Standards

HPC Healthline products are regulated under the following categories: Medical , PPE and Biocidal. Those products that are not covered by a specific directive are subjected to controls either through a specific European standard or HPC Healthline internal specification.

MEDICAL DEVICES DIRECTIVE: 93/42/EEC

This is the European Directive presenting the safety standards for medical devices; it has been amended by directive 2007/47/EC. Compliance with this Directive is indicated by affixing a CE pictogram.

CE

Class I medical devices are self-regulated and compliance is made through a declaration of conformity. Class Is, Im, IIa, IIb and III all require CE certification through a notified body.

GLOVES

The principle intended purpose of the HPC Healthline examination gloves is medical and as such the products (Handsafe® and HPC Healthline®) comply with the requirement of the directive 93/42/EEC as amended by directive 2007/47/EC. The medical examination gloves are tested to and comply with the following harmonised British/European Standards:

EN455

Defines the key areas of testing required for medical gloves.

BS EN455-1: Requirements and testing for freedom from holes

BS EN455-2 + A1: Requirements and testing for physical properties

BS EN455-3: Requirements and testing for biological evaluation

BS EN455-4: Requirements and testing for shelf life determination

Part 1: Freedom from holes:
AQL 1.5 (Acceptable Quality Level)

AQL 1.5

Eg: a 500,000 piece batch will require 500 samples for testing
≤14 failures = Pass, ≥ 15 failures = Fail.

Part 2: Physical properties:
Gloves inspected according to dimensions (length, width) and strength (force at break in Newtons)

Part 3: Biological evaluation:
Gloves tested for powder levels, chemicals, endotoxins, proteins and pyrogens. This section also covers the labeling requirements to guide and protect users.
(eg: claim of hypoallergenic or low protein shall not be used)

Part 4: Shelf life determination:
Real time and accelerated shelf life studies, to enable manufacturers to prove the product will withstand ageing without losing strength and barrier properties

ASTM F-1671: Viral Penetration:
The medical grade examination gloves have been tested to ASTM F-1671 for viral penetration. This involves subjecting the film of the gloves to penetration using the viral bacteriophage PHI-X174.

DISPOSABLE PULP

All Caretex® pulp products are classified as Class I medical devices in accordance with directive 93/42/EEC as amended by directive 2007/47/EC. All pulp products are tested to and comply with PAS:29 Disposable Pulp products for use in healthcare. This involves the following two stages:

1. Performance for retention: water retention of minimum of 4 hours at 35°C ± 3°C

2. Performance for disposal: must be capable of disposal in a sluice room macerator at a generally 2 minutes cycle time.

In addition, the pulp products are Kitemarked under the BSI kitemarking scheme for quality and safety.

FACEMASKS

Our medical facemasks DK01 are regulated by the Medical Devices Directive and are tested to and comply with the following European standard:

EN14683: Protection against bacterial contamination.
Defines the Bacterial Filtration Efficiency of the facemasks and divides its tests into 3 categories:

Part 1: Bacterial Filtration Efficiency in vitro (BFE)
Standards of the filtration of a controlled concentration of Staphylococcus aureas.
Results: BFE of 95% = Type I
BFE of 98% = Type II

Part 2: Breathing Resistance (Delta P)
Testing of the air flow pressure passing through the mask.
Results: Type I & II (non splash resistant) = <3.0 mmH2O/cm^2
Type IR & IIR (splash resistant) = <5.0 mmH2O/cm^2

Part 3: Splash Resistance
Testing of a determined quantity of artificial blood sprayed on the mask.
Results: Type I & II not applicable
Type IR & IIR minimum 120 mmHg

Standards

PPE DIRECTIVE: 89/686/EEC
This is the European Directive presenting the safety standards for personal protective equipment. Compliance with this Directive is indicated by affixing a CE pictogram.

CE

The PPE Directive covers a wide range of head to foot protective workwear (disposable and non-disposable). This Directive classifies protective workwear into 3 categories:

Simple Design:	*Products offering protection against*
(Category I)	*hazards of minimal risk.*
Intermediate Design:	*Products offering protection against*
(Category II)	*hazards that are not covered by simple or complex design.*
Complex Design:	*Products offering protection against*
(Category III)	*hazards of serious or mortal risk.*

GLOVES
Our disposable and industrial gloves comply with the PPE Directive. The following standards regulate gloves under the PPE Directive:

EN420 + A1: Protective gloves: General Requirements and test methods:
Defines general requirements for ergonomy, product design, construction, comfort, efficiency and marking. It also details the relevant pictograms related to each product category.

EN388: Protective against Mechanical Hazards
Specifies the requirements against abrasion, blade cut, puncture and tear.

EN374: Protective against Chemical and/or Biological Hazards
Specifies the requirements against penetration and permeation of chemicals and biological hazards. This standard comprises of 3 parts:

EN374-1: Terminology and performance requirements

EN374-2: Determination of resistance to penetration (water and biological hazards)

EN374-3: Determination of resistance to permeation by chemicals

EN421: Protection against Radioactive Hazards
Specifies the requirements against Radioactive contamination and ionising radiation.

EN407: Protection against Thermal Hazards
Specifies the requirements against fire and/or heat hazards.

PROTECTIVE WORKWEAR
Our range of apparel is also regulated by the PPE Directive 89/686/EEC. Most of our workwear will fall under the minimal risk category. However certain items are also regulated by specific industry standards.

