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Ministry of Health

الإدارة العامة لمكافحة عدوى المنشآت الصحية

General Directorate of Infection Prevention and Control in Healthcare Facilities

(GDIPC)

Sterile Service Unit (SSU) Guideline in Primary Health Care (PHC)

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In the name of ALLAH, Most Gracious, Most Merciful

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General Director's Message

The sterile service unit is one of the critical units in the primary healthcare centers that need to control the activities inside it for the seek of infection prevention and control. The sterile service unit (SSU) is responsible for reprocessing reusable medical devices and equipment's in all primary healthcare centers (PHC), aiming to provide the highest care and handling towards patient safety, staff protection, and environment control. The fundamental role of the SSU is to receive, clean, decontaminate, package, sterilize and distribute safe reusable medical devices.

We hope this guideline will provide SSU personnel with the information and skills needed to standardize the work practices, thereby decreasing the risk of operator errors and improving patient outcomes. Moreover, this guideline serves as a scientific-based guide for approved SSU Supplies and Equipment Specifications.

I would like to present the first version of SSU guideline for the primary health care facilities which was developed based on updated international references by professional experts in the field serves as a reference for SSU in the primary health care facilities in the Kingdom of Saudi Arabia.

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Introduction to Sterile Services Unit (SSU)

Sterile Supply UNIT (SSU) is the service unit responsible for reprocessing the reusable medical devices for all clinics in primary healthcare under strict infection control for patient and staff safety. The process involves collecting, transporting, sorting, disassembling, cleaning, disinfecting, inspecting, packaging, sterilizing, storing, and distributing reprocessed items. The SSU staff is qualified by experience and training in sterilization.

Infection Prevention & Control in SSU

Hand Hygiene (HH)

- Handwashing stations includes handwashing sinks, Soap, and paper towels, it should be located in or near each working area.
- Hand sanitizer dispensers should contain at least 60% alcohol concentration.
- All HCWs that are allowed to enter the SSU should perform Hand Hygiene before and after entering each area.
- Hand Hygiene should be performed before Donning and after Doffing of PPE.
- Hand Hygiene should be performed before and after handling any instrument.
- Hand Hygiene should be performed before preparing or handling items during sterile packaging.
- Hand Hygiene should be performed before you touch the sterile packages and transfer them to their storage area, and before the point of use.
- In case of visible soil on hands during the process, immediately remove gloves and wash your hands using soap and water.
- In case of gloves tear or fluids leak into the gloves, stop the process immediately and wash your hands using soap and water.
- Re-perform hand hygiene if your hands get contaminated during transferring sterile packages, e.g. touching your face or potentially soiled surfaces.
- Perform hand hygiene more frequently by practicing hand rub technique (right technique during the right time in the right sequence).
- Always make sure your hands are completely dry before handling sterile packages.
- Do not eat or drink after washing your hands or when handling (or packaging) sterile items.

Personal Protective Equipment (PPE)

- SSU technicians must be trained in the correct Donning and Doffing of PPE according to MOH standards.
- PPE includes heavy-duty gloves (fitted at the wrist or above), waterproof gown level 4, facemask, medical foot protector, and face shield.
- Full PPE should be worn in the Decontamination area.
- A clean attire, headcover, and detected shoes should be worn in the Inspection Assembly Packaging area (IAP) and Sterile Storage area.
- Do not touch your face or adjust PPE with contaminated gloves, only touch the necessary and acceptable surfaces.
- PPE is removed in completion of the task for which it was indicated and before leaving the decontamination area.
- Used PPE should be discarded in the regular black containers according to MOH standards.

Dress Code

- SSU technicians should wear clean surgical attire, dedicated shoes, head & facial hair cover.
- Attire changed and laundered daily or as needed if wet or visibly contaminated.
- Personnel should not wear jewelry or watches on the hands or wrists.
- SSU staff should change into street clothes whenever leaving the health care facility.
- SSU technicians should always keep fingernails short and clean. Nail polish or acrylic nails are not allowed during duties.

Environmental Hygiene

- Environmental cleaners and disinfectant agents must be approved for use in healthcare facilities.
- Environmental cleaning is not allowed during the sterilization process due to the possibility of dust spread into reusable medical device (RMD).
- Apply environmental cleaning methods regularly;
    - Floors are swept and wet mopped at least after each decontamination processed in the decontamination area.

- Floors are swept and wet mopped at least after each shift in the cleaning area.
- High-touch surfaces are horizontally cleaned and disinfected at least at the beginning and end of each shift.
- Decontamination sinks should be cleaned after each shift and more frequently as needed.
- Worktables are preferably cleaned before and after starting the sorting process in the decontamination area or the Inspection process in the IAP area.

- Shelves, cabinets, racks, walls, light fixtures, air vents and ceilings are cleaned frequently according to the center policy and procedure.
- Cleaning equipment are separated and dedicated (mops and buckets) for each area.
- Proper storage of the cleaning equipment after use, it must be kept clean and dry.
- Record cleaning activities and monitor the quality of the cleaning regularly.
- All areas must be free of dust, and insects.
- The sequence of cleaning shall be from clean to dirty areas, from high to low areas, and from least to most contaminated areas.

Occupational Healthcare and Safety

- Optimal use of recommended vaccines (Hepatitis B, Influenza, MMR (Measles, Mumps, Rubella), Varicella (Chickenpox), Td/Tdap (tetanus, diphtheria & pertussis), Meningococcal), helps maintain immunity and safeguard HCW from infection, thereby helping protect patients from becoming infected.

