can be considered met (Q-requirement).
3. **Qualification / Commissioning**
   1. The supplier is financially and in terms of activities responsible for preparing protocols and test plans for all activities through ie. DQ, FAT, SAT, IQ, OQ. This applies to both C-requirements as Q-requirements. The work with these documents has to be coordinated with the project team at RAP, who also approve the documents (Q-requirement).
   2. The Supplier has to be open minded for a RAP QA approval - so that are approved to participate in the qualification work (making documents, perform test in DQ, IQ and OQ) (Q-requirement).
   3. Protocols and test plans and relevant documentation and reports must be available on time for RAP's QA approval, typically 14 days before test (Q-requirement).
   4. C requirements must undergo commissioning according to GxP (here Good Engineering Practice). Protocols and test plans should be based on a recognized standard in the pharmaceutical industry, for instance. ISPE Good Practice Guide: Good Engineering Practice and ISPE Baseline Guide Volume 5: Commissioning and Qualification (C-requirement).
   5. Q-requirements shall be subject to qualification according to GxP (here Good Qualification / Validation Practice). Protocols and test plans should be based on recognized standard in the pharmaceutical industry, for instance. ISPE Baseline Guide Volume 5: Commissioning and Qualification and ISPE Good Practice Guide: Good Engineering Practice (C-requirement).
   6. Any test result and any report must be approved by the RAP and activities i relation to tests witnessed by RAP, where RAP wish to do so (Q-requirement).
   7. The supplier must document its own and used third-party accreditation status (Q-requirement).
   8. The supplier shall document the training and education for every engineer, tester, etc., involved in the project from the FAT (Q-requirement).
4. **DQ - must contain at least:**
   1. Functional Specification and operation, purchaser should participate in DQ meeting where supplier demonstrate DQ (Q-requirement).
   2. A process overview of the critical processes in the robot (Q-requirement).
   3. Based on the process overview a risk assesment as described in EU GMP annex 20 has to be delivered (Q-requirement).
   4. Documentation of how the requirement in this URS are/will be implemented in the robot (Q-requirement).
   5. Eventually drawings (Q-requirement).
   6. PI diagrams (Q-requirement).
   7. Electric diagrams/charts (Q-requirement).
   8. Supply diagram(s) (Q-requirement).
   9. Information about maintenance and recommended service plan (Q-requirement).
   10. Examples of protocols / test plans for FAT / SAT and XQ activities (Q-requirement).
   11. Examples on commissioning-activities (Q-requirement).
   12. Code review and/or software-development history (Q-requirement).
5. **FAT**
   1. FAT should generally test all installation, functional and performance requirements. To reduce subsequent C and XQ activities the FAT will be used partly as IQ. Protocols and reports has to be approved by RAP. The test has to be performed with RAP. (Q-requirement).
6. **IQ - must contain at least**
   1. Testing of all Q-related installation requirements, including the reference in this specification for where the documentation exists (Q-requirement).
   2. Checking all charts for compliance with the equipment - PI, electricity supply etc. (Q-requirement).
   3. Checking all certificates (Q-requirement).
   4. Checking all connections for supply and drainage (Q-requirement).
   5. Checking the message and the alarm text (Q-requirement).
   6. Checking the system records - program / regulatory management, user management, audit trails, data capture, screen displays, report views (data and graphics), etc. (Q-requirement).
7. **SAT**
   1. SAT should generally test the installation, functional and performance requirements that might be affected as a result of relocation and new connections. To reduce subsequent C and XQ activities the SAT will be used partly as OQ. Protocols and reprots has to be apporved by RAP. The test has to be performed with RAP. (Q-requirement).
8. **OQ - must contain at least**
   1. Testing of all Q-related functional requirements, including the reference in this specification on where the documentation can be found (Q-requirement).
   2. Testing of all alarms (Q-requirement).
   3. General testing of functionality (Q-requirement).
9. **C - must contain at least**
   1. Verification of compliance with all C-related requirements, including the reference in this specification for which documenation evidence exists (Q-requirement).
   2. Simple reference to how requirements are found satisfied if the claim is immediately obvious fulfilled. Reference must be verified - best by copy annexed. (Q-requirement).
   3. "Test-compliance where the requirement is not immediately obvious fulfilled. Can be C-test or be included in the XQ-test." (Q-requirement).
10. **Additional documentation of final delivery**
    1. Design documentation for all equipment items (Q-requirement).
    2. Equipment drawing (Q-requirement).
    3. Technical Specifications (Q-requirement).
    4. Component list (Q-requirement).
    5. As part of the documentation, the supplier must provide a list of required and recommended spare parts in accordance with the following definition of the critical components: Critical components are components, which: (1). greatly influences the quality of the product and which has great significance for the subsequent maintenance work. (2). Components / elements that has to be calibrated or checked regularly. (3) Components / elements for which it is reasonably/ probable that they need replacing during the life time of equipment. (4). Components / elements that are not readily replaced by an equivalent product, why unambiguous identification is important (Q-requirement).
    6. Spare parts list shall include the following: 1 Component number or similar unique specification., 2. Supplier's name, address and telephone number, 3. Delivery time, 4. By identifying the critical components, operating time, replacement time and cost for these parts must be disclosed (Q-requirement).
    7. FAT/IQ & SAT/OQ-protocols/reports apporved by RAP (Q-requirement).
    8. XQ-protocols/reports (Q-requirement).
    9. C-protocols/report (Q-requirement).
    10. User Manual in english. Including the list of messages and critical alerts (Q-requirement).
    11. Procedures for user administration and inventory of registered users with access rights (Q-requirement).
    12. Procedure for software-backup/restore (Q-requirement).
    13. Software back-up media (Q-requirement).
    14. Emergency procedures (Q-requirement).
    15. Maintenance manual (Q-requirement).
    16. Maintenance plan (Q-requirement).
    17. Calibrationplan for measuring instruments (Q-requirement).
    18. CE Declaration of Conformity (Q-requirement).
    19. AT- approval (Q-requirement).
    20. Electronic documentation (Q-requirement).

