Technical Specification

Thumb Looped Aprons/Thumb Looped Gowns

Version: 2021-07-02

Introduction

This specification is intended to provide performance requirements for thumb loop aprons which exhibit sufficient mechanical properties, resistance to microbiological challenge, and resistance to chemical/liquid penetration for standard clinical use by healthcare staff. It is based on the "*Essential technical requirements for new High-Volume Manufacture of Personal Protective Equipment (PPE) and Medical Devices (MD) during COVID-19*" with additional microbiological and chemical penetration requirements taken from British Standards used for protective clothing. The terms thumb looped aprons and gowns are used interchangeably. In this document no distinction is made between these terms.

Scope

This document specifies design and performance requirements for fluid-resistant single-use Thumb Looped Aprons, also known as Thumb Looped Gowns, intended to provide fluid and splash protection for healthcare workers when undertaking healthcare procedures.

This specification specifically excludes surgical and medical gowns.

Thumb loop aprons are single transient use items, worn by healthcare workers for single episodes of care or other tasks in a healthcare environment. They may be used in situations where exposure to splashes, droplets and fluids containing infectious agents or chemicals is likely, such as endoscopy.

Thumb looped aprons may also be used to protect medical or surgical gowns in the clinical environment.

Thumb looped aprons are not intended for use in environments where they will be exposed to heat, sharp objects or significant mechanical stress.

Design requirements

A thumb looped apron is made from a plastic, such as low density polyethylene (LDPE), constructed in a similar manner to a gown, and has thumb loops to ensure that the cuff remains in place during

use and when, for example, gloves are donned. They are also referred to as a thumb looped gown. They are usually non-sterile.

Thumb looped aprons:

- Should be made of low-density polyethylene (LDPE) or equivalent.
- Must not contain natural rubber latex.
- Must be of a length that is below the knee but above the ankle, include sleeves long enough to ensure the arms are fully covered, provide adequate coverage of the whole of the torso including the front and back of the body and neck, and be sufficient to cover the wearer's uniform or scrubs.
- Must have ties that secure the apron around the body. These ties should be at the back or the side to avoid contamination in use, and should be sufficient to keep the gown secure without requiring additional means of retention.
- *'Over the head*' designs should be perforated to facilitate removal so that the head loop doesn't have to be pulled over the head when doffing.

Performance Requirements

Thumb Loop Gowns must meet the requirements in Table 1. Testing shall be performed on the finished product and shall include potential weak spots.

NOTE: In particular, all types of joints in critical areas (such as, for example, seams in sleeves) are regarded as potential weak spots.

Table 1

Test	Standard	Requirement	Notes
Gravimetric thickness	BS 2782-6 Methods 631A:1994 or equivalent	≥ 21.5 microns (0.0215 millimetres)	Equivalent to a minimum weight of 20 grams per square metre (gsm). Some users may require thicker material if the gown is being used outside, such as in the ambulance service.
Impact strength	BS EN ISO 7765-1:2004	≥30g	
Tear resistance (machine direction)	BS EN ISO 6383-2:2004	≥60mN (0.06N)	
Resistance to infective organisms	BS ISO 16604:2004	Class 5 (14kPa) as defined in EN 14126:2003 (Table 1)	
Resistance to penetration by liquids.	BS EN 14325:2018 Clause 4.13	A performance level of at least Class 2 shall be obtained for all of the following chemicals: ● 70% ethanol ● 70% isopropanol ● 30% hydrogen peroxide ● 1% (10,000 ppm) Sodium hypochlorite	Requirements are based on BS EN 13034:2005+A1: 2009. The chemical list is based on chemicals frequently used in clinical situations,

Packaging and Labelling

Thumb loop aprons complying with this technical specification:

1. shall be marked, labelled and packaged in conformance with the appropriate regulations;
2. shall indicate the name, trademark, or other means of identifying the manufacturer including the postal address;
3. shall indicate the material from which the apron is manufactured (for example, low density polyethylene - LDPE).
4. shall indicate the type/model of product (for example, as “thumb loop gown”);
5. shall include at least the year of manufacture, and also the month of manufacture if the expected shelf-life of the clothing is less than 24 months. This information may be marked on every commercial packaging unit instead of being marked on every item of clothing;
6. shall indicate the size range, such as length and width of the gown;
7. shall include a reference to complying with Annex II of Regulation (EU) 2016/425;
8. if sterile, shall indicate the sterility status with the word STERILE;
9. shall be labelled as ‘*Do not re-use*’;
10. shall not be labelled as a medical or surgical gown;

The manufacturer should also consider the use of appropriate or recognised symbols and information as specified in relevant standards.

Information supplied by the manufacturer

This information shall accompany every item of protective clothing or at least every commercial packaging unit. The purpose is to guarantee that the wearer is confronted with these instructions.

The information shall be at least in the official language(s) of the country or region of destination. They shall be clear, legible, unambiguous and, if helpful, illustrations, part numbers, marking etc. shall be added. If appropriate, warnings shall be given against problems likely to be encountered.

The instructions together with the information on the marking shall contain at least the following information:

a) the name, trademark of other means of identification of the manufacturer and/or his authorised representative established in the European Union or the country where the product is placed on the market;

b) reference to this document and compliance with Annex II of Regulation (EU) 2016/425.

c) identification of the item as single use partial body protection;

d) if applicable, a statement to specify additional personal protective equipment with which the suit shall be worn, and how to attach or connect them, to achieve the claimed performance classification. This statement shall be precise enough to help the user to select the appropriate equipment, e.g. a glove type;

e) the manufacturer's type, identification or model number;

f) the size range (as defined in EN ISO 13688) – for example width and length of the gown;

g) a list of chemicals and chemical products (including the names and approximate concentrations of the components) to which the protective clothing has been tested and the

performance levels obtained in penetration testing. In principle the use of the clothing shall be restricted to the chemicals listed, but if the list represents only a selection of the available information, then this shall be clearly stated and the reference to where additional information can be obtained shall be mentioned, e.g. a separate brochure, the manufacturer's telephone, email, a web site on the internet etc.

h) all other test performance levels, preferably in a table, with explanations on the meaning of these performance levels, e.g. mechanical and biological testing;

i) care pictograms according to EN ISO 3758 if appropriate, and the explanation of any pictograms used;

j) the expected shelf-life of the garment if ageing can occur;

k) a statement to advise that the wearing of protective clothing may cause heat stress;

l) If applicable, the warning phrase: "Flammable material. Keep away from fire."

m) the type of packaging suitable for transport e.g. transport in original packaging;

n) the name, address and identification number of the notified or approved body or bodies involved in the conformity assessment of the PPE;

o) information necessary for trained persons on:

- application and limitations of use (for example, temperature range)
- tests to be carried out by the wearer before use (if applicable),
- fitting,
- use,
- removal,
- storage,
- if applicable, disposal (contaminated chemical protective clothing may be harmful and should be disposed of as hazardous waste in accordance with national regulations),

Annex A - Rationale

The performance requirements set out in this document are based on the following:

Thickness, impact strength and tear resistance

These have been taken from the "*Essential technical requirements for new High-Volume Manufacture of Personal Protective Equipment (PPE) and Medical Devices (MD) during COVID-19*", Oct 2020, which in turn were based on pre-pandemic NHS Supply Chain specifications.

Resistance to infective organisms

This is based on the requirements of the protective clothing standard, *EN 14126 (Protective clothing — Performance requirements and tests methods for protective clothing against infective agents*) which states that one of the functions of clothing passing the standard is to prevent infective agents from reaching the (possibly injured) skin.

Penetration by liquids

This is based on EN 13034 requirements (Protective clothing against liquid chemicals). The list of chemicals is based on discussions with NHS clinicians and is intended to reflect the type of chemicals that clinicians are routinely exposed to in clinical situations. The sodium hypochlorite concentration is based on the concentration used for disinfection following blood spillage and items contaminated with, for example, mycobacterium tuberculosis.