

Maintenance Agreement

Agreement governing the maintenance and servicing of software and equipment

The Norwegian Government's Standard
Terms and Conditions for IT Procurement
SSA-V

*Tender for delivery of Blister Unit Dose Dispensing
and Packaging Machine*

**SSA-V Appendix 1 Customer requirements
specification**

Case number: 2022/511

Appendix 1: Customer requirements specification (requirements for the maintenance services)

1. Introduction

This appendix is the Customer requirement specification (requirements for the maintenance services) in respect of the deliverables. The Contractor's proposed solution for delivery of the Blister Unit Dose Dispensing and Packaging Machine, including necessary software, training and documentation in the Purchase Agreement, will hereby be referred to as the "Offered Solution".

2. The Agreement, clause 2.1.2 Cooperation plan

The Contractor shall provide support and maintenance services for all software delivered with the Purchase Agreement, in accordance with the requirements and procedures agreed upon.

3. The Agreement, clause 2.2.1 Scope of the maintenance services

The services provided under this Agreement shall include the following objectives:

- Ensure that the solution has sufficient availability (98 %)
- Ensure that the Offered Solution provided is updated in accordance with applicable laws and standards
- Ensure that errors and vulnerabilities are corrected through version upgrades
- Ensure that the Offered Solution maintains and improves its quality so that the Offered Solution does not deteriorate over time
- Provide a predictable and stable solution
- Provide cost-effective maintenance services

The Customer may require that this Maintenance Agreement ("the Agreement") includes:

- Correction of reported errors (corrective maintenance)
- Identification and correction of latent errors before occurring (preventive maintenance)

Optionally, the Customer may require that the service also include:

- Changes to meet changing software requirements and/or systems that the software interacts with (adaptive maintenance)
- Changes to increase performance, maintainability, ease of use, etc. (Perfective maintenance)

4. The Agreement, clause 9.1 General external legal requirements and measures.

The Contractor shall comply with all laws, regulations, rules, and guidelines. In particular, the Contractor shall ensure that the proposal and its conduct comply with Good Manufacturing Practice ("GMP"), as published in EudraLex Volume 4. Furthermore, the proposal must enable the Customer to comply with GMP, as packing of pharmaceuticals is defined as "manufacturing".

5. The Agreement, clause 9.3 Personal data

In accordance with the Agreement

6. The Agreement, clause 11.4.3 Standardized damages and hourly liquidated damages

Liquidated damages may be imposed in accordance with clause 11.4.3 of the Agreement.

7. Instructions for answering the requirement specification

7.1 INSTRUCTIONS FOR ANSWERING REQUIREMENT

Importance of requirements

Information (“I”) is just a request for information. This will not be evaluated and is not an obligatory requirement.

Obligatory requirements (“O”) must be fulfilled or the proposal will be rejected. “O” requirements will therefore not be graded. The other requirements will be graded according to their high, medium or low importance.

The table below lists up the applicable classifications:

Type of requirement	Description	Highest possible grade score
I	Information	Will not be evaluated
O	Obligatory. All obligatory requirements must be satisfied	Pass/Fail
H	High importance	15
M	Medium importance	5
L	Low importance	2

7.1.1 Description of requirements

The Contractor shall provide an in-depth description of how the Offered Solution responds to the requirement in the “The Contractor’s description/confirmation” column, or refer to a description in a separate document.

7.1.2 Confirmation of requirements

Contractor shall insert “confirm” or “does not confirm” in the “The Contractor’s description/confirmation” column.

7.1.3 Tender evaluation

Quality criteria will be assessed according to the degree of added value that the offered solution provides. Example of added value could be solutions that ensure high uptime, short response time and good services.

8. Requirements regarding the delivery of the Offered Solution

No.	Requirement	Type	Award criteria	The Contractor's description/confirmation
General requirements regarding the delivery of the solution				
1.	<p>The Contractor shall in V Appendix 2, provide a description of offered services, support and maintenance of the offered solution.</p> <p>The Contractor services must in an integrated manner, serve the purposes specified in the maintenance agreement (SSA –V) with appendices.</p>	O		<i>Describe</i>
2.	The Contractor shall, in V Appendix 2, confirm that it is the Contracting Authority's understanding of requirements; implied by laws, regulations, rules, instructions and guidelines by the Contracting Authority in its capacity as a member of the Norwegian health sector, that are to be followed under this maintenance agreement, SSA - V with appendices.	O		<i>Confirm</i>
3.	The Contractor shall, in V Appendix 2, describe any other equipment and software that is a prerequisite for maintenance of the offered solution to function optimal. All necessary equipment and software must be included in the prices stated in K Appendix 7a Price sheet.	O		<i>Describe</i>
4.	The Contractor shall, in V Appendix 2, confirm that the Contractor is responsible for ensuring that they	O		<i>Confirm</i>

