Witness Name:
Graeme Tunbridge
Statement No.: 1
Exhibits: GT1
Dated: 24 January 2025

UK COVID-19 INQUIRY

WITNESS STATEMENT OF GRAEME TUNBRIDGE ON BEHALF OF BSI GROUP

I, GRAEME TUNBRIGE, will say as follows: -

1. I am the Senior Vice President, Global Regulatory and Quality at the British Standards Institution (**BSI**). This is my first witness statement to the Inquiry. It is provided in response to the Inquiry's Request for evidence under rule 9 of the Inquiry Rules 2006, dated 15 October 2024 and it relates to BSI's role in the procurement of key healthcare related equipment and supplies between 1 January 2020 and 28 June 2022 (**Relevant Period**).

2. For evidence I provide that solely relates to the National Standards Body (**NSB**), I have relied on input from colleagues responsible for the delivery of that function, as I describe below. Should BSI be required to appear before the Chair to give oral evidence, I recommend that Scott Steedman, Director-General, Standards, be present to answer any questions that relate directly to the NSB and its work.

3. In my role as Senior Vice President, Global Regulatory and Quality, my responsibilities include ensuring BSI's regulatory compliance in undertaking a range of global certification and accreditation activities. This includes BSI's role as an EU Notified Body and UK Approved Body, as described further below. I should make clear to the Inquiry that prior to joining BSI in January 2022, I was Director of Devices at the UK Medicines and Healthcare products Regulatory Agency

(**MHRA**), where I was responsible for ensuring the safety and performance of medical devices in use in the UK.

4. The statements which I make in this witness statement are either from my own knowledge in the context of my role at BSI, or derived from documents/records held by BSI which I have inspected and/or conversations which I have had with my colleagues and other employees of BSI. Where facts and matters are within my knowledge, I believe them to be true. Where I have referred to information supplied by others, the source of that information is identified, and the information is true and correct to the best of my knowledge and belief. I have attempted to answer each of the questions as fully as possible. If the Inquiry wishes for further information, BSI will endeavour to provide it promptly.

5. Attached to this witness statement is a bundle of documents to which I refer, marked "GT1", followed by the Inquiry Unique ID.

SECTION 1: GENERAL

The formation and development of BSI as the National Standards Body

6. The Engineering Standards Committee (ESC) was formed in 1901, under the principle that agreed technical standards for the manufacture of goods and services would speed up production and reduce costs. The ESC's remit was extended in 1918, and it became the British Engineering Standards Association. In 1929, the Association was incorporated by Royal Charter. By a Supplemental Charter in 1931, the name of the Association was changed to the British Standards Institution, which reflected the expansion of the type of work undertaken by the Association for different industries.

7. As BSI has grown and evolved over time, the Royal Charter has been amended several times. BSI's present Charter was granted on 1 April 1981 (**GT1/1 [INQ000538166]**) which incorporates a collection of Byelaws. In broad terms the document sets out BSI's purpose and defines the range of activities that it can conduct.

Primary purpose and function of the Institution

8. Article 3 of the Royal Charter sets out the objects and purposes for which BSI is constituted:

   a) *to co-ordinate the efforts of companies and persons for the improvement, standardization and simplification of materials, products and processes, so as to simplify production and distribution, and for the improvement, standardization and simplification of systems for the management of business, safety, technology, services and the environment and to eliminate the wastage of time and material involved in the production of an unnecessary variety of patterns and sizes of articles for one and the same purpose;*

   b) *to set up, sell and distribute standards of quality for goods, services and management systems and prepare and promote the general adoption of British and international standards and schedules in connection therewith and from time to time revise, alter and amend such standards and schedules as experience and circumstances may require;*

   c) *to register, in the name of the Institution, marks of all descriptions, and to provide and affix or licence the affixing of such marks or other proof, letter, name, description or device;*

   d) *to advertise, promote, sell and deliver the services of systems assessment, registration, product and materials inspection, testing and certification, training, consultancy and arbitration, provided that this object shall not be pursued in a manner that would prejudice the objects set out in paragraphs (a) to (c) of this Article;*

   e) *to take such action as may appear desirable or necessary to protect the objects or interests of the Institution.*

9. Article 6 of the Royal Charter provides that its affairs shall be managed by a Board which shall be the governing body of BSI. Article 9 provides that the Board may,

so far as it deems expedient, delegate any of its powers in accordance with Byelaws.

10. Section V of BSI's Byelaws provides for the Board to establish such Committees and Advisory Councils as may be required for the convenient administration of the work of BSI. The Byelaws provide, amongst other things, for the preparation of standards to be undertaken by committees that are representative of the respective interests of users, manufacturers, government departments and other persons or Bodies concerned with their work.

Organisational structure

11. As permitted by the Royal Charter and Memorandum of Understanding between the UK Government and BSI (**MoU**) (**GT1/2 [INQ000538175]**) BSI undertakes commercial activities. As such, BSI is organised as a global group of companies that operate in a number of jurisdictions across the world (legally known as **BSI Group**). I exhibit to this statement an organisational chart which provides an overview of the BSI Group structure (**GT1/3 [INQ000538184]**). BSI's various legal entities are organised into four business divisions, each of which offer a range of services that are distinct from each other: Knowledge Solutions, Assurance Services, Regulatory Services and Consulting Services. More information relating to the four business divisions can be found in the BSI Annual Report 2023[1].

12. Consequently BSI is a multifaceted business, however, for the purposes of this statement and in the context of procurement during the COVID-19 pandemic, the relevant divisions of BSI that will be discussed in this statement are Knowledge Solutions (and BSI's function as the NSB) and Regulatory Services (BSI's function as an assessment and certification body).[2] In understanding BSI's role in relation to the COVID-19 pandemic (and the organisation more generally), it is important to note that the activities of the NSB are entirely separate to other relevant BSI services.

