# Purchase Agreement

## Agreement governing the purchase of software and equipment

The Norwegian Government's Standard Terms and Conditions for IT Procurement
SSA-K 2018

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

## SSA-K Appendix 1 Customer requirements specification

**Case number: 2022/510**

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# Appendix 1: Customer requirements specification

# 1 Introduction

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

# 2 The Agreement, clause 1.1 Scope of the Agreement

The Offered Solution shall function together with the Customer's current technical platform and intended workflow, which is stated in "K Appendix 3 Customer technical platform".

# 3 The Agreement, clause 2.1.2 Customisations and installation, etc.

The Contractor is responsible for implementation activities for the Offered Solution. Implementation should cover activities necessary for the Customer to use the Offered Solution as intended, including; transportation, installation, validation/testing and programming the Offered Solution for use.

# 4 The Agreement, clause 2.1.4 Documentation and training

The Contractor shall help provide the necessary training for the Customer's personnel, and all relevant documentation shall be made available for the Customer.

# 5 The Agreement, clause 2.2.2 Duty to examine

Validation and testing of the Offered Solution (Customer's acceptance test) will be conducted. See "Appendix 5 Approval test" for further description and requirements.

# 6 The Agreement, clause 2.7 External legal requirements

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

# 7 The Agreement, clause 4.3 Free software

If parts of the Offered Solution are based on free software, including customizations and further developments of the free software, the Customer shall be granted the rights necessary to distribute the results further under the relevant free software license, or under a compatible free software license if this is specified.

# 8 Instructions for answering the requirement specification

## 8.1 Instructions for answering requirement

### 8.1.1 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 |

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### 8.1.2 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.

### 8.1.3 Confirmation of requirements

Contractor shall insert "confirm" or "does not confirm" in the "The Contractor's description/confirmation" column.

### 8.1.4 Tender evaluation

Quality criteria will be assessed according to the degree of added value that the offered solution provides, in accordance with the intended workflow in "K Appendix 3". Example of added value can be: efficiency, ease of use, security, capacity, flexibility, methodology and technical quality.

# 9 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. | Offered solution Sykehusapotekene i Midt-Norge (Region Central):<br>The Contractor shall, in K Appendix 2, confirm that the offered solution has sufficient capacity to produce 5,65 million unit doses per year. Expected production time is 60 hours per week.<br><br>The offered solution must consist of a minimum of 2 production units to ensure redundancy.<br><br>Fill in all details and pricing in Appendix 7a - Price sheet | O | | *Confirm and describe in K Appendix 7* |
| 2. | The Contractor shall, in K Appendix 2, confirm that the offered solution is able to dispense, pack and produce unit doses. | O | | *Confirm* |
| 3. | The Contractor shall, in K Appendix 2, confirm that the offers solution is suitable for installation in classified rooms (Class D) in accordance with EU GMP (Chapter 3 (equipment) and Annex 1, 4), with controlled ventilation. | O | | *Confirm* |
| 4. | The Contractor shall in K Appendix 2, confirm that the offered solution meets formal requirements for validation according to EU GMP (Annex 1, 4), EU GMP Annex 11: "Computerized Systems", EU GMP | O | | *Confirm* |

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| | Annex 15 “Qualification and Validation” and established industry standards including GAMP. | | | |
| 5. | The Contractor shall, in K Appendix 2, confirm that the offered solution, included logging, is compliant with GDPR (The EU General Data Protection Regulation) and describe how the solution will meet GDPR requirements. | O | | *Confirm* |
| 6. | The Contractor should, in K Appendix 2, describe the minimum required area needed for installation of the offered solution as well as minimum ceiling height and weight. | H | Quality - Technical solution - General | *Describe* |
| 7. | The Contractor shall, in K Appendix 2, confirm that the software application and database must be able to manage special letters, such as Ü, Æ, Ø, Å. | O | | *Confirm* |
| 8. | The Contractor shall, in K Appendix 2, confirm that the unit dose label, on each individual bag, as a minimum include the following:<br><br>• dispensing pharmacy<br>• medicinal product name, strength and form<br>• administration and dosing instructions<br>• warnings and storage instructions as applicable<br>• expiry date of the medication after re-packing to unit dose<br>• batch identification number to ensure full traceability<br>• active substance<br>• drug manufacturer<br>• barcode (GS1-standard) | O | | *Confirm* |
| 9. | The Contractor should, in K Appendix 2, describe any special adaptations or additional functions that are included in the offered solution. | H | Quality - Technical | *Describe* |

