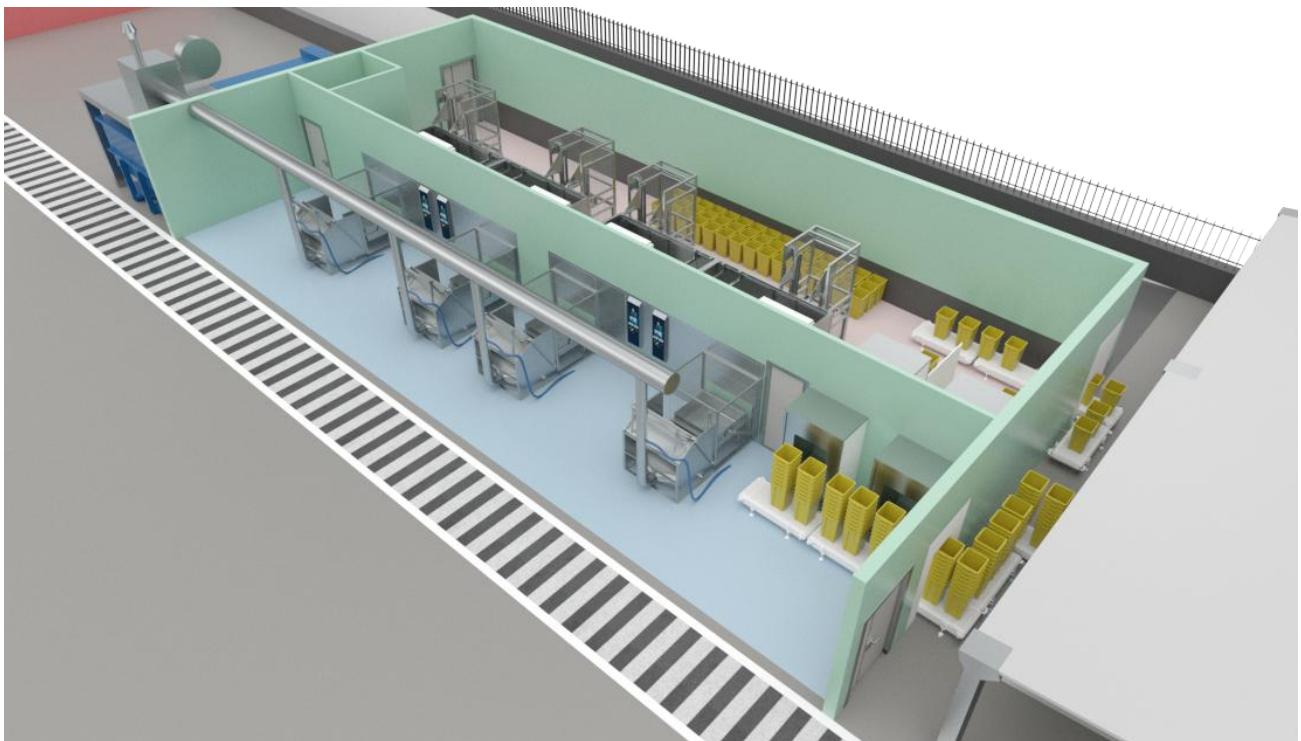


Hamburg, 2022.02.21

TO: **SC IMUNOTEHNOMED SRL,**
42 Gh. Asachi str.,
MD-2028, Chisinau,
Republic of Moldova

Commercial offer for waste treatment equipment; number 04-2026 on January 14, 2026.

**DESCRIPTION COMPOSITION WASTE TREATMENT LINE WITH SATURATED STEAM SHREDDING AND
STERILISATION**



The potentially infected hospital solid waste treatment plant must guarantee repeatable saturated steam shredding and sterilization processes over time in conditions of "total safety" both for the microbiological result, for the material treated, for the operators, as well as for the environment by applying the concept of redundancy and the use of devices and components certified for safety through a parametric control in safety, keeping the material at the correct pressure, at the correct temperature and at the correct saturation of the steam for a defined time.

Objectives

A significant part of the 'Waste Management' project relates to the sterilization and grinding process of infected medical waste as it determines its level of hazardousness, making it similar to urban waste and consequently allowing the same method of disposal.