[1] bsi-annual-report-2023.pdf

[2] During the Relevant Period, part of this business resided in the Assurance Services Division, however all relevant services now sit under Regulatory Services.

13. As such, I provide an overview of the function of the NSB within the Knowledge Solutions, and separately, an overview of the assessment and certification business within the Regulatory Services Division. Indeed, paragraph (xviii) of the MoU states that BSI "*must aim to ensure how it operates as NSB is clearly understood by businesses and the public, and to avoid confusion with its non-NSB commercial activities.*"

Knowledge Services: NSB

14. As stated previously, BSI's NSB activities are managed under the Knowledge Solutions Division of BSI. Activities within Knowledge Solutions include standards creation; publication and sale of British Standards and other standardization products; and policy and strategy activities. A summary of the NSB's activities include:

- The general adoption of British Standards and international standards in furtherance of improvement, simplification of materials, products and processes (per paras. 3(a) and (b) of the Royal Charter).

- International activity undertaken in the interests of BSI as the NSB.

- The development, coordination, publication, promotion, licensing, sale and distribution of:
    - British Standards;
    - Publicly Available Specification (PAS) standards in response to commercial demands;
    - other consensus standards such as BSI Flex which enables the rapid and flexible standardization in situations where ideas are developing; and
    - European standards, international standards, and any other standards document produced by the International and European Standards Organizations.

- Any other standardization work carried out as part of BSI's membership of the International and European Standards Organizations.

- Services offered in support of the implementation of consensus standards including technical assistance and advisory services (such as the work of the International Projects team) where these relate to the obligations of the NSB under the MOU between BSI and the UK Government.

- Engagement in various forms with the UK Government, industry, consumers and other stakeholders with an interest in standards.

15. The NSB's role in the development, publication and sale of standards does not extend to any enforcement role in their use and application. The standards are developed and adopted to benefit the manufacturing and development of products and services, and to guide businesses in adopting sustainable and ethical practices. It is for a manufacturer to claim conformity with a standard. Certification schemes might be offered by independent bodies in respect of published standards, though that is wholly independent of the standards-making process and BSI's activities as the NSB.

16. As a Royal Charter company, the authority for the grant of a Charter comes from the Royal Prerogative on the advice of the Privy Council. However an institution incorporated by Royal Charter is subject to the general law, self-regulating and not answerable to the Privy Council or the Privy Council Office in relation to the conduct of its internal affairs.

17. Furthermore, BSI is not subject to oversight by investors as is found in joint-stock companies. Nevertheless, it applies the principles of the Financial Reporting Council's UK Corporate Governance Code where applicable, and it has established internal governance procedures that reflect best practice.

BSI membership of other standards bodies

18. As I set out at paragraph 11, the MoU between BSI and the UK Government (latest

version signed 14 September 2024) details the Government's recognition of and appointment of BSI as the NSB of the United Kingdom. This includes BSI's activities as the UK member of the international and European standards organizations ISO (International Organization for Standardization), IEC (International Electrotechnical Commission), CEN (European Committee for Standardization) and CENELEC (European Committee for Electrotechnical Standardization). This recognition also extends to BSI's functions undertaken in connection with the European Telecommunications Standards Institute (ETSI).

19. BSI is a founder member of these bodies and plays a full role in their operation, both through participating in their governance structures and through the participation of UK technical experts in standards development activities. BSI's counterparts in these bodies are the national standardizing bodies of other countries. Their outputs (international and European standards) are the product of collective development, where BSI is responsible for coordinating the participation of independent UK experts to ensure UK industry and stakeholder views are represented. BSI is one of six top-tier members of both ISO and IEC, which means that is has a permanent seat in various governance functions. The European standards bodies CEN and CENELEC are independent of the EU, with 34 national members

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20. International and European standards are the basis for the vast majority of BSI's Standards: BSI has a longstanding policy of promoting international collaboration where possible, in line with its stakeholders' wishes. The UK's participation in international standards work is coordinated via its network of 1,200 national committees and its 13,000 volunteer committee experts, who brief and coordinate the UK delegations to international standards committees.

Impact of Brexit

21. BSI continues to provide the standards development framework that our stakeholders need to support trade nationally, in Europe and globally. This includes the ability to develop standards to support regulatory compliance in the UK, in line with autonomous regulatory policy.

22. In January 2021, a new system of designating standards for regulatory conformity purposes was introduced in the UK. This replaces the approach of the EU to cite harmonized European standards to support compliance with EU single market legislation. As EU regulations continue to apply in Northern Ireland, British Standards and ENs (European Norms) continue to provide manufacturers a route to demonstrate conformity in Northern Ireland.

23. BSI maintains UK leadership in the development of international standards, which year on year make up 95% of the adopted British Standards. It achieves this through continued membership of the international standards organizations discussed at paragraph 18, which are independent of the EU.

24. The statutes of CEN and CENELEC were modified in 2021 to reclassify the members according to whether they come from a country in the European Economic Area, or in EFTA but not in the EEA (Switzerland), or an EU accession country (e.g. Serbia) or a European country which is none of those but who has a compatible system for using standards. The members approved the new statutes and BSI's full membership of CEN and CENELEC has been confirmed. The new classification means members will retain the rights to provide chairs and secretaries to committees, to vote on standards and to adopt them.

Regulatory Services: Assessment and certification

25. Distinct from BSI's NSB activities, both organisationally and legally, BSI undertakes a range of independent assessment and certification services across a wide variety of sectors. These are provided through the Regulatory Services and Assurance Services Divisions, though the sectors of relevance to the Inquiry are serviced by BSI's medical device and product certification business areas, both of which are organisationally within the Regulatory Services Division.

