Andhra Pradesh MedTech Zone Ltd (AMTZ)

Annexure-A

DEFINITIONS

- **BIS:** Bureau of Indian Standards
- **Barrier Properties:** Ability of the material to resist the penetration of fluids
- **Bioburden:** Population of viable microorganisms on or in a product and/or a package.
- **Bleaching:** Use of an oxidizing agent within a laundry to decompose some types of stains and/or disinfect contaminated textiles.
- **Alkalization:** Use of alkali salts in a laundry to enhance soil removal.
- **Chemical Dispensing Equipment:** Equipment/ system by which laundry chemicals are delivered to washing equipment.
- **Contaminated:** A state in which the article is actually or potentially in contact with microorganisms.
- **Cooling Down:** Process of cooling of hot textiles, usually inside the drying equipment. This is done to prevent damage, minimize mishaps in handling and to reduce/ eliminate fabric wrinkling.
- **Critical Zone:** Area of healthcare protective apparel where direct contact with blood, body fluids, and OPIM (Other potentially infectious material) is likely to occur.
- **Decontamination:** In healthcare, decontamination refers to the process of cleaning and disinfecting medical equipment, instruments, and surfaces to prevent the spread of infectious diseases. It is a critical aspect of infection control and is required to maintain a safe and sterile healthcare environment.
- **Device Master File:** A compilation of technical specifications & procedures of a finished device.
- **Disinfection:** Disinfection is the process of killing or eliminating disease-causing microorganisms, such as bacteria, viruses, and fungi, from surfaces, objects, or fluids. It is an essential process in preventing the spread of infectious diseases and maintaining public health.
- **Extraction:** Use of high speed rotational forces/ hydraulic pressing to remove excess water from a wash load prior to drying.

- **FIFO:** FIFO stands for "first in, first out." It is a method of inventory management that ensures that products or materials are used or sold in the order in which they were received.
- **Flush Process:** Flush process laundry refers to a method of pre-cleaning heavily soiled or contaminated laundry items before they are washed in a washing machine. This process involves soaking the soiled items in a large sink or tub of water and detergent, and then agitating them to help loosen and remove dirt, stains, and other debris.
- **ISO:** International Organization for Standardization
- **Isolation Precautions:** Isolation precautions are a set of infection control practices designed to prevent the transmission of infectious agents from patients to healthcare workers and other patients. These precautions are used in addition to standard precautions, which are designed to prevent the transmission of common pathogens. There are three types of transmission-based precautions namely Contact Precautions, Droplet Precautions, Airborne Precautions. Transmission-based precautions may include the use of personal protective equipment (PPE), such as gloves, gowns, masks, and respirators, as well as special handling and disposal procedures for contaminated materials. The specific precautions used depend on the infectious agent and the mode of transmission.
- **Laundry Equipment:** Laundry equipment refers to the machines and tools used in the process of cleaning and drying textiles, such as clothing, towels, and linens. There are several types of laundry equipment used in both commercial and residential settings:
  - **Dosing systems:** These systems automatically measure and dispense laundry detergents, fabric softeners, and other laundry products during the washing process. This ensures that the correct amount of product is used, which can improve cleaning performance and reduce waste.
  - **Dryers:** These machines are used to dry wet clothing and linens after they have been washed. They use heated air to evaporate moisture from the fabric.
  - **Drying racks:** These are used to air-dry clothing and other textiles that cannot be dried in a dryer. They are often used in homes and apartments that do not have a lot of space for a large dryer.
  - **Extractors:** These machines are used to remove excess water from clothing and linens after they have been washed. They use

centrifugal force to spin the water out of the fabrics, reducing drying time and energy usage.

- **Irons and ironing boards:** These are tools used to remove wrinkles from clothing and other textiles after they have been washed and dried.
- **Folding machines:** These machines are used in commercial laundry facilities to fold and stack large volumes of linens and other textiles quickly and efficiently.
- **Laundry carts and hampers:** These are used to transport soiled and clean linen between the washing and drying machines and storage areas. They come in different sizes and designs to suit different laundry needs.
- **Laundry sinks:** These are large sinks that are used for soaking and hand-washing delicate or heavily soiled items. They are often found in commercial laundry facilities or in homes that do not have washing machines.
- **Stain removal machines:** These machines are used to pre-treat stains on clothing and linens before they are washed. They apply cleaning solutions to the stains, which help to break down and remove them during the washing process.
- **Steamers:** These are machines used to remove wrinkles and freshen up clothing and other textiles without the need for ironing.
- **Water heaters:** These are used to heat the water used in washing machines. Hot water can help to improve cleaning performance and remove certain types of stains, such as grease and oil.
- **Washing machines:** These are machines used to clean clothing and other fabrics. They come in different sizes and types, including top-loading, front-loading, and high-efficiency machines.

