Technical Guide

Protective Clothing and Medical Devices

A technical guide for clothing manufacturers of garments for medical use.

Published Standards

EN 13795:2011+A1:2013 Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment — General requirements for manufacturers, processors and products, test methods, performance requirements and performance levels

EN 14126:2003 Protective clothing against infective agents, combined with one or more of:

- **EN 943-1:2015** Performance requirements for Type 1 (gas-tight) protective suits.
- **EN 943-2:2002** Performance requirements for Type 1 (gas-tight) protective suits for emergency teams (ET)
- **EN 943-1:2002** Performance requirements for ventilated Type 2 (non-gas-tight) protective suits (Withdrawn)
- **EN 14605:2005+A1:2009** Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including partial protection (Types PB [3] and PB [4]).
- **EN ISO 13982-1:2004+A1:2010** Performance requirements for protective clothing providing protection against airborne solid particulates (Type 5)
- **EN 13034:2005+A1:2009** Performance requirements for protective clothing offering limited protective performance against liquid chemicals (Type 6), including partial protection (Type PB [6])
- **ISO 16602:2007+A1:2012** Performance requirements for protective clothing (Types 1 to 6)

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Introduction

Compliance of protective garments with the Medical Devices Directive 93/42/EEC or the Personal Protective Equipment (PPE) Directive 89/686/EEC was originally a choice between the two when the Directives were first issued. The choice was usually based on the protective garment's primary use. This changed completely when Directive 2007/47/EC was issued on 5 September 2007 amending Directive 93/42/EEC concerning medical devices. Protective garments that were identified as medical devices, now became PPE as well.

> *'Where a device is intended by the manufacturer to be used in accordance with both the provisions on personal protective equipment in Council Directive 89/686/EEC and this Directive, the relevant basic health and safety requirements of Directive 89/686/EEC shall also be fulfilled.'*

This came into effect from 21 March 2010.

As a manufacturer you need to be aware of this requirement, as it will affect your ability to legally place your protective garments on the market in the EU, and other countries requiring the CE mark as a measure of conformance.

- If your protective garments claim to protect the wearer from hazards, they will be PPE regardless of their medical use. This applies equally to full suits and garments that only protect part of the body (PB).
- The category of your garments as PPE may not be the same level as the Class in the Medical Devices Directive:
  - Category I PPE (Simple) applies to protective garments 'for contact with cleaning materials of weak action or prolonged contact with water', and is self–declaration, requiring no Notified Body involvement
  - Category III PPE (Complex) applies to protective garments that protect from substances and mixtures which are hazardous to health, and/or harmful biological agents, requiring an EC Type Examination Certificate along with ongoing surveillance through a Notified Body for PPE
- The typical standard used for garments in common use that are medical devices is *EN 13795:2011+A1:2013, Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment,* but this clearly states in Annex ZA it *'…does not provide presumption of conformity for the PPE Directive'*
- *EN 14126:2003 Protective clothing against infective agents* is a harmonised standard for the PPE Directive 89/686/EEC (and the future PPE Regulation (EU) 2016/425), and can be combined with other garment standards listed below to demonstrate compliance with the PPE Directive or Regulation.

Support from BSI

Please contact us to start the process of certification to the protective clothing standards.

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EN 14126:2003

Protective clothing against infective agents

- This standard is used to demonstrate the performance of protective garments against infective agents. This is not a 'stand-alone' standard and needs to be combined with standards for Type 1, 2, 3, 4, 5 and/or 6 protective garments, as listed in Clause 4.3, Table 5. Types 1, 2 and 5 protective garments are required to be of the 'full body' type. Type 3, 4 and 6 protective garment standards include partial body 'PB' garments covering only a part of the body.

- The type of protective garment claimed will be relative to the type and severity of protection claimed for the garment

Suit type	Standard	PB Option	Common Suit Name
1	EN 943-1:2015	No	Gas tight
1ET	EN 943-2:2002	No	Gas tight
2	EN 943-1:2002	No	Ventilated (PPE annex II approval only)
3	EN 14605:2005+A1:2009	Yes	Jet or splash tight
4	EN 14605:2005+A1:2009	Yes	Spray or light splash tight
5	EN ISO 13982-1:2004+A1:2010	No	Dust tight
6	EN 13034:2005+A1:2009	Yes	Light spray tight
1-6	ISO 16602:2007+A1:2012	Yes (3, 4 & 6 only)	As above for type (PPE annex II approval only)

- Other products that may be combined with EN 14126 but are not listed in Clause 4.3, Table 5, are:.

Product type	Standard	Common name
Powered filtering devices incorporating a hood, half-suit or suit	EN 12941:1998+A2:2008	PAPR hood, half-suit or suit
Airline breathing apparatus incorporating a hood, half-suit or suit	EN 14594:2005	Air hood, half-suit or suit
Ventilated protective clothing	EN 1073-1:2016	Nuclear air suit
Non-ventilated protective clothing	EN 1073-2:2002	Nuclear coverall

- Manufacturers should not be confused by the term chemical protective suit for the above types of protective garment. In order to comply with the requirements of EN 14126, Clause 4.3, the garment has to be marked with the type e.g. Type PB[4]-B. By marking the protective garment with the type, this infers that it complies with all of the applicable requirements of the protective garment standard, including the requirements for material properties

- If the protective garment does not claim to provide protection against chemicals, it should be clearly stated. The term chemicals includes strong cleaning agents and pharmaceuticals, wherever there is a risk from the effects of immediate or long term cumulative exposure.
- The most common protective garments used in medical scenarios are Types 3, 4 and 6 including partial body 'PB' garments. The choice of which type to claim is dependent on the intended use and degree of exposure
- Partial body garments (e.g. gowns, aprons, jackets, etc.) is an area that can be confusing within EN 14126, EN 14605 and EN 13034. However, in order to comply with the requirements for EN 14126, Clause 4.3, the garment still has to comply with all of the *applicable* requirements of EN 14605 or EN 13034.