26. Of relevance to the subject matter of the Inquiry is BSI's role as an EU Notified Body (**NB**) and UK Approved Body (**AB**) for Medical Devices and Personal Protective Equipment (**PPE**). The key role of an NB and AB is to undertake third-party conformity assessment to determine a product's compliance with relevant

legislation. This activity takes place under legislation that originated in the 1990's under the EU's "new approach" framework. This approach aimed to streamline and harmonise a range of EU product legislation to restrict its content to 'essential requirements', leaving technical details to the related implementation of international standards on quality and risk management. This approach moved away from a more "traditional" approach to product regulation which involved an assessment of compliance with detailed and technical legislation by government agencies.

Function of BSI as an EU Notified Body and UK Approved Body

27. NBs are EU-based conformity assessment bodies which have been appointed by EU member states and notified to the European Commission on the basis of their ability to carry out the examinations and tests required for CE marking under certain EU legislation. To qualify, they must also be independent, impartial and subject to routine surveillance.

28. BSI is designated as an NB under number of EU Regulations and Directives, including Regulation (EU) 2016/425 for personal protective equipment (**PPE Regulation**); Regulation (EU) 2017/745 for medical devices (**MDR**), and Regulation (EU) 2017/746 for *in vitro* diagnostic medical devices (**IVDR**). As an NB, the role and responsibilities of the BSI encompass a range of legal and regulatory duties, functions and powers, and those are described in further detail below.

29. It is important to explain that during the Relevant Period, BSI's NB activities were impacted by the UK's exit from the EU on 31 January 2020 and the end of the transition period on 31 December 2020. Prior to Brexit, BSI's NB activities were located in the UK and overseen by UK authorities. To allow BSI to continue to operate as an NB and provide product certification and assessment services in the EU after Brexit, BSI gained designation in the Netherlands. For a period of time, therefore, BSI operated NBs in both the UK and the Netherlands. BSI's clients were given the option of transferring their existing certificates to BSI Netherlands in order to maintain valid certification for the EU.

30. At the end of the transition period, NBs designated in the UK became ABs, operating under revised UK legislation that ensured the ongoing supply of products into the UK and introduced a new, UK-specific product marking (UKCA).

31. It is also important to note that the Relevant Period also spanned the transition of EU legislation for medical devices; certification and assessment were primarily undertaken under the Council Directive for Medical Devices 93/42/EEC (**Medical Devices Directive** or **MDD**). The delayed implementation of the MDR to May 2021 due to the COVID-19 pandemic and following the UK's exit from the EU, meant that it did not form part of the UK's "retained EU law" at the end of the Brexit transition period. As such, during the Relevant Period the UK continued to piggyback on EU legislation as at that stage, there was no UK legislation. The fact that the UK had not yet exited the EU added a layer of political challenge during the early stages of the pandemic.

32. It is still the case that CE certification provides access to the UK market across a range of product sectors. For PPE this applies indefinitely and for medical devices CE marked medical devices can still lawfully be sold within Great Britain up until either 30 June 2028 or 30 June 2030 depending on the nature of the device in question. It is possible – but not certain – that the UK Government may extend that unilateral recognition for medical devices beyond that date.

CE marking of PPE and medical devices

33. CE marking is a legal requirement to place certain products on the market in the EU. The CE mark on a product is the manufacturer's declaration that their product complies with the essential requirements of all the EU Directives and/or Regulations that apply to it. The requirements for CE marking differ across all the Directives and Regulations and may also vary for different products within a Directive or Regulation. Depending on the risk class of a product, requirements for CE marking range from a manufacturer's self-declaration against the requirements of applicable legislation up to mandatory full NB assessment of the product and associated manufacturing controls.

34. The nature of the assessment by an NB depends on the requirements within the relevant legislation and the conformity assessment route chosen by the manufacturer. For the purposes of this statement, in the following paragraphs I briefly summarise the different regulatory regimes for PPE and medical devices.

35. I have not gone into detail on the classification of products into the different regulatory regimes as extensive guidance has been produced[3]. However, as a general point of clarification, the primary function of PPE is to protect the wearer from health and safety risks, usually in healthcare settings. Medical devices are used for the diagnosis, prevention, control, treatment of mitigation of disease. As such medical devices are typically intended to protect the patient.

36. The requirements for the design, manufacturing and placing on the market of PPE are laid down in the PPE Regulation. Annex II of the PPE Regulation sets out a number of essential health and safety requirements based on a risk classification against which it is intended to protect users. Article 19 of the PPE Regulation lays down the specific conformity assessment procedures which apply to the different categories of PPE. Pursuant to this Article, category III PPE, such as products designed to protect against harmful biological agents should be subjected to a specific combination of conformity assessment procedures, which are described respectively in Annexes V, VII and VIII of the same Regulation.

37. The current regulations governing medical devices in the EU is the MDR. This EU harmonised legislation came into force on 26 May 2021. The requirements for the design, manufacturing and placing on the market of medical devices was initially laid down by the MDD. That Directive was repealed by the MDR, however the implementation of the MDR was delayed by one year due to the COVID-19 pandemic. As such, two different regulatory regimes were applicable during the Relevant Period.

38. Article 11 of the MDD and Article 52 of the MDR lay down the specific conformity assessment procedures which apply to the different risk classes of medical

[3] For example, see https://www.gov.uk/guidance/regulatory-status-of-equipment-being-used-to-help-prevent-coronavirus-covid-19.

devices. Annex I to MDD and MDR set the general safety and performance requirements (termed essential requirements under the MDD), and Annex I to the MDR sets out which medical devices must meet in order to be CE marked.