- **Laundry Process:** The laundry process typically involves the following steps:

  - **Sorting:** This is the process of separating laundry items based on their color, fabric type, and degree of soiling. This helps to prevent color bleeding, damage to delicate fabrics, and ensures that heavily soiled items are treated appropriately.
  - **Pre-treatment:** This involves treating stains and heavily soiled areas on the laundry items with a pre-treatment solution or stain remover.

- **Washing:** This step involves using a washing machine to clean the laundry items. The washing machine may use different temperatures, agitation levels, and detergents depending on the type of fabric and degree of soiling.
- **Rinsing:** This step involves rinsing the laundry items to remove any remaining soap or detergent.
- **Drying:** The laundry items are then dried using a dryer, clothesline, or other method.
- **Folding:** Once the laundry is dry, it is typically folded or hung up.

- **Medical Clothing:** Medical clothing refers to the various types of clothing worn by healthcare professionals to provide protection against exposure to infectious agents, bodily fluids, or other potential hazards. Medical clothing may include items such as scrubs, lab coats, gowns, aprons, face masks, gloves, and shoe covers.
- **Medical Device:** All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of —
  - diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
  - diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
  - investigation, replacement or modification or support of the anatomy or of a physiological process; (iv) supporting or sustaining life;
  - disinfection of medical devices; and (vi) control of conception.

- **Medical Drape:** A Medical/ Surgical Drape or Medical/ Surgical Towel is a sterile sheet of material that is used to cover a patient or a specific area of the body during a medical procedure. Medical drapes are designed to create a barrier between the patient and the healthcare provider, reducing the risk of infection or contamination.
- **Medical Gown:** A medical gown is a type of protective clothing worn by healthcare professionals during medical procedures or other activities that

may expose them to bodily fluids or other potentially infectious materials. Medical gowns are designed to provide a barrier between the wearer and the patient or environment to reduce the risk of infection or contamination.

- **Medical Linen:** Medical linen refers to the textile products used in healthcare settings, such as hospitals, clinics, and long-term care facilities. These products are designed to be durable, comfortable, and able to withstand frequent washing and sterilization. Medical linen includes items such as sheets, blankets, towels, washcloths, and patient gowns. These items are used to provide comfort to patients and to maintain a clean and hygienic environment.
- **Microorganisms:** Microorganisms are tiny living organisms that can only be seen under a microscope. They are also known as microbes and include bacteria, viruses, fungi, protozoa, and algae.
- **PPE:** Personal Protective Equipment. It refers to equipment and clothing designed to protect the wearer from hazards that may cause injury or illness. PPE can include items such as gloves, goggles, respirators/ masks, face shields, hard hats, safety shoes, gowns, aprons and full body suits. The use of PPE is important to ensure the safety and health of workers in hazardous work environments.
- **Pilling:** Pilling is a phenomenon where small balls or pills of fibers form on the surface of fabrics, especially after repeated wearing and washing. It is caused by the rubbing of the fabric against itself or other surfaces, which causes the fibers to become loose and tangled. The loose fibers then roll up into small balls or pills on the surface of the fabric.
- **Pre-sort:** Pre-sort laundering is a process of separating and organizing laundry items based on their fabric type, color, and washing instructions before they are laundered. It is an important step in the laundry process to ensure that the items are washed properly and to prevent damage to the fabrics
- **Post-sort:** Post-sort laundering refers to the process of sorting laundry items after they have been washed and dried. It is typically done to organize the items and make them easier to put away or fold.
- **Soiled Material:** Soiled material refers to any item or surface that has become contaminated with dirt, grime, or other unwanted substances.
- **Soil Sort:** Soil sort process in laundry involves separating laundry items based on the level of soil or dirt present on them. This is an important step to ensure that the clothes are cleaned effectively and to prevent damage to the fabrics. This is done at a designated space called the Soil sort area in a

laundry. The soil sort area is typically located near the washing machines and may be a separate room or a designated area within the laundry facility.

