

BSI: Your testing and certification partner for excellence

Testing and certification for Personal Protective Equipment



# Introduction

At BSI we have a full range of testing and certification services to enable you to bring your products to market effectively. We are independent of all product suppliers, distributors and manufacturers, so we can guarantee a confidential and impartial service, and provide you with reliable objective guidance.

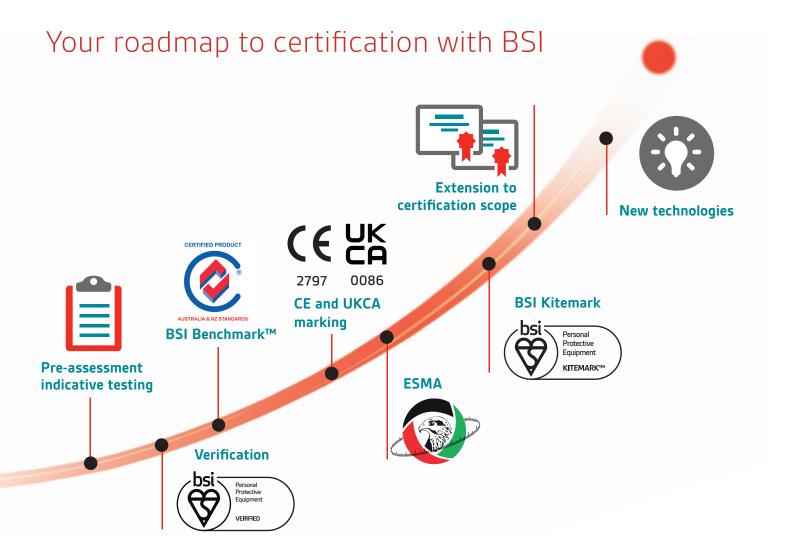
Use BSI to help you independently demonstrate compliance of your new and innovative products or services. We can support your CE and UKCA declaration, porvide third party certification such as ESMA or BSI Kitemark™ as your passports to new markets and opportunities.

#### As a UKAS Approved Body and RVA Notified Certification

**Body,** we have the expertise and integrity to independently endorse your product development, your credentials and your brand. Plus with our Notified (CE) and Approved (UKCA) Body status for specific Directives and Regulations, we're committed to helping you meet and demonstrate compliance to the relevant standards and legislation. We focus on delivering a testing and certification partnership underpinned by quality, safety, reliability and accuracy aligned to your product development requirements.

## Where are you on your journey?

We have a full suite of testing services for you to choose from, to help you get your products to market. Plus if you are developing new products, talking to our experts early in the development process can help you realize the full potential and commercial advantage of certification, with significant efficiencies and increased profits to be gained for your business. And with our global reach — with partner laboratories in the UK, Europe, USA, Hong Kong and China for example, we can support your business locally.



# Our services include:

## Pre-assessment/indicative testing



We can help support your product development process to test your innovation as a more cost effective solution before you apply for third-party certification. Any nonconformities can be identified at an early stage, reducing the need for re-testing during a formal compliance test.

#### Your commercial advantage:

Get your products to market more quickly. Investment at this stage could help you steal a march on your competitors.

#### Verification



If you have self-declared your products in order to meet specific regulations or directives, you'll have your own test data,

BSI Benchmark is a registered

technical files and test reports. Or if no standard exists in the marketplace, you may have your own test data or evidence that your product has been assessed to a certain requirement. If you're looking for additional verification of that data, we can help. We can review all your technical information, carry out further tests if appropriate and issue

a Verification Certificate to you. Verification certificates are typically available for three years and don't include ongoing product system compliance and product surveillance.

#### Your commercial advantage:

Self-declaration supported by BSI Verification can offer your customers increased levels of confidence in your products. We'll give you the independent overview in specific technical areas, and you'll be able to use verification to support procurement specifications and meet the requirements of bids and tenders.



## BSI Benchmark™ - enter the AU/NZ international markets

certification mark that is highly recognized and respected as a symbol of quality and safety. A product bearing this mark indicates that BSI has conducted a rigorous audit of its manufacture and production, and symbolizes that the product complies with the appropriate Australian, New Zealand and/or International Standard.