39. There may be overlap of the legislation that covers a particular product, however the primary purpose of the product is what will determine by which legislation it will be covered. Some examples of products covered by the PPE Regulation include disposable and re-usable face masks ensuring protection against particulate hazards; disposable and re-usable coveralls; and gloves and eyewear protection; which are used for prevention and protection against harmful biological agents such as viruses. Surgical masks, examination gloves and some types of gowns are products that may instead fall within the scope of the MDD (and now the MDR). Different regulatory regimes were therefore applicable to the products relevant to the Inquiry.

40. As I note above, neither the PPE nor the medical devices legislation provide any specific mandatory technical solutions or specifications for the design of the relevant products, and instead the legislation focuses on the essential requirements that products must meet in order to be CE marked. Harmonised standards developed by European standardization organisations (e.g. CEN or CENELEC) and published by the European Commission in the Official Journal of the European Union may be used by a manufacturer to demonstrate conformity with aspects of the essential requirements.

41. However, compliance with the harmonised standards is not mandatory. Manufacturers are free to choose other technical solutions provided that the specific solution which is retained ensures that its product complies with the applicable essential requirements.

42. Derogations from conformity assessment procedures may be authorised by Member States for the placing on the market and putting into service (within the territory of the Member State concerned) of individual products for which its use is for the protection of health.

Regulatory enforcement and oversight

43. In its capacity as an NB and AB for PPE and medical devices, BSI assesses compliance against the applicable legislative requirements and relevant international standards. BSI does not have responsibility for the content or design of the regulatory framework within which it operates though we support policy discussions where relevant to our role.

44. In addition, BSI does not have an enforcement role relating to the implementation of PPE or medical devices regulation. Furthermore it does not have a wider market or safety surveillance monitoring role. As set out in both the PPE Regulation and the medical devices legislation, it is the responsibility of Member States to enforce the relevant regulatory requirements. However, where any such activities relate to the investigation of a safety concern of a product with either a CE or UKCA certificate, the relevant competent authority can request information from an NB or AB to support its assessment.

45. With respect to the regulatory oversight of the medical devices NB:

- The MHRA is an executive agency sponsored by the Department of Health and Social Care and regulates, among other things, medical devices in the UK. Pre-Brexit and during the transitional period when BSI was an EU NB in the UK for the purposes of the MDD, the MHRA was the designating authority. The MHRA provided oversight of BSI's competence and capabilities under the MDD as well as having wider responsibility as the competent authority responsible for surveillance and enforcement in the UK.

- Following the transitional period and the designation of BSI Netherlands as a new NB, the Health and Youth Care Inspectorate (**IGJ**), a governmental institution that supervises public health in the Netherlands, provided, and continues to provide oversight of BSI's operations in NL including its competence and capabilities under the MDD, and latterly the MDR. The MHRA remains the designating authority for BSI in its capacity as a medical devices AB.

46. With respect to the regulatory oversight of the PPE Notified Body:

- The Health and Safety Executive (HSE) has a duty to enforce the PPE Regulations in Great Britain. The Department for Business and Trade (DBT) is the designating authority.

- In the Netherlands there are two supervisory authorities that deal with the market supervision of PPE. The Dutch Food and Consumer Product Safety Authority (**NVWA**) supervises compliance with the PPE Regulation for consumers. The Dutch Labor Inspectorate SZW, (now the Netherlands Labour Authority, Nederlandse Arbeidsinspectie) is the supervisor of PPE for professional users.

47. Once an organisation has been designated as an NB or AB it is subject to regular surveillance by the relevant regulatory authority to determine compliance with the requirements of the relevant legislation. In practice, this means that the relevant authorities in the EU and UK subject BSI to a range of different types of assessment and audit conducted by its assessors. The aim of this surveillance is to confirm that BSI performs at the appropriate level of competence and within the scope of its designated activities.

Fit testing

48. As a point of clarification, BSI does not have any role or responsibility in relation to fit testing of the PPE products that it certifies, and it does not provide bespoke PPE. This is the responsibility of the employer of the individuals being provided with PPE.

49. As discussed in Section 1, BSI has a role in the development of PPE standards, however its work in this capacity is entirely separate to its work undertaken by its assessment and certification business. BSI does provide an accredited training programme to support employers in fulfilling their relevant obligations.

SECTION 2: DURING THE PANDEMIC

50. BSI's role did not change during the Covid-19 pandemic with respect to any of its business operations. However, BSI took steps to assist in the response to the pandemic in a number of ways, both from the NSB perspective and in its role as a certification body.

Actions taken by the NSB

51. From February 2020, BSI made publicly available a suite of risk management and business continuity standards, to assist businesses in their response to the pandemic. Between February and June 2020, 102 standards were made available free of charge. A table appended to this statement (**GT1/4 [INQ000538185]**) details the name and reference of these standards, and the date at which they were made available free of charge (where this data is available). The table allocates the standards into nine separate themes:

- Ventilators
- Continuity and resilience
- Risk management
- Community resilience
- Emergency management
- Quality management systems
- In vitro diagnostic test kits
- Personal protective equipment
- Hygiene

52. BSI made these standards available in response to requests from various sources, including requests from the UK Government; European / International Standards Organisations (CEN, CENELEC, ISO, IEC); and requests from individuals and organisations. Various requests from individuals and organisations were ratified by the UK Government. There were instances where individual requests from individuals and organisations were not ratified by the UK Government for inclusion to be made available. In these cases, BSI shared with the inquirer an individual copy of the standard from BSI, free of charge, but it was not made available for

free access to the wider population.