Sharp Injury

- In case of needle stick injuries incidents, the following procedure must be followed:
  - Encourage the wound to gently bleed, ideally holding it under running water.
  - Wash the wound using running water and plenty of soap.
  - Don't scrub the wound and do not squeeze the puncture site.
  - Dry the wound and cover it with a waterproof plaster or dressing.
  - Immediately report the injury to the supervisor; do not wait until the end of the shift or the end of the procedure.
  - Immediately seek medical treatment and follow the directions for any necessary blood tests, vaccinations, or medications to prevent infection.

Chemical and Biological Hazard

- Chemical detergents must be labeled with opening date, stored, and handled appropriately according to manufacturer instructions.
- Use Safety Data Sheets (SDS) and keep them readily available.
- Follow emergency procedures and protocols and manage hazardous materials for spill hazards as addressed in OSHA standards.
- Technicians must follow the SDS instructions for chemical and biological reaction.
- If blood or chemicals, contact with eyes:
    - rinse the eyes gently for at least 30 seconds with water in the eyewash station or by using the eyewash emergency bottle
    - Report the incident to occupational health clinic/infection control for further management and visit the clinic for checkup.
- If blood, chemical, or body fluids are sprayed into the mouth:
    - Spit out and then rinse the mouth with water several times.
    - Report the incident to occupational health clinic/infection control for further management and visit the clinic for checkup.

Waste Management

- Hazard waste container, sharp containers, and regular black containers should be available in sufficient numbers and be located in a place that is easy to reach and access.
- All used PPE should be disposed of inside regular black containers.
- In case of single use instrument arrived to the SSU, technician should dispose it inside the hazard waste container.
- Biological Indicator (BI) vail should be disposed of inside hazard waste container.
- All sharp objects (e.g., needles, blades) must be disposed of in the sharp containers.
- Wastes should be segregated accurately in a way that no medical waste is inside the regular waste container and vice versa.
- Medical waste bags and sharp boxes should not be over filled, it should be disposed of when the container/bag is three quarter full.

SSU Design/infrastructure

Design Layout

- SSU infrastructures should be done under specific standards according to Facility Guidelines Institute (FGI), and MOH-Health Care Facility standards. It must be reviewed before any possible project or reconstructive work by infection prevention and control committee, or those accountable for safe reprocessing practices and must conform to the requirements for reprocessing space.
- The size of the SSU should be appropriate for the volume of work being performed, the processes being conducted, the types of services provided, and the amount of equipment required to perform the required tasks.
- SSU areas include decontamination, preparation and packaging, sterilization, and storage.
- The design of the unit must follow the one-way workflow direction from dirty to clean areas.
- Distinction between soiled and clean work area must be maintained.
- SSU must have physical barriers between the decontamination area and packaging and sterilizing area, it should be smooth, non-particle, non-shedding, washable with clear demarcation for clean and dirty areas.
- Walls should be constructed of non-particulate, non-fiber shedding materials to stand cleaning.
- Windows are not allowed in both areas.
- The ceiling in the restricted area should be constructed of enclosed fixtures that hold all pipes and ductwork.
- The door should be made of a durable, smooth, and cleanable material.
- Floors should be flat and constructed of non-particulate, non-fiber shedding materials to withstand daily mope cleaning.

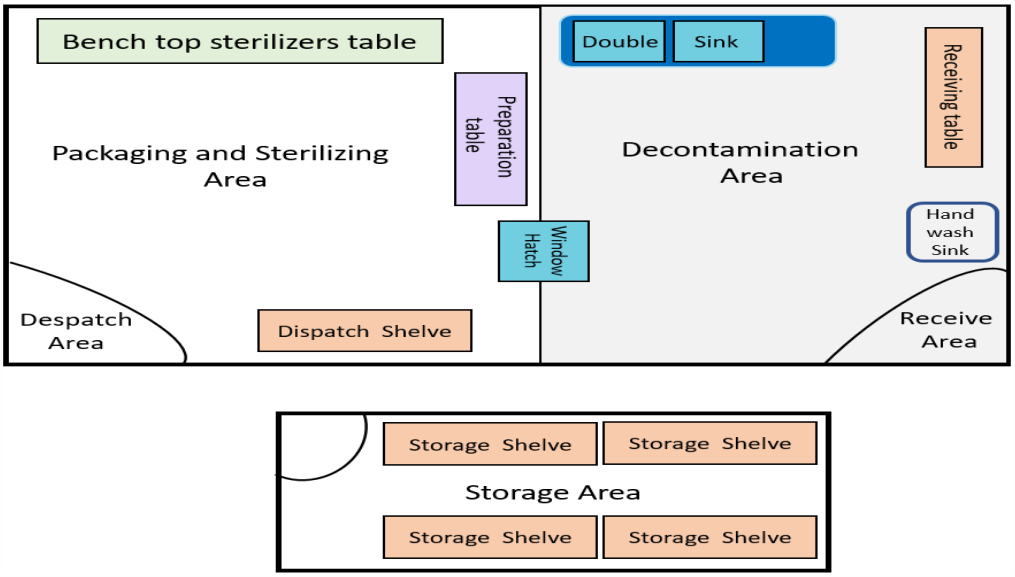

Figure 1: *(SSU design standard)*

Traffic Control and Workflow

- Reprocessing of RMD must be done in the SSU and none of the cleaning, disinfecting, and sterilizing processes is done in the clinics (except for Point-of-use Treatment).
- Point-of-use Treatment means remove gross soil from instrument surfaces with a sterile sponge moistened with sterile water after finishing the procedure at the point of use, it helps prevent material and debris from drying on instruments. It is recommended NOT to use saline to wipe instrument surfaces.
- SSU should be away from the main traffic pattern, and it should be restricted area for authorized personnel, with a clear sign posted on the SSU entrance.
- SSU areas must be physically separated, clean zone is separated from dirty zone to prevent cross-contamination.
- SSU Technicians should be organized so that activities and objects flow in a unidirectional way.