BSI assigns a client care specialist to help you with the pre-audit information exchange and scheduling an

appropriate audit date. Our technical experts assist with testing and developing the audit scope. Qualified auditors complete the initial and annual assessments at your manufacturing plants and provide a prompt report of your status against the accreditation scheme.

#### Your commercial advantage:

The BSI Benchmark is a powerful marketing tool which works around the world as a global passport to help you gain access to new markets.



## **CE** marking



If you want to trade within the European Economic Area (EEA) and your products fall within the scope of the PPE Regulation, they must meet the essential characteristics of the Directive or

Regulation and you must make a declaration of conformity.

CE marking has to be in place from launch. By CE marking you can offer customers a measure of reassurance about the safety of your products. CE marking on a product indicates that the minimum legal requirements for a product have been

met and allows the product to move freely throughout the European Single Market. As a Notified Body (Number 2797) we have the expertise to help you understand what your responsibilities are, and will provide the third-party evidence you need to be able to affix a CE mark to your products.

#### Your commercial advantage:

If the European market is your destination, the CE mark is your route to sales and opportunities.

## **UKCA** marking



If you want to trade with Great Britain (England, Wales, Scotland) and your products fall within the scope of the PPE Regulation and you must make a declaration of conformity. UKCA has to be in

place from launch. By UKCA marking you ca offer clients a measure of reassurance about the safety of your products. UKCA marking on a product indicates that the minimum legal requirements fro a product have been met and allows the

product to be placed in Great Britain. As an Approved body (Number 0086) we have the expertise to help you understand what your responsibilities are, and will provide the third-party evidence you need to be able to affix a UKCA markk to your products.

#### Your commercial advantage:

If the Great Britain market is your destination, the UKCA mark is your route to sales and opportunities.



### ESMA - enter the UAE international market

The UAE has recently introduced the

– 'Regulation for Control on Personal

Protective Equipment PPE Regulation No.

(03) year 2016'. BSI is a Notified Body meaning that we can help you with accessing PPE markets in the UAE. We have an extensive scope for certifying which includes; head protection, hand protection, eye and face protection, breathing

apparatus, protective clothing, foot protection, hearing protection, respiratory protection and fall management equipment. We can issue ESMA certifications for Category 1 (simple PPE like sunglasses), Category 2 (intermediate PPE like safety eyewear) and Category 3 (like RPE) products via the appropriate Emirates Conformity Assessment Scheme (ECAS) or the Emirates Quality Mark (EQM) route, details below.



## **EQM** Route

## **Documents required**

- Test Report from accredited laboratory
- Valid UAE Industry/Trade License.
- Declaration of Conformity.
- User Manual of the products (English and Arabic)
- Quality Procedure Plan of the Products
- Authorization letter

#### Assessment process

- Review of test reports
- Assessment of manufacturing facilities



#### **ECAS Route**

#### **Documents required**

- Test Report from accredited laboratory
- Valid UAE Industry/Trade License.
- Declaration of Conformity.
- User Manual of the products (English and Arabic)
- Quality Procedure Plan of the Products
- Authorization letter

## **Assessment process**

Review of test reports



#### BSI Kitemark™

BSI Kitemark has been in existence since 1903. We're proud to own it.

It's unique to BSI and has helped to address safety, quality and security issues for thousands of products.

Rigorous testing to national or international standards, ongoing sample testing to avoid any slippage of manufacturing quality or product performance, and annual assessments of factory production controls all combine to give truly robust, independent, voluntary third-party certification with the BSI Kitemark.

If you choose to implement ISO 9001, the international management system for quality to help control your factory production, we can offer you certification against this management system too.

#### Your commercial advantage:

The BSI Kitemark is a powerful marketing tool which works around the world as a global passport to help you gain access to new markets.



of clients say BSI Kitemark helps them attract new customers



confirm BSI Kitemark helps to increase sales

Plus you can offer your customers additional peace of mind. Direct future clients to your full range of BSI Kitemark approved products, listed in our online Kitemark directory to give additional reassurance: bsigroup.com/product-directory



## Extending the scope of your certificates

If something has changed which needs to be reflected on your certificate, we can help. From a new location to a new product or modification, we can help you make sure your products still comply, and your certificate is still valid.