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| | | | solution - General | |
| 10. | The Contractor should, in K Appendix 2, describe its future commitment to the development of the offered solution and their vision of development in the next 5 years. If applicable, the Contractor should, in K Appendix 2, provide an overview of the current development plans for the solution for the next five (5) years. | I | | *Describe* |
| 11. | The Contractor shall, in K Appendix 2, confirm that the offered solution has a 10-year minimum life expectancy based on the following: producing unit doses at max capacity, 3640 hours/per year (10 hour a day, 7 days a week and 52 weeks a year). Preconditions for service and maintenance must be described. | O | | *Confirm and describe* |
| 12. | The Contractor should, in K Appendix 2, describe the maximum number of cassettes/boxes/trays (or similar) that the offered solution can contain at the same time. The Contractor should also describe the scalability of the solution. | H | Quality - Technical solution - General | *Describe* |
| 13. | The Contractor shall, in K Appendix 2, confirm that they have the necessary authorizations, rights, etc. in relation to the offered equipment and software to be used. | O | | *Confirm* |
| 14. | The Contractor should, in K Appendix 2, describe all relevant requirements for required components (OS, client applications, server software, etc.) that are not supplied as a part of the offered solution, or that deviate from the Contracting Authority's standards.<br>For example: Browser, web server, databases, Java, Flash, Silverlight, MS Office, .NET Framework, C++ | H | Quality - ICT - General | *Describe* |

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| | Redistributable, MDAC etc. and any specific versions of these. | | | |
| 15. | The Contractor should, in K Appendix 2, describe the delivery time for the offered solution from date of ordering until the solution is installed at site and an expected validation time schedule including the SAT – IQ/OQ is preformed and accepted. The Contracting Authority's tentative time schedule for delivery is described in K Appendix 4. | M | Quality - Installation, test and validation | *Describe* |
| **General security requirements** | | | | |
| 16. | The Contractor shall, in K 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 agreement and the maintenance agreement (SSA-K and SSA-V with appendices). | O | | *Confirm* |
| 17. | The Contractor shall, in K Appendix 2, confirm that they in cooperation with the Contracting Authority will implement changes with respect to the relevant laws, regulations and regulatory requirements that affects the use of the offered solution no later than 6 months before the date the amendment takes effect, unless otherwise agreed upon in writing with the Contracting Authority. The Contractor shall in K Appendix 2, describe their procedures and methodology for change management. | O | D | *Confirm and describe* |
| 18. | The Contractor shall, in K Appendix 2, confirm that training of the pharmacy staff is a part of the implementation of the offered solution. | O | | *Confirm* |

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| 99. | The Contractor should, in K Appendix 2, describe if certification/training of local technical personnel is an option for performing maintenance and error handling of the offered solution. | H | Quality - Installation, test and validation | *Describe* |
| 19. | The Contractor should, in K Appendix 2, give an overview of the training that will be part of the implementation of the offered solution. If there are different levels (training courses) of training given to the pharmacy staff, this should be specified. | M | Quality - Installation, test and validation | *Describe* |
| **Documentation** | | | | |
| 20. | The Contractor shall, in K Appendix 2, confirm that any form of documentation and training course material from the Contractor, shall be made available in an electronic format and paper version for the Contracting Authority in accordance with EU-GMP, and should be editable if the Contracting Authority requires it.<br><br>All documentation and training course material must be written in English language. | O | | *Confirm* |
| 21. | The Contractor shall, in K Appendix 2, confirm that the documentation linked to service, maintenance, software updates and training course material provided by The Contractor shall be approved by the Contracting Authority, if the Contracting Authority requires this. Disapproved documents should be revised by the Contractor.<br><br>All electronic documents provided must be searchable. | O | | *Confirm* |
| **Test and acceptance** | | | | |

