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Coronavirus (COVID-19) PPE Testing and Certification at BTTG®

BTTG® are providing testing and certification for PPE clothing and gloves to protect medical personnel, care workers, and others who are in contact with those who have, or may be suffering from COVID-19. BTTG®'s laboratories remain open during the COVID-19 Pandemic, and Fast-Track services for PPE testing and certification are available.

We have introduced a fast-track service for Certification of UK PPE for COVID-19 response, and are prioritising testing for surgeon's gowns and COVID-19 related PPE above other testing work. As the only UK laboratory accredited to perform the ISO 16604 viral penetration resistance test, for testing of protective clothing materials to penetration by blood-borne pathogens, BTTG® are ideally placed to provide the testing and certification needed by the NHS, PPE manufacturers, and other users.

UK Government guidance for manufacturers

In order to speed up the supply of COVID-19 related PPE to the NHS and other users, and following European Commission recommendation (EU) 2020/403, the UK Government have introduced guidance for UK market surveillance authorities, UK Notified Bodies and testing laboratories, and new and existing manufacturers of PPE. This guidance is available from:

<https://www.gov.uk/guidance/opss-coronavirus-covid-19-guidance-for-business-and-local-authorities>

There are two routes for manufacturers:

1. Supply of COVID-19 related PPE to the Government to be used by NHS healthcare workers
2. Supply of COVID-19 related PPE to other users in the United Kingdom ('fast-track' assessment)

For supply to the Government and NHS, manufacturers should follow the guidance and register at the appropriate place. For supply to other users, manufacturers must use the fast-track route, and apply to a UK Notified Body.



1. Supply of COVID-19 related PPE to the Government to be used by NHS healthcare workers

For supply directly to the Government and NHS, the Government has published 'Essential technical requirements' for COVID-19 related PPE. These are available from:

<https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe>

For protective clothing, there are four types of garments listed in the UK requirements.

ITEM (MEDICAL DEVICE or PPE)	TYPE OF PRODUCT	STANDARD(S)	NOTES
Medical Device: SURGICAL GOWN	Sterile: Single use/ disposable OR Non-sterile: Reusable or Single use/ disposable	BS EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods	
Medical Device: SURGICAL SCRUBS	Reusable - compatible with healthcare laundry decontamination wash processes	No technical standard for surgical scrubs	No testing required
PPE: ISOLATION GOWN	High Performance gowns: Type PB[4]-B OR Standard Performance gowns: Type PB[6]-B Non-sterile and non-surgical; Single use / disposable	BS EN 14605:2005 +A1:2009 (Type 4) Part Body OR BS EN 13034:2005 +A1:2009 (Type 6) Part Body AND EN14126 (barrier to infective agents = B) Including ISO 16604 minimum level 2	Satisfy Annex II of PPE Regulation (EU) 2016/425. These include comfort, ergonomics, and innocuousness.
PPE: COVERALL	Cat III Type 4B Coverall OR Cat III Type 6B Single use/disposable or Reusable	BS EN 14605:2005 +A1:2009 (Type 4) OR BS EN 13034:2005 +A1:2009 (Type 6) AND EN14126 (barrier to infective agents = B)	Satisfy Annex II of PPE Regulation (EU) 2016/425. These include comfort, ergonomics, and innocuousness.

BTTG®'s laboratories can provide most of the necessary testing for these items and arrange any additional testing. Contact PPE@BTTG.co.uk for more details.

2. Supply of COVID-19 related PPE to other users in the United Kingdom ('fast-track' assessment)

The fast-track route allows manufacturers to supply PPE that has been tested and assessed as conforming to the relevant technical requirements. It is a temporary measure during the current Coronavirus health crisis, and is not intended to replace the requirements of the existing legislation, the PPE Regulation (EU) 2016/425, which still applies in the UK, and which will be adopted into UK law after the Brexit transition period.

The process is as follows:

- The manufacturer must apply to a UK Notified Body whose scope includes this type of PPE, for CE marking under the PPE Regulation
- The Notified Body will assess the PPE and any existing test reports against the essential requirements for that product, and request or arrange for any necessary testing.
- Once the Notified Body confirms that the PPE meets the essential requirements, the manufacturer can label the PPE according to the fast-track guidance, and supply the PPE to users in the United Kingdom.

Once this fast-track assessment is completed, manufacturers must continue the CE-marking process, including annual checking for Category III PPE (Module C2 or Module D of the PPE Regulation). CE marking the product will allow it to be sold throughout the European Union, and in the UK after the Coronavirus health crisis is over.

As UK Notified Body 0338, BTTG® can provide initial approval for UK fast-track supply, and full CE marking for Europe-wide supply. The stages are as follows:

1. APPLICATION

The manufacturer must submit a PPE Regulation Module B application to BTTG®. We will then ask for the relevant information and any existing test reports on the PPE, and ideally also samples of the PPE.

2. ASSESSMENT

Our Certification Team will carry out an initial assessment on the PPE, including any existing test reports. We will then provide an Assessment Report, identifying any necessary testing in order to establish compliance with the relevant standards / technical specification and Annex II of PPE Regulation (EU) 2016/425.

3. TESTING

Once the manufacturer has completed any necessary testing, through BTTG® PPE Customer Services or another accredited laboratory, we will complete the assessment, in order to verify compliance.