Bearing in mind the type of waste to be treated, it is essential to comply with safety requirements such that the effectiveness of the sterilization process does not generate risks for the safety of operators and the environment. Hence the objectives we set ourselves for the realization of the project:

1. Centralize the process in a single area with routes, equipment and controls and a healthy environment.
2. Completely separate dirty and clean routes.
3. Sterilization using known and validated techniques.
4. Pass-through sterilizers for dirty-side loading and clean-side unloading.
5. Sterilization with redundant microbial load reduction level.
6. Grinding, sterilization and waste drying process in fully sealed environment.
7. Manual or automatic sterilizer loading and unloading.

The production line is based on the T25 model and consists of:

Steam sterilizer with integrated shredder 270 liters capacity with integrated: steam generator of adequate power suitable for the system's consumption and vacuum system consisting of dry-running mechanical vacuum pump.

The plant meet the following essential minimum requirements:

1. Production capacity of 25 - 35 kg / h
2. Ratio between weight and volume equal to 1:10 (1Kg = 10 liters)
3. Reduction in the volume of waste after shredding of approximately 80%
4. Reduction of the weight of waste at the end of the cycle approximately 15%
5. The combined mechanical shredding and sterilization treatment with saturated steam
6. Elimination of air in the preliminary vacuum phase
7. Penetration of saturated vapor into the
8. Effectiveness of the sterilization process
9. NO risk of biological pollution or transmission of infections.
10. NO risks of environmental pollution.
11. Hermetically sealed environment

12. Elimination of bad smells.
13. Shredding into small pieces, no longer identifiable or recyclable
14. Repeatability of the cycle over time
15. Through design (the loading side must be separated from the unloading side)
16. The complete cycle must take place in an airtight environment with no emissions into the environment

Phases of the cycle:

1. manual or automatic waste loading
2. pre-chamber filling
3. dirty side door closure
4. start of the cycle
5. waste shredding
6. vacuum
7. heating
8. sterilization
9. drying
10. clean side door opening
11. manual or automatic waste discharge.

Steam sterilizer and shredding waste biohazard



Steam sterilizer and shredding waste biohazard Model: Truster T25

TECHNICAL DESCRIPTION OF THE SYSTEM OF WASTE TREATMENT WITH SHREDDING AND STEAM STERILIZATION

Main technical characteristics of the plant

The system must be designed with a bearing structure in welded and painted carbon steel, front access doors built entirely in AISI 304 stainless steel with a "scotch brite" surface finish

Internal dimension pre-storage chamber dimensions 600x750x600 mm (W x H x D),

External dimensions of 1840X1960X1230 (W x H x D) and dimensions external dimensions with scale 2940X2780X1230 mm (Wx H x D).

Chamber

Chamber quadrangular section sterilization chamber

Approval of dimensional calculations for relative design pressure from -1 to +3.5 BAR.

Design temperature 148 ° C.

8mm thick AISI 316L stainless steel chamber.

Jaket in AISI 316L stainless steel. "Total" coverage of the chamber from the cavity to improve the elimination of air from the chamber and cold spots.

Continuous internal surfaces of the chamber, rounded corners and without protruding parts for easy cleaning and guarantee hygiene.

Steam injection into the chamber on two or more sides to improve heating

Electrolytic or mechanical polishing for the chamber and the "Mirror" type front, final roughness degree at 0.5 µm.

Doors

The doors must be made of AISI 304 stainless steel or higher quality starting from thick sheet metal in a single homogeneous piece without welding.

Approval of dimensional calculations for relative design pressure from -1 to +3.5 BAR.

Design temperature 148 ° C.

Internal polishing for "Mirror" type doors, final roughness less than 0.5 µm

Door closing device

Fully automatic door closing device by means of an electro-pneumatic or electromechanical device operated directly by the control system through the touch-screen control monitor of the equipment. Sealing device between chamber and door

Sealing device between the chamber and the doors by means of a gasket made of silicone pressed with compressed air as a means of force for the seal for dynamic movement and ensure the seal.

Thermal insulation Thermal insulation for the room, the doors and the generator are insulated using a high thickness Fonitek foam mattress resistant to a temperature of 250 ° C, fire behavior class B1 tested according to the test method of the DIN4102 standard and with a conductivity coefficient equal to 0.30 Watt according to the test method of DIN 52612.