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| 22. | The Contractor shall, in K Appendix 2, accept that the Contracting Authority will not approve the FAT and SAT until the following number (or less) of errors (ref. definition of errors in SSA-K) is achieved:<br><br>A. Critical errors: None (0)<br>B. Serious errors: None (0)<br>C. Less serious errors: 10 | O | | *Confirm* |
| 23. | The Contractor shall in K Appendix 2, confirm that in order to get the Customer Acceptance Test (CAT) accepted the following number of errors (ref. definition of errors in SSA-K) must not exceed:<br><br>A. Critical errors: None (0)<br>B. Serious errors: None (0)<br>C. Less serious errors: 5 | O | | *Confirm* |
| 24. | The Contractor shall, in K Appendix 2, confirm that they are in terms of activities responsible for preparing protocols and test plans for all activities through FAT, SAT, IQ and OQ. The Contracting Authority shall approve the protocols before they are used. For an overview of the validation and testing activities, see K appendix 5. | O | | *Confirm* |
| 25. | The Contractor shall, in K Appendix 2, confirm that all relevant validation and testing shall be performed as stated in K Appendix 5. | O | | *Confirm* |
| 26. | The Contractor shall, in K Appendix 2, confirm that documentation from testing will be handed over to the Contracting Authority. The documentation shall as a minimum contain information stated in K Appendix 5. | O | | *Confirm* |

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| 27. | The Contractor should, in K Appendix 2, describe their methodology and standards used for testing of the offered solution.<br><br>The Contractor should, in K Appendix 2, provide one example of a protocol for validation activities. | L | Quality - Installation, test and validation | *Describe* |
| 28. | The Contractor shall, in K Appendix 2, confirm that a Test Manager will be appointed. The Test Manager will be responsible towards the Contracting Authority, and:<br>• Ensure that the Contractor's deliveries are in accordance with this document.<br>• Have overall responsibility for all tests to be performed and documented by the Contractor in accordance with this document.<br>• Assess reported errors in collaboration with developer, testers, and test managers.<br>• Ensure that the reported errors are corrected and delivered as soon as possible.<br>• Maintain regular dialogue with the Contracting Authority's test manager in relation to the follow-up of issue-reporting. | O | | *Confirm* |
| 29. | The Contractor should, in K Appendix 2, deliver a complete list of both Contractor's and Contracting Authority's responsibilities in all phases of the implementation of the offered solution. | M | Quality - Installation, test and validation | *Describe* |
| 30. | The Contractor shall, in K Appendix 2, confirm that they will provide qualified personnel to the Contracting Authority throughout the project. | O | | *Confirm* |
| **Functional requirements of the Offered Solution<br>Process requirement** | | | | |
| 31. | The Contractor should, in K Appendix 2, give an overview of the offered solution (software and | H | Quality - Technical | *Describe* |

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| | hardware), and describe the production workflow for unit doses from start to finish. What is performed automatically and what is performed manually, needs to be specified. High level of automation is strongly preferred. The overview should describe how the offered solution functionally and technically supports the tentative workflow as described in K Appendix 3 when implemented. | | solution - General | |
| 32. | The Contractor shall, in K Appendix 2, confirm that the offered solution is able to scan and retrieve information regarding the drug, when scanning the barcode of the drug (linear and 2D-barcodes). | O | | *Confirm* |
| 33. | The Contractor should, in K Appendix 2, describe which standards of barcode that will be interpreted, and which information from the barcode that may be used to automatically fill information fields in the production. | H | Quality - Technical solution - General | *Describe* |
| 34. | The Contractor should, in K Appendix 2, describe which information (input) is required in order to start the production that must be entered manually and which master data the solution can have stored or imported. Import is strongly preferred. | H | Quality - ICT - Integration | *Describe* |
| 35. | The Contractor should, in K Appendix 2, describe what consumables the operator supplies the solution with, and if there are any special preparations to be done with the material, in order to start the production (e.g. packaging material, ink/toner etc.). If there is, a need to change between different consumables (e.g. size or material) between productions this should be specified in the description. The Contracting | H | Quality - Technical solution - Ease of use | *Describe* |