## New technologies



Where new or adapted products are ahead of the curve, a relevant standard may not yet be available. We can still help. We can often use other specifications or technical documents,

such as trade association specifications or what are known as publicly available specifications (PAS's). As long as they are robust, developed by consensus and publicly available, we can run a valid certification scheme to them. We are also, where

appropriate, able to combine clauses from specific standards in order to be able to offer third-party certification.

### Your commercial advantage:

You could be first to market, gaining a significant competitive edge. Combining this with the BSI Kitemark could significantly boost confidence in your products.

## Medical Device Regulation and PPE crossover

Since the amended Medical Device Directive (MDD) 93/42/ EEC came into force in 2010 which allowed MDR products to be dual CE marked both as PPE and MDR we have seen a steady flow of products such as surgical and examination gloves, eye and face protection used in orthopedic procedures, surgical drapes and radiation attenuating products being certified as PPE. This has resulted in us

working closely with the BSI Medical Devices Notified Body team in helping manufacturers gain market access in a joined up approach including joint ISO 13485 and Module D assessments. We can also offer Kitemark for a number of MDR products such as surgical masks and examination gloves which are self declared Class I MDR products.

# Our facilities

We offer a comprehensive range of testing and certification for over 90 different standards for BSI Kitemark, CE and UKCA marking, Verification, plus Australia and UAE standards including on-site witness testing and integrated multi-assessments.



At our Centre of Excellence, and with our UKAS ISO 17025 accredited test laboratory status, we have the facilities to undertake a wide range of testing services. Accreditation by UKAS, the United Kingdom Accreditation Service demonstrates the competence, impartiality and performance capability of our services for clients.

With our industry experts and our state-of-the-art testing capability, we are dedicated to striving for excellence for our clients. Our equipment includes TIL (Total Inward Leakage), gas capacity testing for filters, CO², Impact Drop and Penetration rigs, all designed and maintained for precision testing and accuracy. But we don't just test what's needed now. We also look to the future. For example, with the standards that PPE needs to comply with becoming ever more exacting, our TIL rig already measures at the levels required by the forthcoming ISO standards. This means that we test your products to the most accurate levels possible not only giving you confidence in the testing for your current requirements, but also helping you with your testing requirements of tomorrow.

The BSI Kitemark can help customers easily identify products that they trust to protect them. Most equestrian head protection is certified to the BSI Kitemark, with the Pony Club of Great Britain specifying it. This gives confidence that members are protected and helps riders to easily select a fit-for-purpose product. The BSI Kitemark is a simple and powerful way to differentiate your PPE product from others.

You and your clients are welcome to view the testing of your products, to meet with our technical engineers and experience testing first-hand to share with colleagues and technical teams. Plus if you wish to film the testing of your products for promotional or technical purposes, we are happy for you to choose this option\*.

\*an additional charge may apply

# Our PPE testing portfolio

## Facial protection

## **Hearing protection**

Hearing protection requires mandatory CE and UKCA certification under the PPE Regulation (EU) 2016/425.

We also offer voluntary certification with BSI Kitemark and Verification Certificates for certain products. Below



are common examples of products that we test. Similar products can also be tested, please ask us for details.

### Examples of hearing protection include:

- Ear plugs
- Ear muffs
- Helmet mounted devices
- Level dependant earplugs

#### Services available:

- BSI Kitemark
- CE/UKCA marking
- BSI Benchmark
- Verification
- ESMA

## Respiratory Protective Equipment (RPE)

RPE requires mandatory CE and UKCA certification under the PPE Regulation (EU) 2016/425.

All RPE falls into category III PPE and therefore requires EU Type Examination and ongoing surveillance under Module C2 or D of the Regulation. As a Notified Body (EU) and Approved Body (UK) we have the expertise and recognized status to offer this service.

We can offer voluntary certification with BSI Kitemark, and Verification Certificates for certain products. We can also offer certification for breathing apparatus, escape sets and all other types of RPE.

We have increased our capacity in testing RPE, with the opening of our new gas testing lab in 2017. This covers filters testing for face masks used in mining, petrochemical, pharmaceutical, industrial and niche or specialist areas for example. Initially offering Type, A, B, E and K gases we will look to be developing this area to increase its scope.