- **Standard Precautions:** Standard Precautions are a set of infection prevention and control practices that are designed to be used in the care of all patients in healthcare settings. Standard Precautions are based on the principle that all blood, body fluids, secretions, excretions (except sweat), non-intact skin, and mucous membranes may contain infectious agents and should be treated as potentially infectious.
- **Sterile Field:** A sterile field is an area that is free from microorganisms, including bacteria, viruses, and fungi. In a medical setting, a sterile field is created to prevent the transmission of microorganisms and to ensure a safe environment for surgical procedures, medical interventions, and other sterile procedures.
- **Strike-Through:** Strike-through refers to the passage of liquid through a barrier or material that is intended to be impermeable. This can occur in a variety of settings, including medical procedures, manufacturing, and everyday use of consumer products.
- **Water Recycling:** Water recycling is an important practice in the laundry industry, where large amounts of water are used for washing and rinsing laundry items. Water recycling in laundry typically involves the following steps:
  - **Filtration:** The first step is to filter the wastewater to remove any large debris or solids. This helps to prevent clogs and damage to the recycling equipment.
  - **Sedimentation:** The wastewater is then allowed to settle, allowing any remaining solids or particles to settle to the bottom. This can be done in a sedimentation tank or using other methods.
  - **Chemical treatment:** Chemicals such as coagulants and flocculants may be added to the wastewater to help remove impurities and contaminants.
  - **Biological treatment:** Biological treatment methods such as activated sludge or biofiltration may be used to further treat the wastewater and remove organic matter and other pollutants.
  - **Disinfection:** The treated wastewater is then disinfected using methods such as chlorination or ultraviolet (UV) light to kill any remaining bacteria and pathogens.

- **Storage and reuse:** The treated water is then stored and can be reused for washing and rinsing laundry items.

- **Water Softening:** Water softening is the process of removing minerals and other impurities from hard water. Hard water contains high levels of dissolved minerals such as calcium, magnesium, and iron, which can leave scale buildup on pipes, appliances, and fixtures, and make it difficult to lather soap and detergents. Water softening typically involves using an ion exchange process, where the hard water is passed through a resin bed that contains sodium or potassium ions. The hard water ions are exchanged for the sodium or potassium ions, resulting in softened water that is free from mineral buildup. There are several methods for water softening, including:
  - **Salt-based water softening:** This method involves using a water softener that contains a resin bed and a brine tank. The hard water is passed through the resin bed, and the resin is periodically regenerated using salt water from the brine tank.
  - **Salt-free water softening:** This method uses a filtration system or other technology to remove minerals and impurities from the water without adding sodium or potassium ions.
  - **Magnetic water treatment:** This method uses a magnetic field to alter the physical properties of the water, preventing minerals from adhering to surfaces and reducing scale buildup.

Andhra Pradesh MedTech Zone Ltd (AMTZ)

Annexure-B

Immunization/Vaccination Declination Form

I, _____, a healthcare textile processing facility worker, have been advised of the recommended vaccines for employees in this industry. I have considered the information provided to me regarding the benefits of immunization against infectious diseases, including but not limited to Hepatitis B, Influenza, and COVID-19. Despite this information, I have decided to decline the following vaccination(s):

1.
2.
3.
4.
5.

I understand that by declining these vaccines, I may be at increased risk of infection with these diseases, and that the risk of transmission to others is also increased. I also understand that the consequences of declining vaccination may include serious illness, hospitalization, and even death.

I further understand that I have the right to change my decision and receive the recommended vaccines at any time in the future. I have been given the opportunity to discuss any questions or concerns I may have with a healthcare professional and have had those concerns addressed to my satisfaction.

I hereby release and discharge M/s. _____ and its employees, agents, and representatives from any liability for injuries or damages I may suffer as a result of declining the above vaccines.

Signature:

Date:

Witness:

Annexure-C
TABLE-I
APPLICABLE STANDARDS & TEST METHOD

Description	Applicable Standard
Water quality - Determination of pH	ISO 10523
Water quality - Determination of total dissolved solids	ISO 7888
Water quality - Examination & determination of color	ISO 7887
Water quality - Sampling for microbiological analysis	ISO 19458
Water quality - Calibration and evaluation of analytical methods and estimation of performance characteristics	ISO 8466
Water quality - Determination of free chlorine and total chlorine	ISO 7393
Textiles - Commercial laundering procedure for textile fabrics prior to flammability testing	ISO 10528
Textiles - Professional care, drycleaning and wet cleaning of fabrics and garments	ISO 3175
Safety of Machinery - General Principles for Design - Risk assessment and risk reduction	ISO 12100
Occupational Health & Safety Management Systems - Requirements with guidance for use	ISO 45001
Safety Requirements for Dry-Cleaning Machines	ISO 8230
Specifications for industrial laundry machines - Definitions and testing of capacity and consumption characteristics	ISO 9398
Surface active agents - Determination of pH of aqueous solutions - Potentiometric method	ISO 4316
Textiles - Tests for color fastness	ISO 105
Textiles - Determination of dimensional change in washing and drying	ISO 5077