53. The aim of making certain standards available free of charge was to provide organisations with access to best practice guidance and the collective input of experts on how to approach and manage some of the difficulties faced during the pandemic. The BSI Marketing Team provided a landing page for businesses to be able to download the standards.

54. All freely accessible standards were made available for a 12-month period and after this time the relevant standard reverted to a paywall. I understand that our decision to do this was influenced by CEN/CENELEC/ISO/IEC decisions to withdraw their mandate for free standards. There were approximately 124,000 downloads of the free standards while they remained freely available.

55. During the pandemic, rapid and flexible standardization was required to meet an urgent market need that required multiple iterations due to the fast-developing situation. There were certain amendments made to existing standards in reaction to the circumstances during the Relevant Period. In addition and as set out in Section 1 of this statement, in response to commercial demands, BSI also produces commissioned standards products. BSI provides two main routes for organizations and industries that want to sponsor the development of a new standard: PAS is best suited to areas where new concepts are becoming widely accepted and minimal change is expected. BSI Flex is designed for emerging areas where there is a lower level of certainty, and good practice needs to evolve through a series of iterations. These products are commissioned by individual organizations and trade associations to meet their needs for certain standardized specifications, guidelines, or codes of practice. Because they are not subject to the same consultation and consensus requirements as formal standards, the lead time for development is shorter.

56. In order to help organizations adapt quickly to COVID-19 and protect public health, two specifically relevant documents were created during the early stages of the pandemic:

- The Flex on Safe Working Guidelines (Flex 45005)
- The Flex on Community Face Coverings (Flex 5555)

57. Employers had a responsibility to protect their workforce from the virus and ensure the wellbeing of the wider public. There was no precedent for "safe" working under COVID-19 conditions, and a consensus was required to develop such a precedent.

58. The first version of Flex 45005 was available within weeks of the project initiation. This was followed by a number of new iterations and updates as new scientific evidence emerged. In total, BSI published three versions of Flex 45005 over the summer of 2020 (**GT1/5 [INQ000538186]**). Following this, the Flex was then withdrawn and replaced by ISO/PAS 45005 Occupational health and safety management — General Guidelines for Safe Working During the COVID-19 Pandemic — which BSI was heavily involved in developing.

59. The Flex Standards were written in accordance with BS drafting rules, and followed the BSI Principles of BSI Flex standardization, BSI Flex 0 v2.0:2022-08. This means that the content must be technically robust and cannot be technically constrained (*i.e.* it cannot include patented or proprietary methods or products). It is written unambiguously and with objectively verifiable requirements or recommendations. The documents cannot conflict with, or contradict, existing or draft work within the formal standards arena and must complement, not conflict with, any legislation in the subject area.

60. In January 2021 in response to an urgent request from the Cabinet Office, BSI developed Flex 5555 on Community Face Coverings (**GT1/6 [INQ000538187]**). This BSI Flex specified the minimum performance requirements and associated test methods for face coverings intended for the general public. Community face coverings were not subject to a mandatory conformity assessment by Approved Bodies or laboratories, and their design and production quality control remained the producer's responsibility. The Flex did not apply to PPE or medical grade face masks. Prior to the development of Flex 5555, BSI had published a BSI guide to

masks and face coverings for use in the UK, which described the different types of face coverings along with the applicable standards and regulations (**GT1/7 [INQ000538188]**).

61. In response to the COVID-19 pandemic, BSI has continued to develop new standards in the years following. I discuss these in section 4 of this statement.

62. Webinars on business continuity and crisis management were held in partnership with the Emergency Planning College (Cabinet Office Civil Contingencies Secretariat), with over 3,000 participants.

63. Guidance for FCO trade officers regarding manufacture of PPE for Covid-19 was produced to help British Embassies and High Commissions in procuring PPE supplies. It provides an overview of PPE, regulation, standards and certification along with answers to key questions that help them procure PPE that is fit for purpose (**GT1/8 [INQ000538189]**).

Actions taken by the certification and assessment business

64. As described above, BSI's relevant activities as an assessment and certification body was acting as a medical devices and PPE NB. In undertaking this role, BSI acted in accordance with regulations and standards relevant to the performance of its services. BSI also took into account the expectations of the competent and designating authorities in addition to other recommendations and guidance produced during the Relevant Period.

65. BSI also provided more general assistance to a number of government bodies, to contribute to the effort to deliver PPE and other key healthcare equipment to hospitals and the general public as quickly as possible.

66. I should also clarify that BSI did not undertake any certification activities in relation to diagnostic tests for COVID. The majority of diagnostic tests for COVID did not require certification by an NB under the applicable legislation and BSI did not certify any COVID diagnostics for self-testing.

Interactions with regulatory and public bodies

67. I have detailed how BSI's oversight bodies interact with BSI in paragraphs 45-47. In its capacity as an NB, BSI usually has formal interactions with the EU Commission approximately every 3 months. However during the Relevant Period BSI held conversations with the Commission at least every other week. The calls generally related to applications for ventilators and related equipment; Continuous Positive Airway Pressure (**CPAP**); facemasks; and PPE.

68. BSI participated in EU PPE Coordinating Groups such as the PPE Horizontal Group, and Vertical Group 2 that covered respiratory products. The purpose of this was to find coordination between notified bodies on how to approach certain aspects of the PPE Regulation.[4]

69. Before the start of the pandemic, BSI interacted with HSE, Trading Standards and OPSS through meetings such as the British Safety Industry Federation. Meetings would also be held when required to discuss specific issues. However during the Relevant Period, BSI had more frequent meetings – as often as weekly at the beginning of the Relevant Period – meetings with BEIS (including with those attending from the office of OPSS).