Hydraulic plant

The hydraulic system must be made entirely of AISI 316 stainless steel and built with components from world-leading companies. Tri-clamp connections must be installed between the different groups or sub-groups to facilitate disassembly, maintenance and improve sealing. The hot pipes must be insulated to allow safe interventions. They must be rigid except for some components that can cause vibrations such as the vacuum pump and the water filling pump in the generator for which a connection with flexible pipes must be provided. The condensate drain for the chamber must be of the float type while that of the interspace is of the thermostatic type. The sterile air filter assembly must be operated by a pneumatic valve to restore the atmospheric pressure in the chamber through a bacteriological filter protected by a non-return valve.

Vacuum group

The vacuum group is made up of a pair of vacuum pumps of the "dry" mechanical type, that is, it does not use fluids to produce the vacuum; this means that there is no water consumption and no oil or other fluids that are involved in creating the vacuum should be periodically replaced. The large capacity to produce vacuum due to the hourly flow rate effectively contributes to the reduction of the sterilization cycle time compared to the traditional method and through the control of the motor revolutions to create specific vacuum curves if necessary.

Incinerator

The air in the preliminary vacuum phase must not be discharged outside unless sterilized through an incinerator. The incinerator must automatically activate in the critical phases and the effectiveness of the removal of the microbial load must be demonstrated.

Shredder

The shredding must take place inside the sterilization chamber and must be able to reduce the waste into small pieces that make the original component no longer identifiable and no longer reusable. Shredders of various shapes and technical construction solutions are allowed as long as they remain included in the sterilization chamber and are sterilized at each cycle. They must be built with materials suitable for their function in operating conditions with saturated steam and temperature and guarantee a life of the cutting edges (blades) of at least one year. The shredder must be controlled by a gearmotor with adequate power and number of revolutions. If necessary, one or more pushers must compress the waste against the blades to ensure constant cutting.

Electrical system

The electrical system of the system must comply with the following European standards in force: EN EN 61010-1 (93) -A2 (95), IEC 204.1, EN 61010-2-041 (96), EN 60204-1 Equipment classification: class I type B. All the electrical components of leading brands worldwide are mounted connected to a terminal block and enclosed in a cabinet with IP55 protection, with the exception of the command and control components, which are provided on the facade.

Electrical cabinet

The electrical panel must have an IP55 degree of protection and must be installed laterally inside the equipment to allow easy maintenance.

Pneumatic system

The pneumatic system must be made entirely of stainless material, compatible and resistant to operating pressure. The pipes must be made of Teflon, the fittings with quick-fixing ogive, the pneumatic valves and pilot valves group of world-leading companies perfectly compatible with steam and pressure reduction units complete with air filtration Management device. The plant must be completely managed by industrial programmable electronic controllers produced by leading companies worldwide. The hardware configuration of the microprocessor must consist of CPU, analogue boards, signal input boards, signal output boards and serial boards and color touch-screen monitor as operator interface. This allows the management of sterilization cycles, parameter control, process safety, scheduled maintenance, sensor calibration, and recording through separate hardware and software.

Functionality

The monitors must show several pages in which, from time to time, appear:

Main menu Cycles library (allows the recording of all standard and user cycles carried out)

Cycle parameters

Load data

General conditions of the plant for the start of the cycle

Diagram of process

Process control

Scheduled maintenance

Maintenance instructions

Alarms

The system is capable of performing self-diagnosis and autoclave control for the following audible and visual alarms:

Door open alarm
Temperature probe failure alarm
Pressure probe failure alarm Maximum pressure alarm
Generator water shortage alarm
Water shortage alarm in the network
Cycle interrupted alarm Minimum/maximum temperature alarm during sterilisation Power failure alarm
Thermal relay alarm
Chamber vacuum seal alarm Maximum phase time alarm
Air in chamber alarm

Operators

For the management of the equipment, a minimum of twenty operators must be provided, for each of which an identification code has been entered. The following functions have been defined which can be associated with operators in order to meet the needs of the department:

- Start standard cycles
- Start Bowie & Dick / blank test
- Start user cycles
- Edit user cycles
- Edit standard cycles
- Change date and time
- Change the type of heating
- Change maintenance and forcing outputs
- Change general parameters
- Change print parameters
- Reset alarms
- Manual cycle advancement
- Calibration

Automatic start

The system must be equipped with an automatic start-up system, programmable according to need, which allows you to set the date and time of switching on and off and the unattended start of the cycles. With this function it is possible to automatically start the initial heating cycle, the vacuum seal test and the integrated automatic Bowie & Dick test in order to make the system ready for operation. external.