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| | Authority would prefer as few changes between different types of consumables as possible. | | | |
| **Functional requirements of the Offered Solution**<br>**Safety and efficacy** | | | | |
| 36. | The Contractor should, in K Appendix 2, describe the offered solution's system for ensuring that the correct drug is loaded /used in the system. | H | Quality - Technical solution- Patient safety | *Describe* |
| 37. | The Contractor shall, in K Appendix 2, confirm that the offered solution includes a bar code reading system to identify all drug packages loaded into the system. | O | | *Confirm* |
| 38. | One of the most important safety features in the production is to confirm the correct drug by scanning. The Contractor shall, in K Appendix 2, confirm that all packages that will be part of one or unique production must be scanned individually. | O | | *Confirm* |
| 39. | The Contractor should, in K Appendix 2, describe how the system handles production requests while producing. It should be possible to send new production requests to the system while the system is producing unit doses, without discontinuing the production. | L | Quality - ICT - Functional | *Describe* |
| 40. | The Contractor should, in K Appendix 2, describe the offered solutions possibility for storing, prior to production, different drugs simultaneously. The description should include if there is any manual involvement between the production of the different drugs, how many different drugs that can be loaded into the offered solution simultaneously, and if there are any limitations in the amount of | H | Quality - Technical solution - Ease of use | *Describe* |

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| | drug casettes/boxes/trays or similar that can be used with the offered solution. | | | |
| 41. | The Contractor should, in K Appendix 2, describe how the solution will indicate which cassettes/ boxes /trays (or similar) will be needed for the next batch to be packed. The Contractor should also give a short description of changeover workflow between batches. | H | Quality - Technical solution - Ease of use | *Describe* |
| 42. | The Contractor should, in K Appendix 2 describe how all different boxes/cassettes/trays or similar used to load the drugs are identified (e.g., an RFID chip or barcode). All drug cassettes/ boxes /trays or similar shall have a validated method of identification. | H | Quality - Technical solution- Patient safety | *Describe* |
| 43. | The Contractor shall, in K Appendix 2, confirm that all cassettes/boxes/trays (or similar) must be exchangeable between identical dispensing unit models. | O | | *Confirm* |
| 44. | The Contractor should, in K Appendix 2, describe if the solution can handle continuous production with a low level of manual interference in the process. | H | Quality - Technical solution - Ease of use | *Describe* |
| 45. | The Contractor should, in K Appendix 2, describe the process of validating cassettes / boxes /trays (or similar). Any involvement from the Contractor in the validation process should be described. | M | Quality - Technical solution - Ease of use | *Describe* |
| 46. | The Contractor should, in K Appendix 2, describe the dispensing error rate. Dispensing error rate (%) and calculation method should be documented. | H | Quality - Technical solution - General | *Describe* |
| 47. | The Contractor should, in K Appendix 2, document known errors that can occur during production, | I | | *Describe* |

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| | with corresponding frequency (%). This description should also include the consequences and necessary actions related to fix the error. | | | |
| 48. | The Contractor should, in K Appendix 2 describe the offered solutions response to input of illegal values, illegal combinations of values, or lack of values/input. Example: letters instead of digits or vice versa. | H | Quality - ICT - Functional | *Describe* |
| 49. | The Contractor should, in K Appendix 2, describe what type of master data that may be stored in the software, and which control steps to be performed when storing new master data. The audit trail for the master data should also be described. | H | Quality - ICT - Functional | *Describe* |
| 50. | The Contractor should, in K appendix 2, describe if the process of entering new drugs to the database (e.g., new drugs, manufactures change the design etc.) can be done by the pharmacy staff, without the involvement of the Contractor. The Contractor should also describe, the process of entering new drugs to the database (e.g., new drugs, manufactures change the design etc.). This description should give an example of the time it takes to enter a new drug in the offered solution. | H | Quality - Technical solution - Ease of use | *Describe* |
| 51. | The Contractor should, in K Appendix 2, describe if the offered solution has a system (or mechanism) to recognize if there is a single tablet packed, multiple tablets in each single unit, empty unit bags as well as identify if tablets has been injured during the packing process. This description should include the response of the offered solution and how the pharmacy staff is alerted if there is a deviation. | H | Quality - Technical solution - Patient safety | *Describe* |