Environmental Control of SSU Facilities

Table1: SSU areas environmental parameters:

Area	Temperature	Pressure	Humidity
Dirty Area	**18°C - 20°C**	**Negative**	**30%-60%**
Clean Area	**20°C – 23 °C**	**Positive**	**30%-60%**

Environmental parameters monitoring documents must be kept for 1 year as MOH standards.

SSU Functions

Point of Use treatment /Pre-Cleaning

- Point-of- use treatment does not replace the cleaning process.
- Gross soil should be removed from contaminated reusable instrument surfaces using a sterile sponge moistened with sterile water at the point of use.
- Instruments should be kept moist until they are cleaned by using either saturation with an enzymatic pretreatment product or a towel moistened with water placed over the instruments or placing them inside a package designed to maintain humid conditions.
- Repeat the spray process as needed If the sterilization process will be applied after 2 hours or more.
- It is recommended NOT to use saline to wipe or moisturize instrument surfaces.
- These procedures help prevent material and debris from drying on instruments.
- Single-use instruments, disposable blades, and body fluids must be disposed of according to MOH specifications for medical wastes and discarded at the point of use.
- Disposable sharps such as scalpel blades and suture needles must be removed and discarded into a closeable, puncture-resistant container that is leak proof with a biohazardous label.
- The containers that contain soil instruments in the clinics must be closed and clearly identified with biohazard labels to identify the risk associated with carrying dirty instruments.

Transportation of Contaminated Reusable Medical Device to SSU

- Items must be transported to the SSU for full reprocessing in a closed container or cart with ideal characteristics such as:
    - It must be labeled and marked with a biohazard label, a red bag, or another means of identifying contaminated contents.
    - Secured lid to prevent infection spread.
    - Robust to prevent falling over and protect instruments from damage.
    - Containers should be puncture resistant.
    - Containers should be Leak-proof to prevent liquid spillage.

- Containers and carts used for holding contaminated items should either be single use or made of material that can be easily cleaned and effectively decontaminated.
- Containers and carts must be dried after cleaning and disinfection to prevent recontamination.

- Contaminated instruments should be transported on rotation basis by direct routes far from public traffic.
- PPEs and biohazard spill kits should be available for the transportation process.
- Contaminated instrument container should not be used to transport sterile instruments.
- If only one transportation trolly or cart is available, it must be decontaminated and disinfected before using again to transport clean or sterile items.
- Keep the cart always closed except during loading and unloading.
- During transportation, never leave the trolley or transportation cart unattended with biohazard labels in Arabic and English.
- All instrument coming from procedural areas is considered contaminated and must be contained properly when transported to the decontamination room.

Decontamination Area

Manual Cleaning:

- Manual cleaning is defined as the removal of all visible and non-visible soil, and any other foreign material from medical devices.
- It is a pre-requisite Step to the disinfection or sterilization step.
- When instruments are received in the decontamination area, it must be inspected for any sharp objects before handling them to prevent any possible injures.
- Cleaning must be performed immediately once the instruments are received to reduce the formation of biofilm that adheres to the surfaces of the instruments.
- All soil that adheres to the surfaces of instruments interferes with the effectiveness of disinfection and sterilization if not cleaned.
- Cleaning solution and water must be change when it is visibly soiled, which might be after one use to prevent soil particles from re-depositing on instruments or it should be changed according to manufacture instructions.
- It is important that the water temperature is in the range recommended by the detergent manufacturer for the most effective cleaning, range of temperature is 80˚F

to 110°F to prevent coagulation, if the temperature of the solution does not meet what is required, it should be changed.

- Disassemble all instruments and open all jointed instruments.
- When performing manual cleaning, technicians must involve friction to physically remove debris through wiping, brushing, spraying, or flushing the items.
- Use soft or stainless-steel bristle brushes to clean serrations and box locks, avoid using the stainless-steel brush if the instrument's IFU not recommend it.
- Cleaning should be under the surface of the water to reduce the risk of aerosol production.
- Factors that affect the level of cleaning purity of the surgical instruments which should be highly considered are:
    - Cleanliness of the surface of the RMD.
    - Characteristics or the design of RMD.
    - Type and concentration of the cleaning product.
    - Contact time (Duration) and temperature of exposure to the cleaning product.
    - Water Quality including Water Hardness, and water PH which should be monitored.

Sink Features:

- Cleaning sinks should be designed and arranged to facilitate soaking, washing, and rinsing of RMD.
- The sinks should be approximately 36 inches from the floor and 8 to 10 inches deep, deep enough to allow complete immersion of larger devices and instruments so that aerosols are not generated during cleaning.
- The sink should be at a height that allows workers to use them without bending or straining.
- The sink should be large enough to accommodate trays or baskets of instruments.
- The sink should not be used for handwashing.

Cleaning Tools and Detergents:

- Cleaning solution must be compatible with the instruments and follow the cleaning product manufacturers for proper dilution, concentration, temperature, and contact time.
- Brushes with various shapes and sizes are available & used appropriately.