#### Examples of RPE include:

- Powered respirators
- Disposable face masks
- Filters
- Half masks
- Full face masks
- Gas and combined filters

### Services available:

- BSI Kitemark
- CE/UKCA marking
- BSI Benchmark
- Direct testing
- Verification
- ESMA



# Eye protection

Eye protection requires mandatory CE and UKCA certification under the PPE Regulation (EU) 2016/425.

The majority of eye protection products such as safety glasses, goggles and face screens fall within category II. As a Notified Body (EU) and Approved Body (UK) we have the expertise and recognized status to offer this service.

We also offer voluntary certification with BSI Kitemark, and Verification Certificates for certain products. For BSI Kitemark we offer schemes for safety eyewear for products such as safety spectacles, goggles and face screens. We can offer certification for welding shields, sunglasses and swimming goggles. Motorcycle visors do not fall under the PPE Directive or Regulation. We offer BSI Kitemark and Benchmark for UK, global and Australian markets.

## Examples of eye protection:

- Safety spectacles
- Goggles
- Face screens
- Welding protectors
- Sunglasses
- Swimming goggles

#### Services available:

- BSI Kitemark
- CE/UKCAmarking
- BSI Benchmark
- Direct testing
- Verification
- ESMA



## Hand and foot protection

## **Gloves**

Gloves require mandatory CE and UKCA certification under the the PPE Regulation (EU) 2016/425. The majority of gloves fall within category II or III PPE and therefore require EU Type Examination and if complex, on-going surveillance too. As a Notified Body (EU) and Approved Body (UK we have the expertise and recognized status to offer these services. We can provide certification for both PPE and Medical Device products where applicable and have recently opened a test laboratory for protective gloves.

#### Examples of hand protection:

- Protective gloves against:
  - chemical permeation
  - mechanical risks
  - heat and fire
  - cold
  - chemicals and micro organisms
- Fire fighting gloves
- Surgical and examination gloves

#### Services available:

- BSI Kitemark
- CE/UKCA marking
- BSI Benchmark
- Direct testing
- Verification
- ESMA



## Safety footwear

Safety footwear requires mandatory CE and UKCA certification under the PPE Regulation (EU) 2016/425.

We also offer Verification Certificates for certain products.

Dependant on the standard, or optional testing within a standard, safety footwear may require EU Type Examination and if complex, on-going surveillance too. As a Notified Body (EU) and Approved Body (UK), we have the expertise and recognized status to offer these services.

#### Examples of safety footwear:

- Protective footwear
- Occupational footwear
- Forestry footwear
- Footwear for motorcyclists

Footwear protection against:

- chemicals fire fighting
- molten metal electrical Insulation

#### Services available:

- BSI Kitemark
- CE/UKCA marking
- BSI Benchmark
- Direct testing
- Verification
- ESMA



## Impact protection

## **Head protection**

Head protection requires mandatory CE and UKCA certification under the PPE Regulation (EU) 2016/425. We also offer voluntary certification with BSI Kitemark, and Verification Certificates for certain products.

The majority of head protection products such as canoeists, equestrian, mountaineering, bump caps, industrial safety,ski helmets and cycle helmets fall within category II PPE. For those which claim electrical or molten metal protection or are fire fighters helmets they require category III.

#### Examples of impact protection helmets:

Mountaineering, skiing, cycling, industrial, fire fighter

## Services available:

- BSI Kitemark
- CE/UKCA marking
- BSI Benchmark
- Verification
- Direct testing
- ESMA

## Protective workwear

### Hi-vis jackets

High visibility clothing requires mandatory CE and UKCA certification under the PPE Regulation (EU) 2016/425. High visibility clothing depending on the standard used and colour of the garments, can be either category I or category II PPE. We also offer Verification Certificates for certain products.

### Fall arrest

Fall arrest equipment falls under mandatory CE certification under the PPE Regulation (EU) 2016/425. All fall arrest equipment falls into category III PPE and therefore requires EU type Examination and on-going surveillance. As a Notified Body we have the expertise and recognized status to offer these services.

#### Examples of protective workwear:

Harnesses, connecting devices

#### Services available:

- BSI Kitemark
- Direct testing
- CE/UKCA marking
- Verification
- BSI Benchmark
- ESMA

# Transferring your certification to BSI

If you're looking to gain access to new markets and take advantage of our expertise, transferring your certification to BSI can reap real benefits.