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| 52. | The Contractor should, in K Appendix 2 describe if the offered solution got any functionality for automatic visual control of the finished production of a unit dose batch. (E.g., Picture-, video-recognition). | H | Quality - Technical solution - Patient safety | *Describe* |
| 53. | The Contractor should, in K Appendix 2 describe if the offered solution provides any automatic functionality for preparing unit dose batches for further distribution (E.g., automatic counting/rolling/cutting predefined numbers of unit doses). | H | Quality - Technical solution - Ease of use | *Describe* |
| **Functional requirements of the Offered Solution Application and suitability** | | | | |
| 54. | The Contractor should, in K Appendix 2, describe the offered solution's limitations regarding drugs on the market, e.g. size, coating or other factors that makes the drug not compatible with the offered solution. | H | Quality - Technical solution - General | *Describe* |
| 55. | The Contractor should, in K Appendix 2, describe if the offered solutions outer panels and surfaces are smooth and easy to clean. All surfaces should be compatible with cleaning agents used in D classified rooms, e.g. rectified ethanol 75 %.<br><br>The Contractor must describe the cleaning and maintenance process/procedure that needs to be carried out by the pharmacy staff (daily, weekly, yearly etc.) | H | Quality - Technical solution - General | *Describe* |
| 56. | The Contractor shall, in K Appendix 2, confirm that the GUI (graphical user interface) used by the operator, including field-labels, button-texts, menu-items and other texts is presented in Norwegian or English language. | O | | *Confirm* |

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| 57. | The Contractor shall in K Appendix 2, confirm that all labels regarding the Human Machine Interface (HMI), e.g., pushbuttons, switches etc. must be labelled in Norwegian or English language. | O | | *Confirm* |
| **Functional requirements of the Offered Solution<br>General functional requirement** | | | | |
| 58. | The Contractor should, in K Appendix 2 describe what information is stored in the production log, such as date and name of all process-related events and alarms. The description should also include how long this log is stored in the system, the audit-trail, and how logs can be exported and made available for the customer. | L | Quality - ICT - Functional | *Describe* |
| 59. | The Contractor shall, in K Appendix 2, confirm that the production log in the system shall not be possible to manipulate or delete (except after an agreed storage period). | O | | *Confirm* |
| 60. | The Contractor should, in K Appendix 2 describe if there are any limitations to batch sizes for the end product. | H | Quality - Technical solution - Ease of use | *Describe* |
| 61. | The Contractor should in K Appendix 2, describe how lot/batch number will be assigned and documented, if possible. This description should also include if the lot/batch number can be assigned by the pharmacy. | L | Quality - Technical solution - General | *Describe* |
| 62. | The Contractor should, in K Appendix 2 describe the possibilities for unit dose label design and configuration of layout, and barcode options. The description should also describe the possibilities for symbols and colours. The Contractor should enclose an illustrated example of a possible label design in K Appendix 2. | M | Quality - Technical solution - General | *Describe* |

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| 63. | The Contractor should, in K Appendix 2, describe if it is possible to create a barcode print to label, e.g. boxes used for further distribution of unit doses. | H | Quality - Technical solution - General | *Confirm* |
| 64. | The Contractor must provide a continuous back-up solution. The Contractor shall describe the offered solution's response in case of an emergency power shortage, including potential damage and data loss. | O | | *Confirm* |
| 65. | The Contractor should, in K Appendix 2 describe the possibilities for accessing or generating reports about i.e. the number of approved and rejected preparations, utilization rate, and time periods when the offered solution is running. The description should include how the Contracting Authority can access or generate these reports. | H | Quality - ICT - Functional | *Describe* |
| 66. | The Contractor should, in K Appendix 2, describe the packaging materials for the unit doses. If there are different types of materials and sizes available, this should be specified in the description. The Contracting Authority prefers if the unit dose is in a material that allows easy visual inspection of the content, but would also like to know if other types of packaging materials are recommended or available. | H | Quality - Technical solution- Patient safety | *Describe* |
| 67. | The Contractor should, in K Appendix 2, describe if the disposable materials are made of an environmentally friendly material, or if environmentally friendly material is available. | H | Quality - Environmental | |
| 68. | The Contractor shall, in K Appendix 2, confirm that the packaging materials for the unit doses is in accordance with the requirements of the Ph. Eur. 3.1 and 3.2. | O | | *Confirm* |

