**ANEX II OF TENDER DOCUMENTATION**

**TECHNICAL SPECIFICATIONS**

PROCUREMENT TITLE: CAPSULE FILLING MACHINE, TENDER REFERENCE NUMBER: 17

NOTE: The Tenderer offers the subject of procurement according to this table of Technical Specifications.

The requirements defined in the Technical Specifications represent the minimum technical specifications that the offered good must meet, unless otherwise stated, and they must not be altered by the Tenderer.

The offered item is only valid and acceptable if it meets all the required conditions and characteristics. Deleting or correcting items listed in column 2. Required technical specifications is not acceptable. Tenderer shall complete column 3. Offered technical specifications, defining in detail technical specifications of offered machine (note: tenderer fills the exact specifications of offered machine, while avoiding filling the columns only with words “compliant” and “equivalent„ or “yes”). Tenders which are not filled with the exact technical specifications of the offered machine may be rejected. For all the items listed in the technical specifications in which brand, patent, type, norms, standards, or specific origin is indicated, the tenderer may offer "equivalent" to everything requested or indicated.

Column 4. Notes, remarks, references to documentation may be filled by the tenderer if the tenderer considers it necessary.

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| **1. Item number** | **2. Required technical specifications** | **3. Offered technical specifications** | 4. **Notes, references to documentation**  |
| 1. | **Automatic capsule filling and closing machine** |  |  |
| Quantity: 1 piece |  |  |
| Producer/brand: |  |  |
| Model/type: |  |  |
| 1.1. | Regulatory category: Good manufacturing practice (GMP) or equally valid norm for production of medicinal products and European regulations for manufacturing of food supplements |  |  |
| 1.2. | Filling of hard capsules (gelatin and HPMC) |  |  |
| 1.3. | Filling of capsule sizes: 00 and 0 |  |  |
| 1.4. | Filling of powder |  |  |
| 1.5. | Ability for filling of powder, granulates, pellets, micro tablets, tablets, liquids products and combinations of products into capsule |  |  |
| 1.6. | Dosator method of dosing |  |  |
| 1.7. | One sets for each capsule size change parts to handle capsule size 0 and 00 |  |  |
| 1.8. | Output: 45.000 – 55.000 capsules/hour |  |  |
| 1.9. | Ability to adjust machine speed |  |  |
| 1.10. | Accurate dosing with weight accuracy +/- 3 % from the nominal weight or less  |  |  |
| 1.11. | Machine structure/frame made of stainless steel AISI 304, AISI 316, or some other material approved by Food and Drug Administration (FDA) or equally valid standard for material that is suitable for working inside ISO 8 classified area for working with food/pharmaceutical product, polished |  |  |
| 1.12. | Material in direct contact with capsules and product made of stainless steel AISI 304, AISI 316 or some other material approved by FDA or equally valid standard for contact material that is suitable for contact with food/pharmaceutical product, mirror polished |  |  |
| 1.13. | Dosators for product dosing made of stainless steel AISI 316 or some other material approved by FDA or equally valid standard for contact material that is suitable for contact with food/pharmaceutical product, mirror polished |  |  |
| 1.14. | Anti-dust, anti-noise hood fitted with safety micro-switches on the doors made of methacrylate or equally valid standard material |  |  |
| 1.15. | Modular and flexible layout of machine |  |  |
| 1.16. | The machine should be fully operable by only one person |  |  |
| 1.17. | Accessibility for operation and maintenance personnel should be provided for all parts of the machine |  |  |
| 1.18. | Adjustment points should be identified, and instruction provided on the adjustment |  |  |
| 1.19. | Identified lubrication points with the type and quantity of lubricant |  |  |
| 1.20. | Evidence of compliance of the material that is in direct contact with EN 10204/2004 certification type 2.1 or equally valid |  |  |
| 1.21. | The dimensions of the whole machine must be determined in such a way that it fits in a room dimensions length x width x height (m) 4.05m x 3.57m x 2.80m |  |  |
| 1.22. | Weight of the machine < 1420 kg |  |  |
| 1.23. | Fast change set parts for different capsule size within 45 min |  |  |
| 1.24. | Changeover between capsule size should not require additional specialized tools |  |  |
| 1.25. | All contact parts should be easily dismantled and cleanable with ethanol, isopropanol, water and alkaline and acidic detergents pH 3-12 and a temperature up to 80°C; any exception must be clearly indicated |  |  |
| 1.26. | All product non-contact materials must be suitable for cleaning with ethanol, isopropanol and water; any exception must be clearly indicated |  |  |
| 1.27. | Automatic vacuum or pneumatic product feeder fitted for IBC bins volume: 400 l - 600 l |  |  |
| 1.28. | Ultrasonic level sensor in powder hopper for fill level of the product in hopper; machine stop is required when reached minimum level sensor |  |  |
| 1.29. | Vacuum pump for capsule opening/separation, operating range: 80 - 110 m³/h; -250 mbar; vacuum monitoring, with automatic machine stop if dropping below limit |  |  |
| 1.30. | Local aspiration system or vacuum cleaner with suction hoses and connections, suction capacity: 190 – 270 m3/h; -250 mbar; bin capacity (vacuum cleaner) >70 l |  |  |
| 1.31. | Capsule deduster made of stainless steel AISI 304, AISI 316 or some other material approved by FDA or equally valid standard for contact material that is suitable for contact with food/pharmaceutical product; rotating brushes with nylon bristles; easily dismantled and cleaned |  |  |