HAZARD PROTECTIVE COVERALLS, Category III
Our Shield® Plus, Shield® Advance and Shield® Ultimate coveralls.

EN340: General Requirements for Protective Clothing
Defines general requirements for ergonomy, product design and comfort, sizing requirements according to wearer height, chest and waist circumference and specific labelling of the garment. We refer to numerical types of protection to define the level of protection of each coverall.

Type 4: Liquid spray Hazards
Type 5: Dry particles Hazards
Type 6: Liquid splashes Hazards
In order to classify coveralls into types, other specific industry standards require Standards:

EN14126: Protection against Biological Hazards.
Specifies the requirement of protective clothing against Infective Agents such as Bird Flu.

EN1073-2: Protection against Radioactive Hazards.
Specifies the requirement of protective clothing against Radioactive contaminations.

EN1149: Test method for Anti-static properties.
Specifies the requirements and test method for measurement of electrostatic charge decay.

RESPIRATORS (half masks)
The range of FFP masks is classified as Category III, complex design and are tested in accordance with the following harmonised standards:

EN149+A1: Protection against hazardous particles for Respiratory masks.
Specifies the requirement of Respiratory Protective Face Masks. This standard is divided into 3 categories, which will define the level of filtering protection from each disposable face mask. The level of protection is calculated on the Nominal Protection Factor (NPF), the acceptable level of filtering efficiency based on the amount of hazardous substance in the air. The greater the number, the greater the protection.

FFP1 mask
Protection from low toxicity levels
4 x NPF
Filtration efficiency of 78%

FFP2 mask
Protection from medium toxicity levels
12 x NPF
Filtration efficiency of 92%

FFP3 mask
Protection from high toxicity levels
50 X NPF
Filtration efficiency of 98%

'D'- Dolomite test

This test exposes the respirator to a concentration of dolomite dust at 400 ± 100 mg/M^3 with dust size ranging from 0.7-12 µM. All respirators that have passed with additional optional test to EN149 will be marked with the symbol 'D' after the class of respirator. (eg: FFP3D)

Standards

BIOCIDAL PRODUCTS DIRECTIVE: 98/8/EEC
The directive covers active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.

WIPES
The Shield® range of wipes has been tested against a combination of standards detailed below dependent on the intended action of the wipe:

EN1040: Chemical disinfectants and antiseptics:
Basic bactericidal activity.

EN1275: Chemical disinfectants and antiseptics:
Basic fungicidal and yeasticidal activity

EN1276: Chemical disinfectants and antiseptics:
Evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas.

EN1650: Chemical disinfectants and antiseptics:
Evaluation of fungicidal and yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas.

EN13624: Chemical disinfectants and antiseptics:
Evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area.

EN13727: Chemical disinfectants and antiseptics:
Evaluation of bactericidal activity of chemical disinfectants for instruments used in the medical area.

EN14348: Chemical disinfectants and antiseptics:
Evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants.

MISCELLANEOUS STANDARDS
Other regulatory standards not specifically covered by a European Directive.

BAGS AND SACKS - (including clinical waste)

BS6642: Specification for plastic refuse sacks made from polythene.

BSEN13592: Plastic refuse sacks for household waste collection.

BSENISO7965-2: Sacks drop test. Sacks made from thermoplastic flexible film.

Clinical waste sacks and bags: Regulated and supplied in compliance with the department of health HTM07-01 (health technical memorandum - safe management of healthcare waste)

CHSA: HPC Healthline UK Ltd is a founder member of the CHSA (Cleaning and Hygiene Suppliers Association) which was founded to initiate tighter product quality controls supplied in the industry. The CHSA is a member of the British Cleaning Council setting standards for code of practice of businesses throughout the supply chain.

Food Approval

A wide selection of our product range is food safe, suitable for food contact and therefore can be used in a food preparation environment.

Materials and articles, intended to come into contact with food, in their finished state, must be regulated according to European Regulation (EC) 1935/2004. The framework of this regulation is to ensure that all materials coming into contact with food are tested, so that in their normal use they will not transfer, in quantities, their constituents to food. These could endanger health, cause unacceptable changes in the composition of food or deteriorate its organoleptic properties (taste, texture, aroma, appearance).

Specific labeling requirements are affixed on packaging and products confirming their suitability with food contact. Compliance with this regulation is indicated by affixing the following food pictogram.

Plastics in contact with food: European commission 10/2011

To complete this general Regulation, specific directives per material categories have been put in place in order to set the framework of the testing procedures and acceptability levels.

HACCP Standard

HPC Healthline Ltd offers a complete hygiene solution adapted to the HACCP (Hazard Analysis and Critical Control Points) requirement with its full range of disposable gloves and workwear.

HACCP is a systematic preventive appraoch to food safety and is used to minimise cross contamination during food processing. Food factories have the responsibility to control and establish high level of hygiene at all stages within the food manufacturing process. This principle enables manufacturers to put into place a large range of controlling measures and on-line checks during the manufacturing process and hygiene measures for prodcution personnel.

In order to avoid any cross contamination between food preparation and handlers, all staff working in a food environment must respect a high level of hygiene and must wear clean and appropriate workwear.

Recommended workwear:
- Shoes or shoecovers specifically for the work area
- Headwear covering the hair completely
- Facemasks
- Disposable gloves

Recommendations for the correct usage of disposable gloves:
- Wash hands prior to donning the gloves
- Cover all wounds or cuts
- Change gloves every 4 hours