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| 69. | The Contracting Authority will evaluate the quality of the packaging material, quality of print and the ease of use for the end user of the product.<br><br>The Contractor should upon submission of the offer deliver minimum 10 product samples of each packaging material. The samples should contain a packed tablet/capsule (placebo) representable for a produced unit dose, with all required information printed, as described in requirement number 8. If there are different sizes of the packaging material available, a sample for each size should be delivered.<br><br>If applicable the Contracting Authority would like to see how different unit doses are linked together, e.g., strip, ribbon, ring etc. The product samples will not be returned to the Contractor.<br><br><br><u>Address of delivery:</u><br>Sykehusinnkjøp HF / Att: Deborah Suarez<br>Richard Johnsens gt. 2,<br>4021 Stavanger<br>Norway | H | Quality - Technical solution - Patient safety | *Describe* |
| 70. | The Contractor shall, in K appendix 2, confirm that the print on the unit dose bags is readable for a minimum of 12 months. | O | | *Confirm* |
| 71. | The Contractor shall, in K appendix 2, confirm that the unit dose packaging material is suitable for a shelf life of minimum 12 months after the packaging material is delivered to the Contracting Authority and stored correctly. | O | | *Confirm and describe* |

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| | If any stability studies have been performed, this should be described. | | | |
| 72. | The Contractor should, in K Appendix 2 describe the different options/solutions for separating a defined number of unit doses in a strip/ribbon/ring or similar. | H | Quality - Technical solution - Ease of use | *Describe* |
| **Functional requirements of the Offered Solution<br>Alarms, alerts, messages** | | | | |
| 73. | The Contractor shall, in K Appendix 2 confirm that messages and alarms will contain audio and/or be easily visible, for example by blinking or change of colour. | O | | *Confirm* |
| 74. | The Contractor shall, in K Appendix 2, confirm that notification / alarm / alerts / messages will appear in full text on the screen with a reference number for that individual alarm/alert. | O | | *Confirm* |
| 75. | The Contractor should, in K Appendix 2, describe the different alarms and messages on the solution, including a description of which alarms (and messages) that will interrupt/stop the process. The offered solution should display how to resolve the different issues causing the alarms. | H | Quality - ICT - Functional | *Describe* |
| 76. | The Contractor shall, in K Appendix 2, confirm that the software logs all errors in an alarm list, which clearly indicates the nature of the error, date and time, and action. | O | | *Confirm* |
| **Functional requirements of the Offered Solution<br>User access** | | | | |
| 77. | The Contractor should, in K Appendix 2, describe the possibilities for electronic signatures in the system. It is preferred that it is possible to co-sign selected process steps. | L | Quality - ICT - Functional | *Describe* |

| Functional requirements of the Offered Solution<br>Health and Work safety | | | | |
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| 78. | All equipment that is a part of the solution must be designed and have the necessary protective devices so that the operator and/or service personnel is protected against injuries.<br>The equipment must be in accordance with relevant standards, laws and regulations, including:<br>• FOR-2009-05-20-544 Forskrift om maskiner (Directive 2006/42/EC)<br>• Lov om arbeidsmiljø, arbeidstid og stillingsvern mv. (arbeidsmiljøloven) | O | | *Confirm* |
| 79. | The Contractor should, in K Appendix 2, describe the safety features of the offered solution when it comes to work safety for the operator (the safety features that prevent the operators from getting cuts or compression injuries etc.). E.g., that the production/operation stops when the doors (or similar) are opened during automated movement. | H | Quality - Technical solution - General | *Describe* |
| 80. | The Contractor shall, in K Appendix 2, confirm that the maximum noise exposure, and the noise level during operation, does not exceed 70 dB (A). The noise level should be measured 1 m height from the noisiest elements and measured from the operator's position at head height, in normal operative conditions. | O | | *Confirm* |
| 81. | The Contractor should, in K Appendix 2, describe the noise level generated by the offered solution. The measured noise level during operation and in idle state, and method of measuring should be part of this description. | H | Quality - Technical solution - General | *Describe* |

