**ANEX II OF TENDER DOCUMENTATION**

**TECHNICAL SPECIFICATIONS**

PROCUREMENT TITLE: BLISTER MACHINE, TENDER REFERENCE NUMBER: 13

NOTE: The Tenderer offers the subject of procurement according in 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”). 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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| **Item number** | **2. Required technical specifications** | **3. Offered technical specifications** | 4. **Notes, references to documentation** |
| 1. | **Blister packaging machine for capsules and tablets** |  |  |
| Quantity: 1 piece |  |  |
| Producer/brand: |  |  |
| Model/type: |  |  |
| 1.1. | Regulatory category: GMP, FDA or equally valid norm for production of medicinal products and European regulations for manufacturing of food supplements |  |  |
| 1.2. | Material in direct contact with the product: stainless steel AISI 304, AISI 316 or some other material approved by FDA or equally valid standard for material that is suitable for contact with food/pharmaceutical product |  |  |
| 1.3. | Evidence of compliance of the material that is in direct contact with food with EU REG 1935/2004 (Food compliance statement) |  |  |
| 1.4. | 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) 5.83m x 4.47m x 2.80m |  |  |
| 1.5. | Standard power: 400 V 50 Hz 3-phase + neutral + ground |  |  |
| 1.6. | Working conditions: <30°C, 30-60% relative humidity |  |  |
| 1.7. | Noise level: below 80 dB within 1 m distance |  |  |
| 1.8. | Maximum forming depth: 12 mm |  |  |
| 1.9. | Capacity: 100-220 blisters per minute |  |  |
| 1.10. | Ability to adjust machine speed |  |  |
| 1.11. | Forming of the blister: thermoforming |  |  |
| 1.12. | Blister lid material: aluminum |  |  |
| 1.13. | Blister forming material: PVC |  |  |
| 1.14. | Blister formats:   1. 60-65mm x 130-135mm, 20 capsules, capsule size 0 2. 60-65mm x 70-75mm, 10 capsules, capsule size 0 3. 70-75 mm x 100-105mm, 15 capsules at the angle of 45°, capsule size 00 |  |  |
| 1.15. | Additional set of tools for feeder for each blister format so manufacturing wouldn’t stop while washing the parts of the machine that are in direct contact with product |  |  | |
| 1.16. | Changeover between blister formats should not require additional specialized tools |  |  | |
| 1.17. | Automatic feeder with the capacity of 30 - 40L with integrated dust collecting system |  |  | |
| 1.18. | Removal of products that are on the blister net after the feeder |  |  | |
| 1.19. | Two (2) carriers of the forming reel (max. external diameter 400 mm) |  |  | |
| 1.20. | One (1) carrier of the lidding reel |  |  | |
| 1.21. | Flat sealing station for sealing of blister lid and forming foil |  |  | |
| 1.22. | Pre-heating time, temperature, pressure in both forming and sealing unit managed from display |  |  | |
| 1.23. | External dedicated cooling unit for temperature control |  |  | |
| 1.24. | Splice detection for forming and lidding foils |  |  | |
| 1.25. | Minimum product load control, forming material, lidding material, with machine stop in phase. Filling level control in feeding hopper. |  |  | |
| 1.26. | Near-end alarm for both forming film and lidding foil |  |  | |
| 1.27. | Centering blister control inside the cutting tool. |  |  | |
| 1.28. | Color camera that detects capsule and tablet defects and checks that blisters are filled out, and installation |  |  | |
| 1.29. | Unit for rejection of defected blisters |  |  | |
| 1.30. | Control Unit for the control of defective blister rejection with stopping the machine |  |  | |
| 1.31. | Programmable function to stop the machine after a number of consecutive (serial) errors |  |  | |
| 1.32. | Unit for embossing of the letters A-Z and numbers 0-9 on the blister |  |  | |
| 1.33. | Inkjet printer for labeling of blister with installation |  |  | |
| 1.34. | A tower visible from a distance with an audiovisual representation of the machine operation phase |  |  | |
| 1.35. | Stopping the machine in an emergency mode |  |  | |
| 1.36. | Overload control of motorized machine parts |  |  | |
| 1.37. | Operating with the machine through a touch screen monitor (Croatian language and language understood for the manufacturer – for service technician). |  |  | |
| 1.38. | Machine operation data: working hours, indication of good blisters, bad blisters, etc. |  |  | |
| 1.39. | Ability to connect to other systems due to data exchange, export of data in easy-to-read format |  |  | |
| 1.40. | Automatic backup and restore of formats |  |  | |
| 1.41. | The machine interface must display the existing process parameters and equipment status |  |  | |
| 1.42. | Software and software development meet 21CFRPart 11 and Gamp 5 or equally valid norm for data and access control |  |  | |
| 1.43. | IQ & OQ documentation will be provided by the supplier – protocol for qualification of installation and qualification of operation in Croatian language |  |  | |
| 1.44. | Validation / documentation of the blister machine in Croatian language |  |  | |
| 1.45. | All equipment must bear an European CE mark and have European CE declaration of conformity |  |  | |
| 1.46. | Machine testing with the manufacturer (Factory acceptance test – FAT) |  |  | |
| 1.47. | Testing of the assembled machine within the customer (Site acceptance test - SAT) |  |  | |
| 1.48. | Packaging of the machine – preparing for transport |  |  | |
| 1.49. | 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) |  |  | |
| 1.50. | Twelve (12) hours of education for at least ten (10) people |  |  | |
| 1.51. | Professional support and service available from the supplier within 24 hours of request |  |  | |

\_\_\_\_\_\_\_\_\_\_\_\_\_, \_\_/\_\_/20\_\_

(Place and date) ON BEHALF OF THE TENDERER:

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*(name, surname and signature of the person authorized*

*to represent tenderer)*