Stand-by function

To reduce energy consumption, the system must be set up for enabling the stand-by function. With this function active, heating is disabled after a period of inactivity at the end of a cycle.

Safety systems and alarms of the programmable electronic controller

Different levels of alarms and signals must be evaluated, which can be distinguished as follows:

- reports that occur during the course of the cycle, before or after it, but which do not modify the course of the same
- alarm signals of minor anomalies, with visual and acoustic signal, which draw the attention of the operator but without intervening in the course of the cycle in progress
- alarm signals with visual and acoustic signal that intervene for serious anomalies and that modify the behavior of the cycle, even arriving at the block of the same.

All warning signs must be displayed and printed.

Conditions of accidental power failure

Given that the accidental lack of voltage does not cancel the programs, the aforementioned lack of voltage must condition the electronic controller system according to the different phases of the cycle and precisely: Pre-vacuum or material pre-heating phase: the voltage drop must determine the recovery of the cycle from the beginning Sterilization phase: if there is a power failure during this phase and the temperature drops below the minimum value set, an alarm procedure must be started, causing the cycle to be reset from the beginning; if the temperature remains above the minimum set value, with the return of voltage the cycle must restart continuing its programmed development Post-sterilization phase: the cycle, after the power failure, must restart, continuing its programmed development.

Management system

The sterilizer-shredder is managed by the ET200SP controller with independent program blocks (the first for the process and the second for recording), both operating simultaneously so that their correct functioning can be confirmed. The process control and recording system receives analogue signals for temperature from a thermos-resistance for the chamber, pressure from a piezoelectric transducer for the chamber, and pressure for the cavity. The values are compared in real time to ensure that the cycle is running correctly. The temperature is adjusted to +/-1°C from the nominal value and is controlled by both

pressure and temperature. Temperature detection and control are carried out by PT100 probes located at the condensate drain (chamber adjustment and recording). The temperature values are displayed in real time and appear in degrees Celsius and tenths of a degree on the various video pages. The pressure values for the chamber are detected by piezoelectric transducers and are expressed in KPa. Using this, the AIR CHECK device calculates in real time the percentage of residual air present inside the chamber during the sterilization phase. This calculation can be printed and displayed to detect any anomalies.

Monitor

The touchscreen monitor must be of the minimum 7 "industrial type or must be graphic, high resolution colors with pages of: cycle diagram, synoptic for hydraulic / pneumatic system, preventive maintenance, programmed cycles, test cycles, cycle values, time remaining at the end of the cycle, language, technical functions, printing and operators, etc.

Loading side control panel

Control panel on the load side at minimum must be composed of: 7 "high resolution flush-mounted color touch screen monitor that manages the interface with the operator, emergency button, ON / OFF switch on / off equipment, vacuum gauge for the chamber and pressure gauge for the generator, door operating buttons, printer and USB port preparation.

Control panel on the discharge side

Unloading side control panel at minimum must be made up of: 7 "high resolution flush-mounted color touch screen monitor that manages the interface with the operator, emergency button, ON / OFF switch on / off equipment, vacuum gauge for the chamber and door activation buttons.

Programs and function F0 (effe with zero)

The sterilizer must be programmed with standard (factory) cycles and user cycles. It must be possible through the interface to modify the parameters of the cycles using a specific password. During the setting of the cycle parameters The management program must include the calculation of F0 to warn the operator if the time and temperature data are consistent for correct sterilization. During data entry, in the cycle summary and confirmation request, the theoretical value of F0 is shown on the display for the just entered time and temperature parameters. This data must be processed and automatically reported if a correct value is reached for a sterilization process.

User cycle

The programs must be able to be freely set by the user via a "touch-screen". Once a program has been set up, it must be able to run automatically and remain available for repeated calls to run. It must be possible to set at least 20 user cycles, identifiable by a number, after locking with an access key.