70. During the Relevant Period, BSI was also in close contact with NHS authorities, including in Scotland and Wales, which was later coordinated by DHSC for the testing of PPE, and these meetings were held as required for individual projects.

71. In addition, BSI had representation on a World Health Organisation group on sterilisation process for products contaminated by COVID.

PPE Testing and certification

72. On 13 March 2020, the EU Commission published Commission Recommendation (EU) 2020/403 on conformity assessment and market surveillance procedures

[4] See ppe-rfu.eu/vertical-groups.

within the context of the COVID-19 threat (**Recommendation**) (**GT1/9 [INQ000538190]**).

73. The objective of the Recommendation was to ensure the availability of relevant PPE and medical devices by requesting that all economic operators throughout the supply chain, including notified bodies and market surveillance authorities deploy "*all the measures at their disposal*" to support the efforts aimed at ensuring that the supply of relevant products throughout the EU market could match the ever-increasing demand.

74. The Recommendation set out the following with respect to conformity assessment procedures and applicable to NBs:

- NBs designated under the PPE Regulation should prioritise the conformity assessment of all newly submitted requests by manufacturers of PPE.

- In the case of PPE products manufactured following technical solutions other than harmonised standards, the WHO recommendations on the appropriate selection of PPE may be used as a potential source of reference for such technical solutions, provided they ensure an adequate level of protection corresponding to the applicable essential health and safety requirements laid down in the PPE Regulation.

- NBs issuing PPE certificates manufactured following other technical solutions than harmonised standards, should immediately inform the relevant notifying authority as well as the other PPE designated notified bodies of the certificates issued and the specific technical solution followed.
- In the case of medical devices, the possibility for Member States to authorise derogations from conformity assessment procedures should also be considered, according to Article 11(13) of the Medical Devices Directive (and Article 59 of the MDR once applicable).

75. BSI implemented the Recommendation in the following ways, which I set out in further detail in the following paragraphs:

- Any application for CE marking relating to relevant medical devices or PPE was prioritised.
- BSI implemented regulatory easements through reduced Technical Solutions to expedite the assessment process.
- BSI engaged with a number of government bodies to support the response to the pandemic in a variety of ways.

Reduced Technical Solutions

76. Testing under existing EU standards for relevant products could take months, so initially there was an attempt by Member States to collectively rationalise harmonised standards for use across the EU. However this was a laboured process, and it was difficult to reach a consensus. For the purposes of expediency, BSI undertook its own project to strip down several relevant technical specifications to support the rapid review of certain PPE equipment, particularly where there was product that has no test data, or test data that did not meet current requirements.

77. The BSI fast-track technical specifications included:

- BSI Face Mask Technical Specification (**GT1/10 [INQ000538167]**)
- BSI Clothing Technical Specification (**GT1/11 [INQ000538168]**)
- BSI Eyewear Technical Specification (**GT1/12 [INQ000538169]**)
- BSI Powered Air Technical Specification (**GT1/13 [INQ000538170]**)

78. The reduction in the requirements of the technical specification did not, however, compromise products being fit for purpose. The nature of the areas that were removed included, for example, testing that related to shelf-life and ageing of the product. BSI's reasoning for removing certain requirements was that they would not be applicable due to the rate of use of PPE being supplied by manufacturers. Another consideration was the applicability of the parameters for uses outside the healthcare environment. For example, FFP2 or FFP3 testing covers all aspects of use including in the construction environment – which was not necessary for the intended use.

79. Although the products certified against these reduced technical specifications were fit for purpose, BSI reduced the validity of the certificates to 12 months (rather than the usual 5-year validity of PPE CE certificates), and BSI made it clear that this was the case for all COVID-19-related client applications. **GT1/14 [INQ000538164]** and **GT1/15 [INQ000538165]** are examples of how this was stated on a certificate issued under these reduced specifications.

80. Reduced technical specifications were in use from approximately April 2020 until April 2021, when BSI did not accept further applications via this route.

81. BSI was transparent in communicating its technical specifications to organisations such as HSE, OPSS, DHSC and the NHS. These were communicated by email and available on the BSI website, and so they were available in the public domain.

Government engagement: COVID-19 Emergency PPE Verification Scheme for NHS Supply Chain

82. In April 2020, following an ongoing dialogue with the UK government, BSI offered its services to BEIS to provide services to NHS Supply Chain for the verification of PPE before it was released and used by healthcare workers. BSI and BEIS entered into a contract to this effect (**GT1/16 [INQ000538171]**). BSI services were offered (to the extent applicable) on its standard Terms of Service that had been approved by Supply Chain Coordination Ltd (**SCCL**) for the provision of NB services, however the fee structure was modified to reflect an hourly rate.

83. At this stage, BSI offered:

- Increased capacity of testing facilities: Initially BSI was operating normal hours at its facility in Hemel Hempstead, however following its offer to assist BEIS, BSI extended normal working hours and put in place initiatives to increase capacity including by utilising employees from other areas of the business who were on furlough. A number of these additional staff had undertaken an apprenticeship at the testing laboratories, so they had previous experience in a variety of areas for testing and further training was offered on the PPE Regulation. This was outside

the norm for BSI operations, however the products that were being tested were simple in design and function. During the Relevant Period, BSI's accredited scope for the testing of the PPE equipment included:

- *Eyewear Products*
    - Face shields to EN 166
    - Goggles to EN 166
    - Spectacles to EN 166
- *Gloves*
    - Surgical gloves
    - Examination gloves
    - PPE gloves against micro-organisms

- *Respiratory Products*
    - Filtering face masks to EN 149
    - Half mask to EN 140
    - Full face masks to EN 136
    - Filters to EN 143 and EN 14387
    - Powered air devices to EN 12941

BSI also arranged the testing of gowns and drapes through a BSI approved subcontractor.