- Using the correct size brush will ensure adequate cleaning the first time; this will eliminate re-cleaning and will also eliminate possible contamination of other instruments.
- Reusable brushes should be cleaned after each use, disinfected, or sterilized at least once a day.
- Discard of damaged brushes or if its bristles are bent or will not come clean.
- Single-use cleaning tools should be discarded after each use.
- Adequate supplies should be available for frequent changing.
- They should use multi-enzymatic detergents which contain protease, lipase, and amylase to clean all types of soil for manual cleaning.
- Stain and rust remover detergent contain acid-based compounds to remove hard water deposits, rust scale, and discoloration from RMD should be available.
- They should use a transport spray agent which commonly contains an enzymatic detergent with an enzyme-germicide detergent to keep the soil moist and loosen.
- Detergent agents must be environmentally friendly, rapidly dissolve soil, nontoxic, low-foaming, non-abrasive, and free-rinsing.

Packaging and Sterilization Area

Transfer the RMD to the packaging area:

- Re-clean if visible soiling on instruments.
- RMD received in this area must be dried before packed to prevent microbial growth, reduce spots, and allow steam to reach the instrument's surfaces.
- Instruments can be hand dried using a lint-free cloth.

Instruments Inspection for Cleanliness and Function:

- If possible, u can use lighted magnification to help detect residue on instruments.
- Each instrument should be inspected separately.
- Devices should be inspected for flaws, damage, debris, detergent residue, and completeness, then dried.
- Box joints, serrations, and crevices should be critically inspected for cleanliness.
- Hinges on devices, such as Artery forceps and Clamps, should be checked for free movement.
- Jaws and teeth should be checked for alignment, so jaws or teeth must be in correct

relative position.

- Ratchets should be checked for security.
- Multi-part instruments (e.g. dental handpieces) should be assembled to ensure that all parts are cleaned, complete and working as per IFU.
- Any damaged, incomplete, or malfunctioning devices should be reported immediately and documented.
- All screws on jointed devices must be tight and have not become loose.
- Place devices in an open position to allow the sterilant to come into contact with all surfaces.
- Sharp instruments should be checked for broken parts and packed carefully without damaging the pouch.
- Devices with ratchets should be closed on the first ratchet only, for steam penetration.

Packages Material Standard:

- The type of material used must allow the sterilant to reach the contents of the packing.
- The material must provide a good barrier to all types of microorganisms.
- The pack must be able to be opened without contamination.
- It should withstand normal handling, resistance to tears and punctures, and proven tamperproof seal.

Paper–Plastic Pouch:

- The paper–plastic pouch should be used, filled, and opened according to the pouch IFU.
- Sealed smoothly without folds, bubbles, or wrinkles.
- When pouching, leave 1 inch after sealing and write on the plastic side.
- Pouches shelf life is affected by sterilization, storage conditions, and time.
- Follow the proper packing, sealing, and visual inspection methods for avoiding any defects.
- Heat sealer should be safety tested annually by the biomedical departments.

Package labeling:

- Packages should be labeled before sterilization.
- Package labels should be visible and legible.

- Consist of non-toxic materials and ink.
- Write only on the non-porous side of the pouch.
- Indicate the lot number, sterilization date, and initials of the operator.

Loading Considerations:

- Technicians should be aware of their sterilizer's IFU loading considerations.
- Ensure there is sufficient room between items to allow the circulation of steam.
- Do not overload the chamber, this can cause wet packs and condensation to the set during sterilization.
- Wrapped instruments should be placed side by side.

Sterile Process Monitoring, Documentation, and Recalls

Documentation should be done manually for the following information:

- Cycle parameters:
  - Visible monitors for the table sterilizer to determine whether the correct sterilizing parameters were met must be done.
  - SSU staff should not release a load for use if the physical monitoring results have failed.
  - The documentation should be saved for a year as per (MOH recommendation).
- Tests results:
  - A Bowie-Dick test is used to rapidly assess whether steam sterilizers properly remove air from the chamber and prevent air re-entrainment.
  - The test should be done at least once weekly and should be run in an empty preheated chamber. If the sterilizer does not pass the Bowie-Dick test, personnel should remove it from service and determine whether it should be retested, serviced, or returned to service.
  - The test sheet should be saved for a year as per MOH recommendation.
  - Biological indicator uses the heat-resistant bacterial endospores (*Geobacillusstearor the mophilus*) to demonstrate whether sterilization has been achieved or not.

- Biological indicators then must be placed in its compatible incubator for periods depending on the specific production time until it is determined whether the microorganisms grow or fail to grow, which means killed by the sterilization process.
- The test BI vial and a control BI vial should be from the same lot to ensure that the control will read the appropriate time. If positive BI is indicated, a recall process must be followed.
- The documentation of BI results should be saved for a year as per (MOH recommendation).
- Internal chemical indicators must be placed in each package, they are used for pack control to determine that the sterilant has penetrated each package.
- If the chemical indicator does not pass, the contents should not be used.

Distribution of Sterile Items

- Before unloading from the sterilizer, Sterilized items should be allowed to cool down before handling to avoid wet packs after unloading of sterilizers.
- Thoroughly inspect the package, inspect the item and packaging for any signs of compromise such as but not limited to the following: staining or watermarks on the packaging, proof of sterility, worn areas, tears-regardless of size, improper packaging (wrong type, wrong method of wrapping or containment) expiration date.
- Return any compromised sterile items for processing (e.g. damage, debris, dust or soiled)
- Transport sterile items in a manner that will prevent the package from puncture or contamination from moisture, excessive humidity, condensation, insects, vermin, dust and dirt, and excessive pressure.
- Extreme care should be taken during transportation, make sure to transport in controlled condition.
- An enclosed cart or box with a solid bottom shelf should be used for transportation, where packages should not be dragged, slid, crushed, bent, compressed, or punctured.
- Ensure your transfer cart, or other device has been properly disinfected before placing items ready to be transferred.
- Return transfer cart, for subsequent cleaning and disinfection after items are issued.
- Do not put sterile packages in pockets or carry them outside the facility or staff break

areas.