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| | If there are any noise absorbing materials included in the offered solution, these should be described. Low noise level is preferred. | | | |
| 82. | The Contractor should, in K Appendix 2, describe the average time to start up and finish a production. The description should include time used to e.g.: insert production data, loading drugs, loading packaging material, unloading unit doses, handling waste, necessary cleaning, etc.<br><br>The Contractor should use the following 3 examples:<br>1) 2000 unit doses of Drug A<br>2) 1000 unit doses of Drug A and 1000 unit doses of Drug B<br>3)1000 unit doses of Drug C prone to cross contamination due to dust and 1000 unit doses of Drug A<br><br>There should be only one tablet per packed unit dose. | H | Quality - Technical solution - Ease of use | *Describe* |
| 83. | The Contractor should, in K Appendix 2, describe the start-up / closing time (including daily maintenance and cleaning time) for the offered solution. | M | Quality - Technical solution - General | *Describe* |
| 84. | The Contractor should, in K Appendix 2, describe the cleaning and maintenance process/procedure that needs to be carried out by the pharmacy staff (daily, weekly, monthly, yearly etc.)<br>A cleaning plan should be provided. | H | Quality - Technical solution - General | *Describe* |
| **Technical Process requirement<br>Air quality and temperature** | | | | |

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| 85. | The Contractor should, in K Appendix 2, describe the offered solutions air treatment system and requirement for air supply that must be provided by the contracting authority. The description should also include an overview of filters included in the offered solution (if applicable). | H | Quality - Technical solution - General | *Describe* |
| 86. | The Contractor shall, in K Appendix 2, confirm that the offered solution will not generate particles or microbiological contamination in the production room, at a rate that exceeds the requirements for Class D (EU GMP) in and out of operation. | O | | *Confirm* |
| 87. | The drugs loaded into the offered solution should not be exposed to temperatures below 8 degrees Celsius or exceeding 25 degrees Celsius during the packaging process. The Contractor should, in K Appendix 2, describe what measures must be implemented to meet these requirements. | H | Quality - Technical solution - General | *Describe* |
| **General technical software requirements** | | | | |
| 88. | The Contractor shall, in K Appendix 2, confirm that the system offered includes the most recently updated software. Further, the Contractor shall confirm that following information will be provided upon software updates: current software version, history, date/reason for revisions, change log. | O | | *Confirm* |
| **Design / Installation Requirements – Mechanical** | | | | |
| 89. | The Contractor should, in K Appendix 2, give an overview of the technical specifications e.g., regarding dimensions and weight of the offered solution, the offered solution's need for power connections, electric supply, voltage stabilization equipment etc. If the offered solution has a pre- | I | | *Describe* |

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| | installation guide (or similar) this should be provided as part of the description (or as an attachment). | | | |
| 90. | The Contractor shall, in K Appendix 2, confirm that the CE marking and declaration of conformity demonstrate that the offered solution has been designed, constructed and conformity assessed in accordance with applicable legislation in the EU. | O | | *Confirm* |
| 91. | The Contractor should provide an example (illustration) of installation (layout) for the offered solution. The Contractor should also describe what is required to create an optimal workflow. | H | Quality - Technical solution - General | *Describe* |
| 92. | The Contractor should, in K Appendix 2, describe dimensions of the largest modules that need to be transported in to the production area (height width, length and weight). | H | Quality - Installation, test and validation | *Describe* |
| **Requirements for the IT-Architecture** | | | | |
| 93. | The Contractor should, in K Appendix 2, describe how data may be exported from the offered solution's database to an external IT solution(s). | H | Quality - ICT - Functional | *Describe* |
| 94. | The Contractor should, in K Appendix 2, describe the possible standard(s) for information exchange (e.g., HL7 FHIR). This description should include which versions are supported and list available services/messages. | H | Quality - ICT - General | *Describe* |
| 95. | The Contractor should, in K Appendix 2, describe if the offered solution uses APIs in a secure manner for integration and information exchange. Elaborate which security mechanisms the offered solution can support using APIs. Any exchange of information should be established using | H | Quality - ICT - General | *Describe* |

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| | international standards. Note: Examples of such standards are HL7 and DICOM. | | | |
| **Technical Infrastructure** | | | | |
| 96. | The Contractor shall, in K Appendix 2, confirm that application- and database software will be able to manage special characters like ®, © etc. | O | | *Confirm* |
| 97. | The Contractor shall, in K Appendix 2, confirm that the software application and database is able to manage Norwegian date and time (dd.mm.yyyy and 24 hour-clock) | O | | *Confirm* |
| 98. | The Contractor should, in K Appendix 2, describe solutions for single sign-on. | H | Quality - ICT - Functional | *Describe* |
| 99. | The Contractor shall, in K Appendix 2, confirm that they have considered and answered all requirements in K Appendix 1a - ICT requirements. | O | | *Confirm* |