- Sharing of test protocols: BSI also shared with BEIS the reduced technical specifications in place for certain PPE equipment that it was using for certification of products with no, or unsatisfactory, test data for use by healthcare workers. The approximate time to test against these regimes was also shared with BEIS so that BSI could give the most accurate indication of lead times.

- Advanced documentation reviews and verification for healthcare PPE products arriving into the UK, particularly gloves, clothing, eyewear and respiratory products. This was a remote review, for which the relevant team of reviewers required:
    - A copy of the user instructions that are supplied with the product
    - Image of any labels or markings on the product

- Copy of an EU Type Examination certificate
- Copy of a declaration of conformity
- Photo of the product(s)
- Test reports

84. BSI was very clear that although it was the Product Certification business that was to provide the services, this was not being offered by the NB and EU laws relating to PPE would not apply to the equipment BSI would be testing. The manufacturer's site would not be accessed, and services would either be performed remotely or at the BSI Hemel Hempstead location.

Other initiatives

85. During the Relevant Period, BSI was involved in a number of different initiatives. These included:

- Certifying face screens manufactured by The Royal Mint
- Validation of the certification on a supply of 5.2 million EN 149 masks
- Validation of test reports and certificates for face masks manufactured by Burberry and Don & Low (participants in the UK Make scheme)
- Testing of prototype materials for the Cabinet Office as part of their project to manufacture face coverings in the UK
- Ad hoc testing for NHS authorities, including testing masks post sterilisation for and issuing test reports for the results.

Medical Devices certification

Ventilator challenge

86. In March 2020 BSI formally agreed to support the Ventilator Challenge, to support the cross-government programme in accelerating new innovative ventilator designs and production. MHRA had developed a process for providing reasonable assurance of safety and performance that could be navigated in the space of weeks rather than months. This was not an approval process but rather an

approach that enabled MHRA to provide an evidence-based derogation and time limited exemption to the MDD, and the requirement for CE marking.

87. BSI assisted by publishing an analysis of ISO 13485:2016 which is required for medical device Quality Management Systems (**QMS**), compared with QMS requirements in other sectors – specifically safety critical industries including aerospace, defence and F1 (ISO 9001 (aerospace) and ISO 16949 (automotive) (**GT1/17 [INQ000538172]** and **GT1/18 [INQ000538182]**).

88. BSI mapped differences and published an analysis of the gaps that would need to be addressed in order to fulfil ISO 13485, such as cleanliness and traceability. This enabled manufacturers and auditors to focus their QMS efforts. BSI also assisted in evaluating ventilators with novel design such as those produced by 3D printing.

Derogations

89. BSI provided assistance to MHRA and IGJ by supporting their decision-making on certain requests for derogation from regulatory requirements. This included, for example, reading test reports; assessing whether a manufacturer had a post-market surveillance system in place; or whether other vigilance requirements were met. This was done purely on the basis of safety, and as BSI had not carried out a full conformity assessment it could not issue a certificate. There was nothing formal issued to MHRA or IGJ in this respect and confirmations were given in email correspondence.

Specific challenges to BSI

Development of the cottage industry

90. One of the main challenges to BSI was the sheer volume of PPE and devices it was receiving for which it needed to provide assessment. The market for PPE products grew very quickly, with a number of manufacturers attempting to bring products to market with little idea of the regulatory requirements. As a result, around 80% of PPE that was assessed by BSI was not fit for purpose.

91. In April 2020, BSI met with OPSS to discuss its concerns about the well-intended "cottage industry" that was emerging in the manufacture of PPE. BSI began to see schools, universities and other individuals and organizations taking the initiative to support the production of PPE with no previous experience in this field. Whilst BSI recognised this as a laudable effort, it was clear that there were issues with the design of the products and the materials used.

92. In response to this, BSI produced a guide to support these initiatives, which was designed to explain step-by-step how PPE should be produced and tested, and how to obtain appropriate certification to ensure the product was safe and effective when being used in a health and social care environment (**GT1/19 [INQ000538174]**). BSI intended for this to complement the guidance that had already been issued by the UK Government.

Counterfeiting and falsification

93. With the market in desperate need of the relevant equipment, certification falsification also rose steeply due to an influx of imports from countries outside of the UK, notably China and Pakistan. There was a contact in every NB to check the validity of a certificate. BSI set up a dedicated compliance team in the UK and the Netherlands to ensure it could respond within a day or two of receiving a query (**GT1/20 [INQ000538176]**).

On-site auditing

94. During the initial stages of the pandemic, restrictions on travel and face to face contact provided challenges for BSI as onsite auditing is mandated in legislation and has been a cornerstone of how NBs fulfil their responsibilities. Whilst some certification work was delayed, for some products it was critical that BSI undertook its audit and assessment work to allow certification. BSI engaged with regulators to agree how and when remote auditing of manufacturing sites could be utilised to support this, which focused on prioritisation on the devices where there was an urgent need at the time. A Business Continuity Plan (**GT1/21 [INQ000538177]**) was drafted which contains some discussion of how BSI dealt with this issue at the

time.

95. During the Relevant Period, applications were being received under the new MDR. Some of the first MDR certificates issued by BSI were for Class Is[5] masks and gloves. By way of example, in August 2021 Class Is products accounted for almost 40% of the certificates issued and a number of these products were certified without conducting onsite audits. BSI had judged that for these types of Class Is devices, sterilisation validation is entirely appropriate if the manufacturer has a relevant QMS in place.