- Assume an item is contaminated if it is dropped on the floor or an unclean surface. Do NOT use it.

Instrument storage in the clinics

- The clinic room must be controlled under specific environmental monitors (Humidity does not exceed 70%, temperature from 20 - 23 °C) to maintain the sterility of the packages.
- The sterile packages set inside the cabinet and drawers in the clinics.
- Sterilized packages should be used on a rotational basis so the process of using these sterile packages follows the FIFO (first in first out) methods.
- Rotate sterile items from "first-in" to "first-out" by placing the newest items towards the storage bin area's back.
- Sterilized packages must be returned to the SSU and prohibited to use if there is any evidence of wet packages, tears, burn pouch, missing indicator, or missing identification of the sterilization date shown.
- Cabinet and drawers used for storing sterilized instruments are free from dust, not stacked arranged.
- Not overcrowding bins or cabinets.
- Not using rubber bands or clips to bind items together or hang them to "fit them all in."
- Reducing the risk of contamination is achieved through minimal handling.
- Protective packaging for sterilized items that could be subjected to environmental challenges or multiple handling before use.
- Do not transport sterile items on a dirty cart or store them with used or contaminated items.
- Do not store items in sterile packaging under sinks.

Supplies Storage

- Supplies storage are available nearby or next by the SSU for providing the sterilization process products including cleaning detergents, cleaning check tools, sterilization quality check, packaging materials.
- The products stored in the supply's storage should be removed from shipping cartons and arranged by categories.

- The room/store area must be controlled under specific conditions to ensure that SSU supplies are in good condition to use:
    - Avoid any external conditions such as humidity, temperature, dust, and sunlight.
    - Avoid wiping packages with disinfectants.
    - Supplies storage shelves are properly cleaned, free from dust and the room has no windows.
    - Items are arranged appropriately in the storage shelves with lighter items on the top shelves and heavier items on the bottom shelves.

Supplies, Equipment, and Accessories

Specifications of PHC Supplies

This section guides the primary healthcare facility on how to determine the Sterile Service Unit's need for supplies, equipment, and accessories.

SSU Supplies:

Personal Protective Equipment

- Foot Protector, Size 37 Healthcare worker foot protector, Anti-slippery, waterproof, puncture-resistant, antistatic, covering the feet and toes with reinforcement heel, lateral ventilation ports, comfortable, ergonomic design to relieve tension in feet and lower back, Lightweight (not more than 150g per piece), easy to clean and disinfect (compatible with washer disinfector hot cycles and can be wiped with chlorine-based disinfectant), colour coded for three different working areas, complies with EN ISO 20347.
- Foot Protector, Size 39 Healthcare worker foot protector, Anti-slippery, waterproof, puncture-resistant, antistatic, covering the feet and toes with reinforcement heel, lateral ventilation ports, comfortable, ergonomic design to relieve tension in feet and lower back, Lightweight (not more than 150g per piece), easy to clean and disinfect (compatible with washer disinfector hot cycles and can be wiped with chlorine-based disinfectant), color coded for three different working areas, complies with EN ISO 20347.
- Foot Protector, Size 40 Healthcare worker foot protector, Anti-slippery, waterproof, puncture-resistant, antistatic, covering the feet and toes with reinforcement heel, lateral ventilation ports, comfortable, ergonomic design to relieve tension in feet and lower back, Lightweight (not more than 150g per piece), easy to clean and disinfect

(compatible with washer disinfector hot cycles and can be wiped with chlorine-based disinfectant), color coded for three different working areas, complies with EN ISO 20347.

- Foot Protector, Size 42 Healthcare worker foot protector, Anti-slippery, waterproof, puncture-resistant, antistatic, covering the feet and toes with reinforcement heel, lateral ventilation ports, comfortable, ergonomic design to relieve tension in feet and lower back, Lightweight (not more than 150g per piece), easy to clean and disinfect (compatible with washer disinfector hot cycles and can be wiped with chlorine-based disinfectant), color coded for three different working areas, complies with EN ISO 20347.
- Foot Protector, Size 44 Healthcare worker foot protector, Anti-slippery, waterproof, puncture-resistant, antistatic, covering the feet and toes with reinforcement heel, lateral ventilation ports, comfortable, ergonomic design to relieve tension in feet and lower back, Lightweight (not more than 150g per piece), easy to clean and disinfect (compatible with washer disinfector hot cycles and can be wiped with chlorine-based disinfectant), color coded for three different working areas, complies with EN ISO 20347.
- Medical boot, Universal size Healthcare worker medical boot, anti-slippery, waterproof, washable and disinfectants, made of polyurethane or light rubber or light PVC, comfortable, puncture-resistant, Washable, Length of neck minimum 30 cm, universal sizes.
- Heavy Duty Glove, medical-grade nitrile, or natural rubber latex, powder-free, finger thickness 15 mm, palm thickness 13mm, long cuffs 29 cm from the index finger, compliant to puncture resistance test ASTM F1342-91, ambidextrous, disposable, single-use, non-sterile, size: Small.
- Heavy Duty Glove, medical-grade nitrile, or natural rubber latex, powder-free, finger thickness 15 mm, palm thickness 13 mm, long cuffs 29 cm from the index finger, compliant to puncture resistance test ASTM F1342-91, ambidextrous, disposable, single-use, non-sterile, size: Medium.
- Heavy Duty Glove, medical-grade nitrile, or natural rubber latex, powder-free, finger thickness 15 mm, palm thickness 13 mm, long cuffs 29 cm from the index finger, compliant to puncture resistance test ASTM F1342-91, ambidextrous, disposable, single-use, non-sterile, size: Large.
- Heavy Duty Glove, medical-grade nitrile, or natural rubber latex, powder-free, finger thickness 15 mm, palm thickness 13 mm, long cuffs 29 cm from the index finger, compliant to puncture resistance test ASTM F1342-91, ambidextrous, disposable, single-use, non-sterile, size: X-Large.
- Heavy-duty gloves, medical-grade nitrile, or natural rubber latex, powder-free, finger thickness 15 mm, palm thickness 13 mm, long cuffs 29 cm from the index finger,