Contract Schedule 4

**Paradigm for site acceptance test**

**(see agreement clause 20)**

Site acceptance test regarding:

Date agreement established:

Order number/agreement number:

Authorisation number/requisition number:

Site acceptance test on behalf of:

Supplier:

Site acceptance test shall comprise the item purchased included in the order/contract, see above, which shall be examined in order to ascertain whether this fulfils the specifications laid down regarding quality, capacity, function and finish, as well as the needs requirement the purchase was to meet.

The item purchased shall be reviewed and trialled in accordance with the description in the order/contract as well as the data sheets and/or brochures etc. referred to in these contracts.

The item purchased can be approved in full without comment.

The item purchased can be approved with comments about less material deficiencies, which shall be stated under “Description of deficiencies” with statement of how and when the deficiencies will be rectified.

To secure rectification of deficiencies, proportional retention of parts of the purchase sum or provision of security may be made by agreement.

The item purchased may be subject to such material deficiencies that the handover is rejected by the Purchaser.

In the event of rejection, the material deficiencies ascertained shall be stated below in “Description of deficiencies”, stating the new requirements for remedy which shall be fulfilled before an invitation to a new Site acceptance test.

The full purchase sum and any provision of security shall be retained in full, until a new Site acceptance test forms the basis for full or part release.

Description of deficiencies (see clauses 2 or 3):

|  |  |  |  |
| --- | --- | --- | --- |
| Description of deficiency | Material/minor deficiency | Scheduled date for remediation of deficiency | Date remediation of deficiency completed |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Approved without comment, see clause 1

Approved with minor deficiencies, see clause 2

Site acceptance test rejected on the grounds of material

deficiencies, see clause 3

Date of Site acceptance test:

Representatives of Supplier and Purchaser confirm with their signatures the above.

On behalf of the Supplier: On behalf of the Purchaser:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Paradigm for two year trial and review of the equipment**

**(see agreement clause 21.5)**

Two years of trial and review regarding:

Date agreement established:

Order number/agreement number:

Authorisation number/requisition number:

Two years of trial and review shall be on behalf of:

Supplier:

The Supplier shall invite the Purchaser in writing for a two-year trial and review of the equipment at the expiry of the remedial period. Trial and review shall be notified within reasonable time and carried out no later than one month before expiry of the remedial period.