Usability

Usability must be the basis of the plant design; both from the point of view of management and from the operational point of view by applying that science that deals with the interaction between the elements of a system (human and other) and the function for which they are designed. The theory, principles, data and methods applied to design in order to improve satisfaction The quality of the relationship between user and system must be determined by the level of usability: the most important requirement to determine this level is safety, followed by adaptability, comfort, pleasantness, comprehensibility, operability, perception, ease of learning, and so on. The relationship between the system user has a significant influence on the efficiency and satisfaction of the individual himself and to improve the overall performance.

Ergonomics

Ergonomics is another fundamental aspect of the system design and must be closely linked to usability.

Standard sterilization cycles

Sterilisation cycle at 134°C for a mixture of solid and liquid waste posing a 'biological risk'.

Sterilisation cycle at 121°C for a mixture of solid and liquid waste posing a 'biological risk'.

Sterilisation cycle at 121°C for blood bags.

Self-sterilisation cycle of the chamber at 134°C.

Shredding cycle only

Steam penetration test cycle (Bowie & Dick)

Integrated automatic electronic steam penetration test cycle according to EN 285 (Bowie & Dick)

Vacuum leak test cycle 13 mbar in 10 minutes (1.3 mbar/min)

User cycle for programming 20 new cycles

For the systems delivered, the validation must be performed and the relative document issued.

Recording device

Through a printer installed on the front loading side panel, all cycle data, parameters, messages, operator codes, all the various phases, date, time, batch, FO, outcome of the cycle must be recorded on paper in real time. cycle, progressive number of the cycle, alarm messages and the graph of the cycle with the trend of pressure and temperature as a function of time. The printer must be paper impact.

Maintenance

Through the management system and the touch-screen monitor, the plant must be able to program all preventive maintenance operations to be carried out over time according to the sterilization cycles

Environmental impact

The plant must be studied by applying eco-design to preserve the environment in which we live as much as possible and to significantly reduce consumption and environmental pollution during the entire life cycle. Recyclability is to be considered

Safety devices

The main safety devices required are:

Device with double temperature control in the chamber with separate sensors
Device with double control of the pressure in the chamber with separate sensors
Pressure sterilization cycle regulation device with temperature control during the whole cycle

Door interlocking

Device that prevents the simultaneous opening of the doors

Device against the introduction of steam into the chamber with the door open or not perfectly closed

Safety device on the pressure control in the gaskets between door and chamber

Mechanical safety device certified for chamber pressure

Device against the opening of the door during the execution of the cycle

Device against the opening of the door with pressure in the chamber

Force control device on the door movement

Door opening device in case of obstacles

Automatic generator unloading device

Pressure control device in the generator

Electric heater temperature control device

Double control device of the minimum and maximum level in the generator

Mechanical safety device certified for the pressure in the generator

Safety device for motor protection

Safety device for electric heaters

Safety device on the duration of all phases of the cycle phases

Safety device on the duration of all operating times and equipment automations

Manual mushroom emergency device for all equipment functions on both control panels with manual reset

Electric steam generator

Using an electric steam generator incorporated in the equipment, the steam to be used for the sterilization cycles must be produced and accumulated. Minimum construction characteristics required:

Approval of dimensional calculations for relative design pressure of 4 BAR.

Construction in AISI 316L stainless steel

Automatic device for feeding the treated water by means of a level-controlled AISI 304 stainless steel pump with minimum filling interventions to keep the pressure stable.

Visual indication group of the water level inside the generator

Automatic pressure regulation and activation of electric resistances

Scalar regulation of the electrical resistances with group activation to reduce the maximum absorbed power value.

Automatic and programmed generator drain device to cause mechanical self-cleaning by eliminating any mineral deposits that may solidify and / or reduce the acidity of the water with scheduled drains.

Automatic heater temperature control device to avoid overheating.

Automatic change in stand-by position if the equipment is not used with a reduction in consumption.

Pressure gauge for controlling the pressure from the outside of the equipment.

Water disconnect device to avoid reverse flow. Non-condensable gas control device
Degassing device for treated water to eliminate non-condensable gases.

Thermal energy recovery device for preheating the treated water.

The generator is insulated using a Fonitek foam mat resistant to a temperature of 250 ° C. Generator electrical power 45Kw.