compliant to puncture resistance test ASTM F1342-91, ambidextrous, disposable, single-use, non-sterile, size: XX-Large.

- Medical gown for instruments/scops decontamination, non-sterile, reinforced Outer layer liquid penetration resistant in critical areas chest and sleeves, with cuff, covers all the body and back, Fabric non-woven material SMS or SMMS, minimum weight 45gsm, length from middle of neckline to bottom: 130 – 140 cm, non-sterile, comply with tear resistance ASTM D5587- ASTM D1424, fluid-resistant meet the international specifications, AAMI level 4 of protection and permeability to liquids, disposable, individually wrapped, deep blue color, size Small.
- Medical gown for instruments/scops decontamination, non-sterile, reinforced Outer layer liquid penetration resistant in critical areas chest and sleeves, with cuff, covers all the body and back, Fabric non-woven material SMS or SMMS, minimum weight 45gsm, length from middle of neckline to bottom: 130 – 140 cm, non-sterile, comply with tear resistance ASTM D5587- ASTM D1424, fluid-resistant meet the international specifications, AAMI level 4 of protection and permeability to liquids, disposable, individually wrapped, deep blue color, size Medium.
- Medical gown for instruments/scops decontamination, non-sterile, reinforced Outer layer liquid penetration resistant in critical areas chest and sleeves, with cuff, covers all the body and back, Fabric non-woven material SMS or SMMS, minimum weight 45gsm, length from middle of neckline to bottom: 130 – 140 cm, non-sterile, comply with tear resistance ASTM D5587- ASTM D1424, fluid-resistant meet the international specifications, AAMI level 4 of protection and permeability to liquids, disposable, individually wrapped, deep blue color, size Large.
- Medical gown for instruments/scops decontamination, non-sterile, reinforced Outer layer liquid penetration resistant in critical areas chest and sleeves, with cuff, covers all the body and back, Fabric non-woven material SMS or SMMS, minimum weight 45gsm, length from middle of neckline to bottom: 130 – 140 cm, non-sterile, comply with tear resistance ASTM D5587- ASTM D1424, fluid-resistant meet the international specifications, AAMI level 4 of protection and permeability to liquids, disposable, individually wrapped, deep blue color, size X-Large.
- Medical gown for instruments/scops decontamination, non-sterile, reinforced Outer layer liquid penetration resistant in critical areas chest and sleeves, with cuff, covers all the body and back, Fabric non-woven material SMS or SMMS, minimum weight 45gsm, length from middle of neckline to bottom: 130 – 140 cm, non-sterile, comply with tear resistance ASTM D5587- ASTM D1424, fluid-resistant meet the international specifications, AAMI level 4 of protection and permeability to liquids, disposable, individually wrapped, deep blue color, size XX-Large.
- Protective fluid-resistant apron, polyethylene disposable medical aprons, waterproof medium neck and back fastener, free size, latex-free. non-sterile in a dispenser box.

- Headcover surgical caps, made of non-woven martial, stitched elastic band or with ties, universal size, disposable.
- o Medical face mask\Ear loop Medical face mask, Complies with EN 14683 standard or ASTM F2100 standard, tested for Bacterial Filtration Efficiency (BFE) ≥ 95%, Particulate Filtration Efficiency (PFE) ≥ 95%, Differential Pressure (Delta P) < 5.0, Resistance to Synthetic Blood 80 mmHg, Breathability < 4.0 mmH2O/cm2, Flame Spread Class I, single-use, flexible bendable nose bridge, Latex, and fiberglass Free, Hypoallergenic, Fluid Resistant, Three Ply construction, three folds, covers the area from the nose to the chin, secured with an ear loop to be placed behind the ears.
- Medical face mask\Ties Medical face mask, Complies with EN 14683 standard or ASTM F2100 standard, tested for Bacterial Filtration Efficiency (BFE) ≥ 95%, Particulate Filtration Efficiency (PFE) ≥ 95%, Differential Pressure (Delta P) < 5.0, Resistance to Synthetic Blood 80 mmHg, Breathability < 4.0 mmH2O/cm2, Flame Spread Class I, single-use, flexible bendable nose bridge, Latex, and fiberglass Free, Hypoallergenic, Fluid Resistant, Three Ply construction, three pleats of folds, covers the area from the nose to the chin, secured with ties to be tied behind the head.