EN 14605:2005+A1:2009

Protective clothing against liquid chemicals — Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])

- Type 3 chemical protective clothing for resistance to penetration by liquids, shall pass the continuous liquid jet test, and shall have materials that demonstrate chemical permeation resistance.
- Type 4 chemical protective clothing for resistance to penetration by liquids, shall pass the liquid spray test, and shall have materials that demonstrate chemical permeation resistance.
- Partial body protection garments offer protection to specific parts of the body against liquid chemicals. Examples of such garments are laboratory coats, jackets, trousers, aprons, sleeves, hoods (not air supplied), etc. As partial body protection leaves some parts of the body unprotected, only the performance requirements for the clothing material and the seams are required.
- The following tests are performed in addition the tests identified in EN 14126:
  - Abrasion resistance EN 530 method 2 - Minimum Class 1
  - Flex cracking resistance ISO 7854 method B - Minimum Class 1
  - Flex cracking resistance at -30°C ISO 7854 method B - Minimum Class 1 (Optional)
  - Tear resistance (trapezoidal test specimen) ISO 9073-4 – Minimum Class 1
  - Tensile strength ISO 13934-1 - Minimum Class 1
  - Puncture resistance EN 863 - Minimum Class 1
  - Seam strength ISO 13935-2 - Minimum Class 1
  - Type 3 Jet test EN17491-3
  - Type PB[3] Jet test EN17491-3 (seams, joins and assemblages only)
  - Type 4 Spray test EN17491-4

- Type PB[4] Spray test EN17491-4 – This is specifically excluded in EN 14605, Clause 4.3.4.1, however manufacturers may optionally carry out this test to verify the spray tightness of the partial body garment seams
- Permeation resistance of the material and seams to any claimed chemicals or pharmaceuticals is tested using EN 16523-1:2015 or EN ISO 6529, Method A or B - Minimum Class 1

EN 13034:2005+A1:2009

Protective clothing against liquid chemicals — Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB [6] equipment)

- Type 6 chemical protective clothing for limited resistance to penetration by liquids shall pass the low level spray test, and shall have materials that demonstrate liquid penetration resistance and repellency.
- Partial body protection garments offer protection to specific parts of the body against liquid chemicals. Examples of such garments are laboratory coats, jackets, trousers, aprons, sleeves, hoods (not air supplied), etc. As partial body protection leaves some parts of the body unprotected, only the performance requirements for the clothing material and the seams are required.
- The following tests are performed in addition the tests identified in EN 14126:
  - Abrasion resistance EN 530 method 2 - Minimum Class 1
  - Tear resistance (trapezoidal test specimen) ISO 9073-4 – Minimum Class 1
  - Tensile strength ISO 13934-1 - Minimum Class 1
  - Puncture resistance EN 863 - Minimum Class 1
  - Seam strength ISO 13935-2 - Minimum Class 1
  - Type 6 Modified low level spray test EN17491-4
  - Type PB[6] Modified low level spray test EN17491-4 – This is specifically excluded in EN 13034, Clause 5.1, however manufacturers may optionally carry out this test to verify the spray tightness of the partial body garment seams.
  - For claimed chemical protection, liquid repellency EN ISO 6530:2005 – Minimum Class 3 and resistance to penetration by liquids EN ISO 6530:2005 - Minimum Class 2 shall be obtained for at least one of the chemicals referred to in EN 14325:2004, Clause 4, table 9.
  - Additional Permeation resistance of the material and seams to any claimed chemicals or pharmaceuticals may be provided from testing using EN 16523-1:2015 or EN ISO 6529, Method A or B

Other considerations

- Protective garments types 1,2 and 5 are less common in medical use, but the applicable combined requirements shall still be applied.
- In order to be both a medical device and a protective garment both medical and PPE standards may apply. There are a number of overlapping tests between medical and PPE standards which can be read across.
- The user instruction requirements for EN 14126 are in addition to the requirements of the protective garments Types 1 to 6, which must both be met in full. This information shall accompany every protective garment or at least every commercial packaging unit. The purpose is to guarantee that the wearer is confronted with these instructions.
- The labelling requirements for EN 14126 are in addition to the requirements of the protective garments Types 1 to 6, which must both be met in full. The marking shall be clearly visible and as durable as adequate for the life of the clothing. A packaging label is not sufficient.
- There are also requirements for the sizing and other general features of the garment that must be complied with in EN ISO 13688:2013 (formerly EN 340).
- Other claims for the protective garment can be made for anti-static, flammability, respiratory protection, etc., which must be validated by additional testing to the appropriate PPE standard.