	have the necessary authorizations and rights for the offered software, equipment and spare parts used during maintenance.			
5.	The Contractors should, as part of the annual maintenance fee, conduct necessary control and preventive maintenance of the offered solution during the maintenance period. The Contractor should describe how this will be carried out and their methodology for preventive / proactive maintenance on the solution offered to the Contracting Authority.	M	Contractor services	<i>Describe</i>
6.	<p>The Contractor should, in V Appendix 2, propose a solution for the Contracting Authority to have access to critical spare parts within 1 working day. This can be solved either by the Contractor keeping stock, or by the Contracting Authority having this stock. The Contractor is asked to describe current solutions and any spare parts that the customer must keep in stock.</p> <p>It is expected that the supplier brings the necessary spare parts on assignments where the fault is known in advance.</p>	M	Contractor services	<i>Describe</i>
7.	The Contractor should, in V Appendix 2, describe the maximum response time for critical services from the Contractor has received notification to technical personnel is at the customer's location.	M	Contractor services	<i>Describe</i>
8.	The Contractor should, in V Appendix 2, describe which parts of the maintenance / monitoring of the solution that should be performed by the Contracting Authority in Service Option 1 (Spare parts included) and Service Option 2 (Spare parts not included).	M	Contractor services	<i>Describe</i>

9.	The Contractor shall, in V Appendix 2, confirm that the Contractor will use English, or any Scandinavian language during the maintenance period when communicating with the Contracting Authority. This includes all personnel performing the maintenance and all future documents provided by the Contractor.	O		<i>Confirm</i>
10.	The Contractor should, in V Appendix 2, describe how service and maintenance during the maintenance period will be organized, implemented, documented and reported. Service and maintenance must be priced in V Appendix 7a - Price sheet.	M	Contractor services	<i>Describe</i>
11.	The Contractor shall, in V Appendix 2, confirm that no changes must be made that could affect the validated status of the machine without this being accepted by the customer.	O		<i>Confirm</i>
12.	The Contractor shall, in V Appendix 2, confirm that the warranty period of the hardware shall be two (2) years, and one (1) year for software, from the Customer acceptance test is accepted by the Contracting Authority. Within the warranty period, there shall be no additional costs for repair or replacement of parts.	O		<i>Confirm</i>
13.	The Contractor shall, in V Appendix 2, confirm that the Contractor for all new versions (software/firmware/hardware) of the offered solution, at any given time, will ensure compliance with the latest version of GMP, GAMP and GDPR.	O		<i>Confirm</i>
14.	The Contractor should, in V Appendix 2, specify recommended upgrade frequency of the delivered software to the Contracting Authority. The Contractor shall also describe its procedures for distributing new versions / patches / of software to	L	Contractor services	<i>Describe</i>

	the Contracting Authority.			
15.	The Contractor shall, in V Appendix 2, confirm if the Contractor at least 18 months before the termination of support of a software release (version number), will notify the Contracting Authority in writing. The Contractor shall in V Appendix 2 describe the termination deadline and the activities related to the termination.	O		<i>Confirm and describe</i>
16.	The Contractor shall in V Appendix 2, confirm that the Contracting Authority decides what is categorized as error and what is categorized as change requests. See SSA – V Appendix 5.	O		<i>Confirm</i>
17.	The Contractor shall, in V Appendix 2, confirm that the Contractor will not change the categorization of errors without the Contracting Authority's consent.	O		<i>Confirm</i>
18.	The Contractor shall, in V Appendix 2, confirm that updates and patches by the Contractor will be confirmed in writing to Contracting Authority.	O		<i>Confirm</i>
19.	The Contractor shall, in V Appendix 2, confirm that if the Contracting Authority is in doubt about the reason/location for an error, the Contracting Authority may request that the Contractor conducts appropriate diagnosis.	O		<i>Confirm</i>
20.	The Contractor should, in V Appendix 2, describe its error handling process from error is detected to it has been resolved for A, B and C errors.	H	Contractor services	<i>Describe</i>
21.	The Contractor should, in V Appendix 2, describe the procedures for detection of errors and how the Contracting Authority can follow reported errors, including monitoring the status. The Contractor should also, in V Appendix 2, describe the possibilities the Contracting Authority has to extract different types of error-reports.	M	Contractor services	<i>Describe</i>