Cleaning Brush for Manual Washing

- Regular cleaning brush with two thick and thin ends Regular cleaning brush, double-ended, high quality white medical grade soft nylon bristles, end #1, 1 x 3.5cm, end #2, 0.5 x 2.5cm, total length 15 -20 cm, disposable, plastic handle.
- Regular cleaning brush, single-ended, high-quality white medical grade soft nylon bristles, overall length 15-20 cm, bristle diameter length 7-inch, disposable, non-sterile.
- Metal cleaning brush for instrument cleaning, high quality, toothbrush-style, stainless steel, disposable, non-sterile.

Cleaning and Disinfection Detergents

- Enzyme solution 3-5 liter capacity (direct in washer-disinfector or manual washing) Concentrated enzymatic cleaner, contains multiple enzymes (amylase, protease, lipase), effective on hard-to-clean soils, dissolves completely in hard or soft water, easy to rinse, low foaming, suitable for manual cleaning, low dilution, compatible with instruments materials (stainless steel, plastic, soft metals, aluminum), enhanced corrosion inhibitor properties to protect instruments from the harmful effects of water and water impurities, 1 manual dosing pump for every 30 gallons, biodegradable, EPA registered, suppler provide EPA/CE certification, Safety data sheet (SDS) should be provided, 3 – 5 L.
- Spray for dirty instruments, transfer Spray. Transport agent for point of use, ready to use surfactant and or enzymatic formula that clings to soiled instruments to maintain the moisture during transport up to 72 hours, the dose does not perform oily film,

dye-free formula to prevent stain and soiled sharps visibility, neutral PH, contains corrosion inhibitors for instruments (safe for aluminum, soft metals, gold handles), rinses easily (no need for special rinsing before automated processing and compatible with all types of washers), easy to rinse even when dried, conforms to relevant ISO standards, Safety data sheet (SDS) should be provided, size: 600ml - 1000ml.

- Neutralizer detergent solution for removing rust 3–5-liter (washer-disinfector and manual) Neutralizer detergent, acidic formula, for rust and scale removal, a phosphate-free formula that restores and maintains the protective passive layer integrity of stainless-steel surfaces, resistant to corrosion and pitting, removing stains, rust, hard water scale deposits, easy to rinse leaving the residue-free surface, it can be used for manual and automated process 3-5L
- Surgical instruments lubricant spray, ready to use, safe formula, for manual application, contains corrosion inhibitors that prevent rust, does not interfere with steam or plasma sterilant, does not leave any oily residue, neutral PH, compatible with all types of metal instruments, non-silicon based, phosphate-free, contains a preservative to ensure that the product will not support the growth of microorganisms, Safety data sheet (SDS) should be provided, spray bottle of 250 - 500 ml.

Cleaning Indicators

Enzymatic indicator for efficiency of manual cleaning of surgical instruments Indicator, for enzyme activity, for use in monitoring the enzyme activity of enzyme detergents, used in a manual bath, compatible with ANSI/AAMI ST 79 – colour of the indicator is directly compared to color blocks on bottle labeled, clearly labeled with lot number and expiration date.

Steam Sterilization Indicators

- Steam penetration indicator (Bowie-deck test). Bowie-deck test pack, designed for daily monitoring of the performance of pre-vacuum steam sterilizers operating at 134C / 3.5 minutes and 121C / 12 minutes, in addition to detecting air leaks, inadequate steam penetration, and vacuum pump failures. The test can detect wet steam, superheated steam and non-condensable gases problems conform to EN ISO 11140-4 and EN285. The test uses thermochromic ink formulation, free from lead or any toxic materials. The indicator reagent should be uniformly distributed on the test sheet to cover not less than 30 % of the surface area of the sheet, with the distance between adjacent areas of indicator reagent should not exceed 20 mm and sufficient strength to withstand steam sterilization. The difference in reflectance density should not be less than 0,3 between the substrate and either the changed indicator or the unchanged indicator as specified by the manufacturer, must be laminated. The back of the test sheet should include inquiries about department, machine number, cycle

number, 120 x 30 mm. Indicator should give remarkable color change.

- Rapid Biological Indicator for steam sterilizers (Daily) Biological indicator, individual vials for steam sterilizers, super rapid readout incubation time less than 30 min, self-contained biological indicator with external chemical indicator type 1, comply with ISO 11138, safety data sheet must be provided with it, the biological vial must comply with the MOH incubator auto reader machine and supplier must provide one auto-reader machine for free for every MOH facility.
- Class 6 chemical indicator Type 6 Emulating Indicator, Steam sterilization cycle verification strip chemical indicator that confirms exposure to certain critical variables (temperature, exposure time, and saturated steam) for a specified sterilization cycle, the product is an internal pack Indicator that can be used routinely invalidated pre-vacuum cycles (Dual Temperatures Indicator: 121 °C for 12 minutes - 134 °C for 4 minutes). Conform to EN 867-1 Class D and ISO 11140-1 Type 6) standards, the indicator ink is non-toxic and free of lead or heavy metals and provides the permanent color change that indicates specified sterilization parameters have been met, with endpoint color standard on each strip to facilitate color comparison, a short strip with fully laminated from both sides, Safety data sheet (SDS) should be provided.
- Adhesive Label rolls for printing cycle data Label rolls, strong, adhesive, keeps label withstand steam sterilization, eliminating the need for relabeling, the label provides 2 lines of information with up to 10 characters per line (one line for load and sterilizer numbers and the second line for sterilization Gregorian dating, labels comes printed with the red area "sterilized" in-between the 2 lines and the statement "sterile unless the package is opened or damaged" labels/roll: 500 - 1200, with label size, not less than 15 mm x 30mm, Supplier should provide one printing machine as per approved specifications for free for every 5000 rolls.
- Printing machine (Date, Cycle Number, Sterilizer Number) Applicator, for CSSD label, well adhesive labels to sterilization & wrapping packages & pouches and record sheets, durable, high-quality printout on the label, 2line labels: lot/ cycle number and machine number, Georgian print of date of sterilization, Supplier should provide one printing machine for free for every 5000 rolls.

