

Attachment No. 1 to the request for quotation No. 5/A1.4.1/KPO/2023 of December 15, 2023

USER REQUIREMENT SPECIFICATION

The subject of the Request for Quotation is the purchase and delivery **ASEPTIC FILLING DEVICE** with parameters not worse than those described below and in accordance with the requirements specified below.

1. Introduction

The subject of this offer is necessary for the expansion of the production capabilities of the ordering party, which is a producer of plant extracts for the food, pharmaceutical and feed industries. The filling device will enable to increase the production capacity, in particular with products based on liquid plant extracts that do not contain preservatives (mainly fruit).

The aseptic filling device should enable safe, controlled pouring into both "bag-in-box" with a capacity of 5-20 liters and into drums - capacity of 200 liters.

2. Execution standard of the Order

The appliance must be made to a food standard. All components in contact with the product should be made of steel 1.4404, Ra < 0.8. Components, structures and control cabinet made of 1.4301 or 1.4307 steel. All gaskets are approved for contact with food.

Any connection between product contact elements or hygienic test and measurement equipment connections, perforated DIN 32676 or DIN connectors. 11851/11864. The Contracting Authority allows other hygienic connections if this is dictated by safety issues (e.g. high pressures).

The entire device will work in the production hall (temperature controlled). The utilities necessary for the operation of the device are available in the room (electricity, compressed air, cooling water, chilled water (propylene glycol), steam).

2.1. Compliance with food requirements – cGMP (Current Good Manufacturing Practice)

All elements of the Device, including storage tanks, are cleaned in the "clean in place" (CIP) system.

Additionally, the fundamentals of equipment design will ensure that:

- a. There will be no dead zones or, when technically impossible, they will be minimized to the lowest possible limits and drainable;
- b. All pipes are completely drained, with appropriate slopes;
- c. All surfaces in contact with the process are free of cracks, distortions, scratches, sharp edges, holes, including welds, and must be thoroughly polished;
- d. Demountable assemblies should be made in accordance with DIN11850/DIN11864-1/2/3 for food industry fittings, with appropriate gaskets. Pipes and fittings are to be perfectly matched, with the same diameters to avoid dead zones;
- e. Demountable assemblies inside the process area should have neither bolts nor nuts if possible;
- f. Exterior parts, including covers, to prevent dust accumulation and facilitate cleaning, with appropriate inclinations, shapes;

- g. Lubrication of mechanical parts should be avoided, but should be FDA grade or equivalent if necessary, even if they are not in direct contact with the process;

2.2. Construction Materials

Stainless steel grades according to EN 10088-3

All parts in contact with the product:	1.4404 - AISI 316L
Other parts:	1.4301 or 1.4307 - AISI 304/304L
Bolts and nuts:	1.4301 or 1.4307 - AISI 304/304L
Support frame/components:	1.4301 or 1.4307 - AISI 304/304L

Gaskets adapted to contact with food, e.g. EPDM, FPM, etc.

Lubricants (oil, grease): supplied FDA 21 CFR certified, approved for use in the food industry (H1 preferred).

2.3. Surface Finish

According to EN ISO 4288 - Geometrical specification of products - Rules and protocols for the evaluation of surface finish

Vessel interior: welds ground smooth + mechanical polishing $Ra \leq 0.8 \mu\text{m}$

Vessel exterior: smooth ground welds + mechanical polishing $Ra \leq 1.6 \mu\text{m}$

2.4. Safety Considerations

The following directives listed below should be considered as a minimum level of compliance with safety regulations and do not exclude any supplier obligations with respect to the standards and technical specifications applicable to the proposed equipment.

The main directives and standards comply with:

- Machinery Directive 2006/42/CE
- EN 294 : Safety of machinery; safe distances to prevent the upper limbs from entering the str
- EN 349 : Safety of machinery. Minimal gaps to avoid crushing human body parts
- Noise emission: maximum noise emission of 80 dB(A), measured at a distance of 1 m from the surface of the device and 1.6 m above the floor. The supplier should also refer to EN ISO 11690-1 and EN ISO 11690-2 to reduce noise emissions.



3. Detailed description of the subject

The Filling installation must include elements that ensure safe operation and control over the production process. The Filling device should operate in semi-automatic mode. The operator delivers a sterile bag into the filling head. The filling device is then responsible for sterilizing the cap, opening, filling and resealing the bag. The automatic opening, filling and closing cycle of an aseptic bag cap begins when the bag neck is manually or automatically inserted into the filling head. The aseptic chamber is always maintained at positive pressure by steam. The temperature probe monitors the temperature, ensuring that the appropriate amount of steam is always present in the chamber during the production and SIP procedure. During the filling cycle, the temperatures of the steam jets and the filling head are carefully monitored and controlled.

The device should be able to be sterilized with both steam and disinfectant. The filling is controlled by a mass flowmeter. Before starting, the device should carry out the sterilization procedure itself. The temperature must be controlled throughout this process. If the temperature drops, the device will send an appropriate message and the preparation procedure is repeated.

The device should be supplied with the necessary accessories enabling ergonomic packaging in barrels (e.g. roller feeder) and bag-in-box packaging (table). The efficiency of the device should be at least 30 bags/h in the case of bag-in-box packaging (5-20 liters) and min. 10 bags/h for barrels (200 liters).

The filling device should be equipped with an aseptic buffer tank with a capacity of min. 700 liters, and optimally 1000 liters. Possibility of inerting with nitrogen. The tank must be equipped with air filters to ensure sterility.

The device must be washable in the CIP system. Preferred separate circulation for the filling part and the buffer tank - possibility of washing the filling system while the product is already in tank.

The necessary media will be supplied to the device: steam (3 barg), condensate collection, electricity, compressed air. The steam is of technical quality and has chemical additives, so it is the Supplier's responsibility to prepare the available steam in such a way that it is suitable for aseptic packaging of food products (steam filtration).

All basic processes such as work, washing and sterilization take place automatically. The operator is only responsible for attaching the bag and initiating the filling process. Start and stop functions, set values, parameters and machine settings can be edited by the user. The device should communicate with the existing SCADA system via MODBUS TCP/IP.

4. Final documentation

To be issued together with the equipment, user instructions for use and maintenance in English or Polish, with the exception of certificates issued for purchased items and materials, in their original language.

The documentation must be provided in two printouts and one complete electronic version. Documentation should include:

- a) Electrical and pneumatic diagrams;
- b) Declaration of conformity;
- c) Complete technical documentation regarding accessories (mechanical seal, electric motor, valves, etc.), clearly indicating the model/series of the material installed on the device;

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- d) User instructions for use and maintenance;
- e) Material certificates.

5. Packing, transportation

Cost of packaging and transport in Suppliers responsibility. - FRANCO Lomża (Poland).

6. Installation, commissioning and training

Unloading and introduction of the device to the production area, mechanical assembly respectively to Suppliers instruction will be performed by Ordering party.

After the installation of the Aseptic Filler, the Supplier will perform commissioning and training.

7. Warranty

Not less than 12 months

At the stage of selecting a supplier, the Ordering Party reserves the right to conduct a reference visit in order to verify a technology similar to the one offered operating in industrial conditions.

Rafał Pietruszyński
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Prezes Zarządu

GREENVIT SP. Z O.O.
ul. Aleja Wojska Polskiego 27a
18-300 Zambrów
KRS 0000362038, REGON 200379382
NIP 7231619950