Scope of trial and deficiency review shall reflect all tests and checks in connection with handover and acceptance procedures.

The technical requirements and results in connection with trials and deficiency review shall be in accordance with the results achieved in connection with the acceptance test. To the extent necessary, the Supplier shall make measuring equipment, phantoms and a competent operator available.

If faults and deficiencies are found during trial and review, the Supplier shall commence remediation immediately.

Once deficiencies have been remedied and documented in writing for the Purchaser, the Supplier may invite to a new trial and deficiency review.

The remedial period shall cease only when trial and review have been completed without deficiencies and only when both parties have signed to this.

If the Supplier fails to invite to a two-year trial and review of the equipment, the remedial period shall continue as before.

The item purchased can be approved in full without comment.

The item purchased can be approved with comments about less material deficiencies, which shall be stated under “Description of deficiencies” with statement of how and when the deficiencies will be rectified.

Description of deficiencies (see clause 2):

|  |  |  |  |
| --- | --- | --- | --- |
| Description of deficiency | Material/minor deficiency | Scheduled date for remediation of deficiency | Date remediation of deficiency completed |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Approved without comment, see clause 1

Approved with minor deficiencies, see clause 2

Date of two-year trial and review of the equipment:

Representatives of Supplier and Purchaser confirm with their signatures the above.

On behalf of the Supplier: On behalf of the Purchaser:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contract Schedule 5

**Bank guarantee for advance payment**

**(see agreement clause 13)**

Guarantee no.:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

At the request of the Supplier (guarantee debtor):

(name, address)

the guarantor (name of bank, credit association or similar) shall provide to the Purchaser (guarantee creditor):

(Region, address)

an on-demand guarantee of DKK xxx: (write Danish Kroner xxxxxx).

as security for repayment of advance payment in accordance with Case no. xx, agreement no. xxxx of xx.xx.xxxx with associated appendices regarding delivery of:

(brief description of the equipment) for department xx, Region xx.

Claims pursuant to the guarantee shall be paid on request and without legal proceeding to the Purchaser, once the guarantor has received a written request for payment from the Supplier.

The guarantee shall only cover the advance payment for which provision of guarantee has been specifically demanded. Claims pursuant to the guarantee shall be paid to the Purchaser no later than two weeks after the Purchaser has put forward the claim to the guarantor.

The guarantee shall lapse once it has been rescinded by the Purchaser after approved handover procedure at the Supplier’s request. The Purchaser shall return the original guarantee document to the guarantor immediately after it has been rescinded.

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Guarantor: (name and address)

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Contract Schedule 6

**Performance guarantee during remedial period**

**(see agreement clause 14)**

Guarantee no.:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

At the request of the Supplier (guarantee debtor):

(name, address)

the guarantor (name of bank, credit association or similar) shall provide to the Purchaser (guarantee creditor):

(Region, address)

an on-demand guarantee of DKK xxx: (write Danish Kroner xxxxxx).

The guarantee provided shall serve as security for any losses suffered by the Purchaser as a consequence of non-compliance by the Supplier with his/her obligations in accordance with Case no. xx, agreement no. xxxx of xx.xx.xxxx with associated appendices regarding delivery of:

(Brief description of the delivery)

Claims pursuant to the guarantee shall be paid on request and without legal proceeding to the Purchaser, once the guarantor has received a written request for payment from the Supplier. Claims pursuant to the guarantee shall be paid to the Purchaser no later than two weeks after the Purchaser has put forward the claim to the guarantor.

The provision of guarantee shall not be temporary, but will be rescinded by the Purchaser at expiry of the remedial period at the written request of the Supplier on the condition that there are no unremediated deficiencies. In such event, the Purchaser shall rescind the guarantee, once the deficiencies mentioned have been remediated.

The Purchaser shall return the original guarantee document to the guarantor immediately after it has been rescinded.

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Guarantor: (name and address)

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_