Transportation Box

- Transportation box (22.5L x 16.5W x 6.5D inch) Box, for transportation, plastic, with lid that attaches securely to the bottom, 57L x 41w x 16d cm (22.5l x 16.5w x 6.5d inch).
- Transportation box (300 X 200 X 120MM) Box, for transportation, propylene, with reversible delivery label pocket lockable and autoclavable, size 300 X 200 X 120MM
- Transportation box (400 X 300 X 220MM) Box, for transportation, propylene, with reversible delivery label pocket lockable and autoclavable, size 400 X 300 X 220MM.

Steam Sterilization Pouches

- Gusseted precut sterilization steam pouch, information printed in the pouch as per EN 868-5 and ISO 11607, medical grade paper face porous material and one laminated polyester and polypropylene face transparent film, should be printed at distance not more than 15 cm, size: 9x5x12.5 cm. or dental pouch size: 9cmx10cm
- Regular precut sterilization steam pouch, information printed in the pouch as per EN 868-5 and ISO 11607, medical grade paper face porous material and one laminated polyester and polypropylene face transparent film, should be printed at distance not more than 15 cm, size: 10x20 cm. or dental pouch size: 11.5cmx23cm
- Regular roll sterilization steam pouch, information printed in the pouch as per EN 868-5 and ISO 11607, medical grade paper face porous material and one laminated polyester and polypropylene face transparent film, should be printed at distance not more than 15 cm, size: 15CMX100M. or dental pouch size: 16.5cmx25.5cm
- Regular precut sterilization steam pouch, information printed in the pouch as per EN 868-5 and ISO 11607, medical garde paper face porous material and one laminated polyester and polypropylene face transparent film, should be printed at distance not more than 15 cm, size: 20x40 cm.
- Gusseted precut sterilization steam pouch, information printed in the pouch as per EN 868-5 and ISO 11607, medical grade paper face porous material and one laminated polyester and polypropylene face transparent film, should be printed at distance not more than 15 cm, size: 25x8x40 cm.

SSU Equipment:

- Bench Top Steam Sterilizer: for Wrapped or unwrapped solid or hollow items porous loads, chamber material is Stainless steel, allow for Bowie & Dick Test and Vacuum Test, have Special user-programmable cycle, alert for low water level alarm, have a cycle finish alarm, alert for cycle malfunction, LCD or touch screen cycle status display, chamber capacity is from 40 – 150 Liters approx, loading from front door single, cycles 121, 134 flash, Manual or Automatic water fill and continuous direct drain, power supply 220 V, 60 HZ, regulatory compliance CE, and FDA approved.
- Worktable: Frame and a top surface made of Stainless steel, dimensions are 1600 x 650 x 900 (h), with all other accessories needed.
- Shelves: Used to store sterile instruments and other sterilized items, made of Stainless steel, at least five shelves, easy to clean, no hidden parts, 450 – 600 X 1000 – 1550 X 1800 -2200 (h) mm.
- Hatch Window: Used to return shelf racks of washer machines and other instruments from packaging areas to decontamination, applicable with washer racks, hatch

window will be just installed washer side, double door passes through, electrically interlocked to prevent simultaneous door opening.

- Heat Sealer: Used to seal sterilization pouches for steam and plasma sterilization, tabletop, fully automated microprocessor control, temperature range from 0 -99 degree centigrade, sealing length 500 – 120 mm, has to overheat protection mechanism, provided with pouch printer to print date/batch number / personal code/department name, with accessories roll wheels and cutting devices, 220volts/60Hz.
- Double Manual Washing Sink: Used for manual washing in decontamination zone in CSSD, double sink, made of stainless steel, dimensions 600mm Lx 300mm W, sink dimensions 60cm W X 40cm L X 25 cm D, with one mixer faucet for hot and cold water, with overhead shower, the lower cabinet closed with 2 doors, workflow from right to left or left to right according to zone layout drawing, with air gun/pressurized water faucet, with glass protection from water splashes, accessories should be provided (nozzles holder, brushes holder).
- Pouch Making Machine: Productivity up to 12 cycles/min, automated, microprocessor-controlled, LCD-display, 400 mm width of seal and cutting lengths & roll holder, with reel holder, seal seam 12 mm, with emergency stop switch, using different sizes of rolls, interface USB/RS232, with contact pressure, sealing time from 0.5 to 10.0 sec., with overheating protection system, operation interruption alarm, the process could be validated, has CE, US-FDA and/ or ISO 11607-2.
- Inspection and cleaning Table: Frame and a top surface made of Stainless steel, dimensions are 2100 (L) x 650 (W) x 900 (H), with all other accessories needed.
- Cart Transport Cleaning: Frame and a top surface made of Stainless steel, dimensions are 2100 (L) x 600 (W) x 1450 (H), three shelves, with wheels and have 2 brakes, with all other accessories needed.
- Water Distiller Machine: with a self-rinsing system to serve steam sterilizer, capacity 5-12 liters/hr.

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