Construction standards and certifications

The system must be CE marked according to the European Directive 2006/42 / EC for Machinery and the European Directive 2014/68 / EU as pressure equipment (PED) and the European Directive 2009/125 / EC as eco-friendly design (ERP). It must also comply with the European Directives: 2014/35 / UE for Low Voltage and 2014/30 / UE for Electromagnetic Compatibility. The construction must be done in compliance with the European reference standards UNI EN ISO 285: 2016 (large steam sterilizers) and those connected to it UNI EN ISO 17665-1: 2016 (development, validation and routine tests), CEI EN ISO 61010-1: 2013 (electrical safety for electronic equipment), CEI EN ISO 61010-2-040: 2015 (requirements for medical material sterilizers), UNI EN ISO 15614-1: 2012 (qualification of welding procedures), UNI EN ISO 9606-1: 2013 (welder qualification), UNI CEI EN ISO 17050-1: 2005 (conformity assessment) and EN IEC 62304: 2006 (software validation). The certification for the Quality System UNI EN ISO 9001: 2015 (quality management system), UNI EN ISO 13485: 2016 (quality management system for medical devices) is required.

Interface

With the management system, it must be possible to create the prerequisite for unlimited uniformity in communication and therefore for maximum transparency across all levels, from the field and command level through the operational management level to the corporate management level and have the possibility of connecting to a local intranet.

Accessories

manual load and unload.

External staircase.



External staircase model SC

The purpose of the manual unloading device is to manually unload the inner trolley with the sterilized shredded material from the sterilization chamber. Given the weights involved, it is normally used on models with limited production capacity. Through the device, the operator has facilitated the manual operations of disengaging, rotating and unloading the internal trolley with the sterilized waste. It is made entirely of AISI 304 stainless steel and consists of a supporting structure with a rotation system on manually controlled fulcrum hinges.

Once the internal trolley has been manually unloaded, it proceeds in reverse by reinserting it into the sterilization chamber and closing the door. Through the monitor and controlled by the management system, the door on the unloading side is closed and a new sterilization and shredding cycle is started.

Alternative

Automatic waste loading into the chamber.



Automatic load device model ALDT

The purpose of the automatic waste loading device is to automatically unload the waste collection trolley or rigid waste containers into the sterilization chamber.

The device consists of:

AISI 304 stainless steel supporting structure completely enclosed with a protective cover and access door for the collection trolleys or rigid containers.

Lifting rails suitably shaped to allow vertical movement and tilting of the basket containing the collection trolley and ROT rigid container.

Lifting basket with fulcrums sliding in the guides.

Lifting by pneumatic devices with adjustable load.

Operator protection and automated stages.

With automatic loading, all manual steps and therefore the risks for operators are eliminated.

The automatic loading is integrated into the Truster's system and consequently controlled via the monitor and managed by the management system.

Manual unloading device internal carriage



Manual unloading device internal carriage model MUDT50

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Mobile collecting waste trolley



Mobile collecting waste trolley model T.240

Mobile collecting waste trolley in high density polyethylene. 2 Rubber wheels. Rear latch. Capacity 240 liters. Complies with EN 840. Also to be used for automatic loading.

Air compressor

Silenced oil free air compressor with a production capacity of 200 Nl per minute and a 200 liters tank.

Remote Control.



Remote Control model RC

Software for remote supervision and maintenance of the equipment.

FAT testing: included. Factory acceptance test. To be performed at our plant in the presence of your skilled technical staff.

Packing: included. The machines will be packed and protected with wooden case.

Installation conditions:

Place of installation: SMI Medical-Schlumbohm GmbH will provide the design with the indication of the utilities and consumptions necessary for the equipment.

Training for your specialized technical staff: included. The training to your staff performed by our technicians specialized in Italy.

Warranty conditions:

Warranty: included. 24 months warranty from the date of delivery, however not more than 28 months from the date of shipment. During the warranty period Schlumbohm GmbH will provide the spare parts and the preventive and corrective interventions shall be carried out by your specialized personnel.

Excludes: all damage caused by improper use or tampering, use of detergents or chemical products, or unsuitable electrical or energy or water supplies. In case of delay in installation of the equipment, it must be stored in such a way as to avoid damage caused by temperature, humidity, dust and shocks.

Country of Origin: Italy

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