Description	Applicable Standard
Sterilization of health care products - Microbiological methods	ISO 11737
Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	ISO 11135
Textiles - Tensile properties of fabrics	ISO 13934
Textiles - Tear properties of fabrics	ISO 13937
Textiles - Determination of the abrasion resistance of fabrics by the Martindale method	ISO 12947
Textiles - Determination of fabric propensity to surface pilling, fuzzing or matting	ISO 12945
Textiles - Seam tensile properties of fabrics and made-up textile articles	ISO 13935
Textiles - Determination of the slippage resistance of yarns at a seam in woven fabrics	ISO 13936
Textiles - Preparation, marking and measuring of fabric specimens and garments in tests for determination of dimensional change	ISO 3759
Textiles - Determination of dimensional change in washing and drying	ISO 5077
Clothing and equipment for protection against heat - Test method for convective heat resistance using a hot air circulating oven	ISO 17493
Clothing for protection against contact with blood and body fluids - Determination of resistance of protective clothing materials to penetration by blood-borne pathogens	ISO 16604
Clothing for protection against contact with blood and body fluids - Determination of the resistance of protective clothing materials to penetration by blood and body fluids	ISO 16603
Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration	ISO 22612

Description	Applicable Standard
Textiles - Determination of the permeability of fabrics to air	ISO 9237
Textiles - Determination of resistance to water penetration — Hydrostatic pressure test	ISO 811
Textile fabrics - Determination of resistance to surface wetting (spray test)	ISO 4920
Textiles - Measurement of water vapor permeability of textiles for the purpose of quality control	ISO 15496
Textiles - Determination of formaldehyde	ISO 14184
Biological evaluation of medical devices	ISO 10993
Environmental labels and declaration	ISO 14025
Greenhouse gases - Carbon footprint of products - Requirements and guidelines for quantification	ISO 14067
Sampling procedures for inspection by variables	ISO 3951
Quality management systems - Fundamentals and vocabulary	ISO 9000
Quality management systems - Requirements	ISO 9001
Medical devices - Quality management systems - Requirements for regulatory purposes	ISO 13485
Environmental management systems - Requirements with guidance for use	ISO 14001
Occupational health and safety management systems - Requirements with guidance for use	ISO 45001
Safety of machinery - General principles for design - Risk assessment and risk reduction	ISO 12100
Energy management systems - Requirements with guidance for use	ISO 50001
Medical Textiles - Surgical Gowns & Surgical Drapes	IS 17334
Medical Textiles - Bio Protective Coveralls	IS 17423

Description	Applicable Standard
Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration	ISO 22610

Note: Any equivalent national or international standards of latest edition of the Table I is also acceptable.

Andhra Pradesh MedTech Zone Ltd (AMTZ)

Annexure-D

List of Committee Members, Steering Committee and Technical Committee

COMPOSITION	
Steering Committee Members:	
Chair	
Dr. G.N. Singh	Advisor to Hon'ble Chief Minister-Uttar Pradesh, Former-DCGI, Eminent Expert in Regulatory
Co-Chair	
Mr. Anil Jauhri	Former-CEO, NABCB, Expert in Accreditation Framework
Members	
Mr. Rajiv Nath	Forum Coordinator, Association of Indian Medical Device Industry (AIMED)
Dr. Sanjiiiv Relhan	Chairman, Preventive Wear Manufacturers Association of India
Dr. Aparna Dhawan	Executive Director, TIC Council
Dr. Girdhar Gyani	Director General, Association of Healthcare Providers (AHPI)
Dr. Jitendra Kumar Sharma	Managing Director & CEO, Andhra Pradesh MedTech Zone Ltd. (AMTZ)
Mr. Mrutunjay Jena	Scientist-G, Head- Quality & Regulatory Affairs, Andhra Pradesh MedTech Zone Ltd. (AMTZ)
Mr. N. Venkateswaran	CEO, National Accreditation Board for Testing and Calibration Laboratories (NABL)
Mr. Raj Nathan	President, International Accreditation Services (IAS)
Mr. Ravinder Singh	Senior Scientist, Indian Council of Medical Research (ICMR)
Technical Committee Members:	
Chair	
Dr. Sanjiiiv Relhan	Chairman, Preventive Wear Manufacturers Association of India
Co-Chair	
Dr. Sunil Khetarpal	Director, Association of Healthcare Providers (AHPI)
Members	
Mr. Vivek Kulkarni	Textile and Laundry Expert
Dr. Lallu Joseph	Quality Manager and Associate General Superintendent, Christian Medical College Vellore

Mr. Mrutunjay Jena	Scientist-G, Head- Quality & Regulatory Affairs, Andhra Pradesh MedTech Zone Ltd. (AMTZ)
Mr. Akash Dharamsey	Textile and Laundry Expert
Mr. Vikrama Jeet Dhankhar	CSSD Technical Consultant
Dr Jayalakshmi J	Professor & HOD, Dept of Microbiology, KMCH Institute of Health Sciences & Research