| 1.32. | One spare brush for capsule deduster included |  |  |
| 1.33. | Metal detector with automatic rejection system capable to detect ferrous, non-ferrous materials and non-magnetic stainless steels |  |  |
| 1.34. | Capsule transfer system from automatic capsule filling machine to Combined unit of capsule deduster and metal detector |  |  |
| 1.35. | Standard power: 230/400 V (±10%) 50/60 Hz |  |  |
| 1.36. | In case of a power failure, the machine should go into a safe modeNo damage should occur to the machine as a result of going to the safe modeOn power restoration, the system should not restart without operator’s input and resetting the system |  |  |
| 1.37. | Working conditions: <24°C; 15 - 60% relative humidity |  |  |
| 1.38. | Noise level should be below 75 dB at 1 m distance, fully operational machine, including a vacuum system |  |  |
| 1.39. | Automatic rejection system capable to reject defects such as not opened capsules, incomplete capsules, damaged capsules, etc. |  |  |
| 1.40. | If the same type of the fault occurs consecutively the machine must be stopped, and an alarm must be activated; the number of consecutive faults for activation of an alarm must be settable within the control panel |  |  |
| 1.41. | A touch screen operator-interface panel shall be provided and mounted on the machine; the interfaces should ensure easy, safe, and reliable operation in Croatian language and language understood for the manufacturer – for service technician |  |  |
| 1.42. | The panel shall provide the necessary screen, switches, indicators, and devices needed to operate the machine |  |  |
| 1.43. | It should be possible to monitor machine status information as well as all other process data on the control panel, e.g. machine speed, alarms, process and batch statistics, working hours, indication about good or bad capsules and any other available process and machine data |  |  |
| 1.44. | Ability to connect to other systems due to data exchange, export of data in easy-to-read format |  |  |
| 1.45. | Automatic backup and restore of data in human readable form |  |  |
| 1.46. | The machine should be equipped with a visual alarm system covering all critical process parameters |  |  |
| 1.47. | Software and software development meet 21 CFR Part 11 or equally valid norm for data and access control  |  |  |
| 1.48. | Operators should be protected from the moving parts of the machine which could cause injury during machine in production mode |  |  |
| 1.49. | Emergency stop buttons should be supplied within the easy reach of the operator at normal operator stations |  |  |
| 1.50. | When activated, the emergency stop buttons should shut the system down immediately and all motion on the machine should stop in a safe manner |  |  |
| 1.51. | Supplier will provide protocol for qualification of installation and qualification of operation (IQ/OQ protocol) in Croatian language  |  |  |
| 1.52. | Qualification/validation documentation of the automatic capsule filling machine in Croatian language |  |  |
| 1.53. | All equipment must bear a European CE mark and have European CE declaration of conformity |  |  |
| 1.54. | All marks and labels on the machine should be in Croatian language  |  |  |
| 1.55. | All format parts should be clearly marked at least with the capsule size |  |  |
| 1.56. | Machine testing with the manufacturer (Factory acceptance test – FAT) |  |  |
| 1.57. | Full installation support should be provided |  |  |
| 1.58. | All components should be calibrated during the installation of machine at customer’s site or before |  |  |
| 1.59. | Testing of the assembled machine within the customer (Site acceptance test - SAT) |  |  |
| 1.60. | Documentation to be send in English and Croatian:* Functional specification
* Piping and Instrumentation Diagrams (as built)
* Mechanical Drawings (as built)
* Electrical Drawings (as built)
* Pneumatic Drawings (as built)
* List of alarms
* Programmable Logic Controller (PLC) system configuration
* Programmable Logic Controller (PLC) functional diagram and specification
* I/O list
* Process views on the screen
* HMI configuration in Croatian and English language
* Licenses for all installed software components
* Maintenance Manual (Preventive, Predictive, Corrective) in Croatian and English language
* Operation Manual in Croatian and English language
* Troubleshooting Manual in Croatian and English language
* Machine product contact parts Certificate in accordance with EN 10204/2004 certificate type 2.1 or equally valid
* Safety Certificates and Instructions
* List of recommended spare parts and consumable items for two years should be provided with an estimated frequency of replacement
* Part List With Code Number
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| 1.61. | Training of operators covering machine set up; machine handling and running; machine parameters set up and monitoring; format change over; maintenance and preparation for cleaning; troubleshooting. Training should include practical workshops directly on supplied machine  |  |  |
| 1.62. | Professional support and service available from the supplier within 24 hours of request |  |  |
| 1.63. | Availability of spare parts min. 10 years |  |  |
| 1.64. | Warranty for quality of sold item is minimum 24 months starting from the date of the acceptance of delivered goods and services. |  |  |
| 1.65. | Packaging of the machine – preparing for transport  |  |  |
| 1.66. | Delivery of the machine to a defined delivery point on the address of Client in accordance with point 2.4. of the tender documentation (DAP – Delivered at place) |  |  |

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 (Place and date) ON BEHALF OF THE TENDERER:

 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(name, surname and signature of the person representing tenderer)*