Water Environment and Life (WEL Nepal)
33/2, Munalpath, Biratnagar, Morang

Specification of Autoclave

Equipment	Pre-vacuum healthcare waste treatment autoclave
Capacity	Approx 250 litres operating volume
Brand/Model	To be specifies by supplier
Minimum operating Temperature	121 centigrade (250 F) or higher
Minimum operating Pressures	2 Bar (30 psig/2280 mmHg) or higher
Sterilization chamber, jacket, door, boiler	Stainless steel, 316 L, low carbon content (L = Low Carbon) to prevent weld decay, temperature resistance high, Suitable for infectious healthcare waste including sharps and
Footprint	Space available (L = W = H =) This should include a specification for the space occupied by the autoclave and the clearance needed around it for maintenance.
Pressure vessel standards	Must meet either: EN13445 or ASME boiler and pressure vessel code section VIII
Safety features- redundant overpressure features	Over pressure safety provisions for chamber and boiler
	Low water protection in boiler
	Emergency stop button
Safety feature – door Interlock	Door interlock system to prevent opening door while vessel is under pressure; safety features shall also prevent start up if the door is not properly closed
Safety feature – emergency shut off	Emergency shut-off button in a readily accessible location
Safety feature – protection from hot surfaces	External insulation to prevent hot surfaces that may come in contact with workers exceeding 50°C
Safety feature – accidental vacuum breaker	Accidental vacuum breaker valve to prevent an accidental high vacuum during a power outage or other failure
Pre-set operating cycles for waste management	Autoclaves shall have programmed cycles for disinfection of infectious waste, and for liquid waste.
Pre-set operating cycles for leak testing	Autoclaves shall have pre-set operating cycle for leak testing.
Microbiological inactivation efficacy	Meets STAATT Level III microbial inactivation efficacy criteria at specified operating parameters as shown by challenge test results from an independent third party (Criteria= 6 log reduction or higher of vegetative bacteria, fungi, ipophilic/hydrophilic viruses, parasites, and mycobacteria as demonstrated using *Mycobacterium phlei* or *Mycobacterium Bovis* (BCG); 4 log reduction or higher of heat- resistant spores as demonstrated using *Geobacillus stearothermophilus* or *Bacillus atrophaeus*).
Independent testing of microbial inactivation efficacy	Vendor to provide evidence of testing by independent organisation, demonstrating waste disinfection cycles can meet the required microbial inactivation efficacy.
Door	Quick opening door (e.g., rotating locking ring (breech lock), extending radial arms, or equivalent)

Electrical	Suitable for installation in Nepal. Information on equipment supply requirements (220 V, 3 phases, 50 Hz) to be included in the information provided by the vendor
Electrical safety	Meets the requirements of IEC 61010-2-040, UL 61010A-2-041, or equivalent electrical safety standard; Meets electromagnetic compatibility requirements under EN 613261997 or equivalent
Controls	The autoclave shall be operated by controls to permit automatic operation using multiple pre-set operating cycles. Must be possible for operator to alter pre-set cycle parameters/add new pre-set operating cycles. For purposes of maintenance, testing, or in cases of emergency, means shall be provided to permit the sequential manual operation of the process. The sterilizer shall be protected against the effects of short circuits in inputs and outputs that are connected to the controller
Display indicators	Pressure and temperature readable by normal vision from a distance of (1.00 ±0.15) m
Other indicator displays	Displays indicating- door locked, operation in progress, major operating cycle stages, and cycle complete; as well as fault condition
Indicator for temperature	± 1% accuracy or better over the scale range 50°C to 150°C; 0.1°C resolution for digital instruments
Indicator for pressure	± 1.6% or better over the scale range -1 bar to 3 bars; 0.01 bar resolution for digital instruments
Indicators for processing	Error not to exceed 1%
Fault condition	In the event of a failure of automatic controls, a means to return to atmospheric pressure shall be provided. If values of the process variables exceed the limits specified by the manufacturer, or if a failure occurs that prevents the completion of the process, the controls shall show a visual indication of failure and an audible alarm which can be mutable. Measurements of chamber temperature and pressure shall be fitted with a broken sensor monitoring system. A broken sensor shall cause a fault to be indicated.
Recording	Recording of time, temperature and pressure can be digital and shall include values during transition points throughout the operating cycle sufficient to confirm that cycle parameters have been achieved and maintained within the manufacturer's specified tolerances. Pressure readings shall have an accuracy of ±1.6% over the range of -1 to 3 bars. Temperature readings shall have an accuracy of ±1% or better over the range 50°C to 150°C. Time periods of 5 minutes or more shall have an accuracy of ±1% or better.
Data download capacity (Automation)	Data shall be recorded digitally so it can be downloaded in formats compatible with widely used software. Manufacturer must specify parameters which are recorded: HMI controller Bowie-dick and Leak test program In-built data monitoring and recording Pressure sensors Temperature sensors
Vacuum	Information on vacuum achievable to be included in the information provided by the vendor; meets section 8.2.2 of EN 285 2006+A2 2009 (i.e. uniform color change throughout a Bowie-Dick indicator when tested on the empty autoclave)
Decontamination of air, air filter	Air removed during the vacuum cycle must be decontaminated by means of a HEPA filter (Class H13 or higher, EN 1822; or >99.97% efficiency on 0.3-micron particles, IEST-RP-CC001), HEPA with activated carbon filtration, steam treatment, or other equivalent method to prevent release of pathogenic aerosols
Safety and Markings	Includes safety valves, overtemp/pressure protection, and door interlock
	Markings per EN 13445, ASME BPVC, EN 61010-1/-2-040 or UL equivalents

Manuals	All to be provide in the English language. 1. Operation instructions (including process description), 2. Loading and maintenance procedures. 3. Short-form of operation and loading procedures. 4. Circuit and pneumatic plan, technical data sheet, pressure vessel certificate.
Other requirements of installation & support	Manufacturer supply and installation at site. On-site operator training (2 days comprehensive training on O&M) Two-years comprehensive warranty from the date of installation (parts/service) Post-warranty maintenance available (at least 10 years) Provide a detailed Service-Level Agreement (SLA) guaranteeing 24-hour response time for service
Documentation and Validation	Includes IQ, OQ, PQ protocols
	Calibration certificates
	O&M manuals
	Logbook templates
Autoclave tape for steam	Adhesive: Pressure-sensitive; compatible with wrapped packages Ink: Heat and steam sensitive; color change typically: Light color to black stripes Operating Temperature Range: 121–134°C
Air compressor, Size, Power, Operating Pressure	motor power: 2HP, Max. operating pressure: 180 pSi/8-12 bar, Single phase motor, compatible to specified autoclave