22.	If the offered solution due to critical errors cannot be used (mechanical or software), the Contractor should in V Appendix 2, describe how the Contractor will rectify the errors/situation.	M	Contractor services	<i>Describe</i>
23.	The Contractor shall in V Appendix 2, confirm that if the Contracting Authority has not explicitly asked for new functionality, any new functionality not ordered following new releases is not chargeable to the Contracting Authority.	O		<i>Confirm</i>
24.	The Contractor shall in V Appendix 2, confirm that requests for support from the Contracting Authority will be logged by the Contractor.	O		<i>Confirm</i>
25.	The Contractor should, in V Appendix 2, describe their system for support tickets (unique reference number).	M	Contractor services	<i>Describe</i>
26.	The Contractor should, in V Appendix 2, describe their change management system.	M	Contractor services	<i>Describe</i>
27.	The Contractor shall, in V Appendix 2, confirm that the Contract Authority can perform audits, and that the Contractor will submit information/documentation requests from the Contracting Authority associated with this type of work.	O		<i>Confirm</i>
28.	The Contracting Authority is on a regular basis audited by regulatory authorities. As part of these audits, the solution as well as the Contractor's quality system and procedures for security and maintenance of the offered solution, may be subject to auditing. The Contractor shall in the event of an audit, and on the request from the Contracting Authority, make available personnel and documentation that is required to complete the audit.	O		<i>Confirm</i>

29.	The Contractor should, in V Appendix 2, describe how maintenance documentation (and its annexes) will be continuously updated and supplemented during the maintenance period.	M	Contractor services	<i>Describe</i>
30.	The Contractor shall, in V Appendix 2, confirm that the Contractor will maintain and develop their expertise on the solution throughout the Contract period.	O		<i>Confirm</i>
31.	The Contractor shall, in K Appendix 7a Price sheet, provide a list, and cost of necessary spare parts for operating the offered solution.	O		<i>Confirm</i>
32.	The Contractor shall, in K Appendix 7a Price sheet, provide a list, and cost of consumables, disposable and additional equipment (e.g. cassettes) that are necessary for operating the offered solution.	O		<i>Confirm</i>
33.	The Contractor should provide a short delivery time for consumables. The Contractor should, in Appendix 2, specify delivery time in days.	L	Contractor services	<i>Describe</i>
34.	The Contractor shall, in V Appendix 2, confirm the Contracting Authority required service levels, response times, obligations, and the consequences as described for A, B and C errors in V appendix 5.	O		<i>Confirm</i>
35.	The Contractor shall, in V Appendix 2, confirm its availability for telephone and email support, as minimum on Monday - Friday between 08:00 to 16:00 (Norwegian time).	O		<i>Confirm</i>
36.	The Contractor is, in V Appendix 2, asked to state options for support outside weekdays at 8-16.	H	Contractor services	<i>Describe</i>
37.	The Contractor shall, in V Appendix 2, confirm that the availability of the offered solution is 98%. This availability is measured over all operating hours per month. Unavailability of the solution due to circumstances beyond the Contractor's control, or	O		<i>Confirm</i>

	planned preventive maintenance, is not covered by the guaranteed availability.			
38.	When deploying software patches of A-and B-error the Contractor is obligated to be available for assistance when needed, and to submit documentation describing the patches. This must be confirmed by the Contractor in V Appendix 2.	O		<i>Confirm</i>
39.	The Contractor shall, in V Appendix 2, confirm that on request from the Contracting Authority, that the Contractor will assist the Contracting Authority in troubleshooting and debugging, even if the Contractor conclude they are not responsible for the error.	O		<i>Confirm</i>
40.	If the downtime is caused by a third party software-components that is a part of the offered solution, the Contractor is responsible, unless otherwise agreed with the Contracting Authority.	O		<i>Confirm</i>
41.	The Contractor should, in V Appendix 2, describe the need for service windows (planned downtime) e.g. associated with upgrades and maintenance.	L	Contractor services	<i>Describe</i>
42.	The Contractor should, in V Appendix 2, provide a complete description of how the Contractor will organize and staff the support and maintenance of the offered solution.	L	Contractor services	<i>Describe</i>
43.	The Contractor should, in V Appendix 2, describe a proposed separation of responsibilities, rights and duties, for the Contracting Authority and the Contractor in the different parts of the maintenance under Service option 2. If the Contractor has requirements regarding the Contracting Authority's competency or capacity, this should be clearly stated in V Appendix 2.	H	Contractor services	<i>Describe</i>
44.	The Contractor shall, in V Appendix 2, provide a	O		<i>Confirm</i>

	contact person to be responsible for the administration and management of this agreement. If the contact person is to be changed, the Contractor shall notify the Contracting Authority within 30 days for approval from the Contracting Authority.			
45.	The Contractor must, in V Appendix 2, confirm that critical spare parts must be available for a minimum of 10 years from approval of customer acceptance test.	O		<i>Confirm</i>