Our certification managers, client managers, test engineers and business development managers have a thorough understanding of the testing and certification process. You'll be assessed by the most appropriately experienced professional, perfectly suited to your requirements.

Contact us

Telephone or email us for a no-obligation review of your needs, and a written quotation. We operate with complete cost transparency for your peace of mind.

- +44 (0)345 0765 606
- product.certification@bsigroup.com

2 Apply

Send us your application together with:

- A copy of your current certificate and full scope
- Your latest assessment report\*
- Your latest audit test report
- A copy of your type test report\*\*
- We'll then send you a written quotation for your review

Receive your certificate from BSI

4 Keep improving

We'll agree a programme of continuing assessment visits and audit testing to help you maintain your certification and continue to drive improvements for your business.

- \* if carried out by an accredited body and not more than 6 months old
- \*\* Your type test report should be preferably less than two years old. The work should be conducted by a reputable, accredited lab where we recognize the equivalence of the work they do matches with our own.

# Additional services

We help manufacturers around the globe by supporting claims of compliance for new and innovative products. You can also use our multiple certification solutions to make sure you have the resilience to be able to cope with growth and be prepared for future challenges. Companies choose our services to protect their supply chain, their data and their operations.

## Training from BSI experts

We offer one of the widest ranges of standards-related training available from quality management to managing your energy effectively. We don't just train you to meet standards – we help you to understand how to embed them into your organization.

We know what an auditor will look for – so we train you to meet it. We know the thinking behind the standard – so we can convey that to drive and inspire your people.

We have a team of expert tutors working across the world who can transfer the knowledge, skills and tools your people need to embed standards of excellence into your organization. They have vast amounts of training and assessment experience, and work across a wide range of business sectors.

For our full training courses please visit:

## bsigroup.com/training

## **Certification to Management Systems**

With more than 81,000 certified clients and more full-time assessors than any other certification body worldwide, we are one of the largest and most experienced certification bodies. This means you'll get the most out of your assessment and certification with the least disruption and cost to your operations.

To discover certification for our management systems please visit:

bsigroup.com/certification

#### **BSI Connect software**

BSI Connect is the integrated technology solution that inspires trust in your audit, compliance and supply chain activities enabling you to build resilience through datadriven insight.

One integrated tool is all that's needed to manage your business on the go. With BSI Connect, we bring our unmatched expertise together with advanced technology to empower you to make resilient decisions built on a single, trusted source of data.

Choose BSI Connect to perform real-time analytics and manage information and operations for your critical business functions and suppliers.



For more information about BSI Connect please visit:

bsigroup.com/software

# **About BSI**

We are the business standards company that equips businesses with the right tools and solutions to turn best-practice standards into habits of excellence. With over 4,000 staff worldwide, we help our clients drive performance, manage risk and grow sustainably.

Founded in 1901 we were the world's first National Standards Body. Now over a century later, we're globally recognized as a champion in best practice. We have been and still are responsible for originating many of the world's most commonly used standards and publish nearly 2,700 standards every year. These standards are developed to address the most pressing issues of today. They also cover various industry sectors, including Aerospace, Automotive, Built Environment, Food, Healthcare, IT and Fire.

All our standards are underpinned by a collaborative and rigorous approach perfected over decades. We always work closely with industry experts, government bodies, trade associations, businesses of all sizes and consumers to develop standards that drive excellence.

We currently work with over 84,000 clients in 193 countries worldwide to help them adopt and cultivate continuous

habits of best practice. We also train our clients and provide them with practical implementation guidance, as well as a comprehensive suite of compliance tools. And to ensure our clients get the very best service, we're also independently assessed and accredited globally by ANAB (ANSI-ASQ National Accreditation Board) and 26 other accreditation bodies throughout the world, including UKAS (United Kingdom Accreditation Service).

Our reach is global and we play a key role within the International Organization for Standardization (ISO). As one of the founding members, we help make sure international standards developed address today and tomorrow's business and social needs, while delivering real benefits to an organization and all its stakeholders.

Speak to one of our experts today or visit our website for more information.

Call: +44 (0)345 0765 606

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