4. 'FAST-TRACK' CERTIFICATE

Once we have confirmed compliance, we will issue a UK 'Fast-Track' Certificate, which will allow the manufacturer to supply the PPE to users in the United Kingdom for the duration of the Coronavirus health crisis. We will provide guidance on the product marking and user information required by the UK process.

5. PPE REGULATION - MODULE B

The Assessment Report will also identify the documentation required to complete Module B of the PPE Regulation. Once these are completed, BTTG® can issue a Module B Certificate for the product, when either Module C2 or Module D have been arranged or are in place.

6. PPE REGULATION - MODULE C2 or D

These products are PPE Category III, and in order to be CE marked must have a Module B Certificate, and undergo annual checking via Module C2 (selection and testing) or Module D (auditing of the quality system). BTTG® can offer both Module C2 and Module D, and if required will provide quotations for both.

Standards and technical specifications for fast-track process

The Government guidance for manufacturers refers to relevant European harmonised standards, standards listed in the World Health Organisation (WHO) Guidelines, and other technical solutions. If a manufacturer has a product which uses a non-harmonised specification or technical solution, the Notified Body must assess that solution against the applicable Essential Health and Safety Requirements (EHSRs) of the PPE Regulation.

For supply directly to the Government and NHS, the Government has published 'Essential technical requirements' for COVID-19 related PPE. These are available from: <https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe>

For the fast-track process, and eventual CE marking, BTTG® have adopted the UK Government's technical requirements as the basis of specifications that will be acceptable for COVID-19 related PPE, and have added elements of existing harmonised standards in order to meet all of the applicable EHSRs. The specifications are listed below. Other technical solutions proposed by manufacturers, which are equivalent to these specifications, will be considered by BTTG® for fast-track assessment and CE marking, and will be assessed against the applicable EHSRs of the PPE Regulation. Contact Certification@bttg.co.uk for more details about CE marking.

Suggested technical specifications for PPE Isolation Gowns, Coveralls and Part Body Gowns

Isolation Gowns (non-sterile/non-surgical) using EN 13795-1:2019 (partial) and EN 14126 as a Technical Specification

Design & Ergonomics:

- Length = mid-calf
- Ergonomic assessment: EN ISO 13688

Material:

Test and classify according to EN 13795-1:2019

- Liquid Penetration, EN ISO 811
- Bursting strength - Dry, EN ISO 13938-1
- Bursting strength – Wet, EN ISO 13938-1
- Tensile strength – Dry, EN 29073-3
- Tensile strength – Wet, EN 29073-3

Tests according to EN 14126:2003/AC:2004

- Clause 4.1.4.1 (ISO 16604); minimum Class 2 (1.75 kPa)

Seams in critical areas (including sleeves, shoulders)

- Seam strength: EN 14325:2018 minimum Class 1 (EN 13935-2)
- Seam Liquid Penetration: EN ISO 811 minimum same classification as material (if joining less critical area, then ≥ 10 cm)

Innocuousness:

- Material: according to EN ISO 13688 (pH value / Azo dyes / other harmful substances)

Labelling, user information and declaration of conformity:

- According to the PPE Regulation, Government fast-track guidance, and relevant standards (EN ISO 13688, EN 13795-1, EN 14126);
- UK Notified Body number in place of the CE mark;
- Liquid resistance according to EN 13795-1 and EN 14126;
- Must include warnings on its use in certain areas (flammability) where appropriate;

Declaration of conformity according to the PPE Regulation completed as far as is possible.

Coverall or Part Body Gown using EN 13034 (Type 6) or EN 14605 (Type 4) and EN 14126 as a Technical Specification

Design & Ergonomics for Part-Body Gown:

- Length = mid-calf
 - Ergonomic assessment: EN ISO 13688
- (Coveralls assessed by spray tests)

Material:

Full testing and classification according to EN 13034 or EN 14605 including chemical repellency & penetration or chemical permeation as applicable.

Tests according to EN 14126:2003/AC:2004

- Clause 4.1.4.1 (ISO 16604); minimum Class 2 (1.75 kPa)

Seams (all items):

- Seam strength according to EN 13034 / EN 14605 (EN 14325:2004).

Seams of Part Body Gowns in critical areas (including sleeves, shoulders):

- Type 6: chemical repellency & penetration on at least one chemical
- Type 4: chemical permeation on at least one chemical

Innocuousness:

- Material and closures: according to EN ISO 13688 (pH value / Azo dyes / other harmful substances)

Coverall:

- Type 6: light spray test according to EN 13034
- Type 4: spray test according to EN 14605

Labelling, user information and declaration of conformity:

- According to the PPE Regulation, Government fast-track guidance, and relevant standards (EN ISO 13688, EN 13034, EN 14605, EN 14126);
- UK Notified Body number in place of the CE mark;
- Part Body Gowns marked as either:
High Performance gowns - Protective performance against liquid hazards, Type PB[4]-B; or
Standard Performance gowns - For use in areas of light splashing and aerosols - Limited protective performance against liquid hazards - Type PB[6]-B
- Must include warnings on its use in certain areas (flammability) where appropriate;

Declaration of conformity according to the PPE Regulation completed as far as is possible.