Supply chain issues

96. BSI identified certain issues in PPE supply chains for which it attempted to offer solutions. For example, it found a that there was a delay in the lead-times for testing of gowns due to a lack of UK capacity for testing to the ISO 16604 standard on bacterial penetration. BSI had proposed to DHSC that it would be able to facilitate a connection to labs in the UK that could be approved to do this.

97. BSI also found that PPE being released had no uniform clearance procedures, and there were delays in getting permission to test product at BSI labs due to a lack of coordination between government agencies. An example of this was receiving NHS samples to the BSI Hemel Hempstead facility but work had still not commenced three days later as it had not received the go ahead to do so.

98. BSI also noted that there were a number of non-compliant products being placed on the market. It was vital that an acceptable level of assurance is provided to any PPE so that it provided the level of protection expected by the user. This was a

[5] As noted previously, a medical device is classified into either class I (which is further subdivided), IIa, IIb or III depending on the risk it presents, with class I carrying the lowest risk. The classification of a device does not have any effect on the general safety and performance requirements with which manufacturers must comply. However the class will determine which conformity assessment procedure is required. An NB is not involved in the conformity assessment procedure for class I devices. However Class Is, Ir and Im are exceptions to this, and these devices require the involvement of an NB. Class Is devices are devices placed on the market in a sterile condition.

particular challenge for 3D-printed equipment. Again, BSI recommended that manufacturers use the Guide for PPE for non-PPE manufacturers, which is referred to above.

BSI's position on the sufficiency of FFP2/FFP3 masks to prevent the spread of COVID-19

99. As explained previously, BSI's role in certification is to assess a product to be safe and effective against the requirements of relevant legislation.

100. The technical specification BSI created for testing respiratory products was based on the requirements of an EN 149 FFP2 classification mask. This in turn was based on guidance documents from organisations such as the NHS, WHO and HSE, which deemed FFP2 masks as adequate in a COVID environment. BSI also applied other international standards such as ASNZ 1716, GB 2626 and NIOSH when considering the content of its technical specification.

101. This position remained constant throughout the time BSI issued certificates under the EU Recommendation.

Escalation of concerns and complaints

102. As mentioned previously in this statement, BSI's role as an assessment and certification body is to act in accordance with the regulation and standards relevant to the performance of its services. During the Relevant Period, BSI's actions were informed by EU and UK recommendations, guidance, or indeed from the regular meetings it was having with both the UK government and other oversight bodies. However, BSI would escalate concerns where it felt that additional consideration was due.

103. For example, on 16 November 2020, BSI emailed BEIS and HSE (**GT1/22 [INQ000538178]**) regarding the latest Essential Technical Requirements for New High-Volume Manufacture of PPE and Medical Devices that had been published in October 2020 (**GT1/23 [INQ000538181]**). BSI wished to escalate that the

document now included aprons, but the wording in the document had reverted to the text for gowns used prior to it being corrected in early May (**GT1/24 [INQ000538182]**).

104. The main issue was that the specification issued in October 2020 reverted to a situation which was untenable, and would permit surgical gowns to be specified and worn as PPE, although they may not act as effective barrier to infective agents or be sufficiently robust to ensure protection. BSI pointed out that EN 13795 was not a PPE standard, and this was clearly stated within the document. If garments are recommended and used without the correct PPE conformity assessment against a COVID-19 hazard, it was possible that the wearer would be placed at risk, and the health and safety legislation current during the Relevant Period would not be met.

105. BSI's concerns resulted from a number of enquiries for CE marking for surgical gowns that clearly did not meet the requirements of Category III PPE against 'harmful biological agents'. It was also receiving enquiries for the off the roll plastic aprons, which were unlikely to be sufficiently robust to be used as primary PPE.

106. BSI did receive a number of its own complaints during the pandemic, but these were generally related to customer service and turnaround timescales. When BSI failed products, test results were sometimes challenged by manufacturers. All complaints that are received by BSI follow an internal procedure in which they are logged on BSI's internal systems and investigated accordingly.

SECTION 3: LIAISON WITH REPRESENTATIVE BODIES

107. BSI did not liaise directly with representative bodies such as the Royal College of Nursing or the British Medical Association. All communication relating to the actions of the NB or support in rapid production of relevant medical devices was with BSI's oversight bodies, and in particular MHRA.

108. BSI was, however, in frequent contact with BSIF during the pandemic. From May 2020, BSI chaired the BSIF Test and Certification committee (BSIF Committee).

The BSIF Committee met on numerous occasions during the Relevant Period. Members of BEIS and OPSS were also in attendance. The BSIF was active in an advisory role to government departments, and BSI was involved in this engagement via the BSIF Committee.

109. BSI is not aware of any concerns raised by any representative body regarding standards and compliance in relation to PPE or medical devices. There were discussions regarding the concerns around counterfeit PPE and falsified PPE certifications (as set out at paragraph 93 of this statement), however BSI had its own internal processes with dealing with these issues.

SECTION 4 – LESSONS LEARNT

110. BSI did not conduct any formal internal or external reviews following the pandemic. However in its capacity as an NSB and as discussed in section 2 of the statement, certain relevant standards were updated or developed during the Relevant Period. In addition to this and in direct response to the pandemic, in subsequent years a number of new standards have been developed relating to healthcare organisation management and facility management on emergency preparedness and management of an epidemic (**GT1/25 [INQ000538183]**).

111. In its capacity as a certification body, BSI does not have a role with respect to the regulation or the setting of standards for PPE and medical devices, so in the event of future pandemic or epidemic, it would implement strategies as determined by its regulators. That said, the introduction of remote auditing during the Relevant Period is a concept that has persisted, both with respect to regulators' continued consideration on what could be incorporated into the future UK medical devices legislation, but also one that has been implemented to some extent into BSI's operations.

112. At the present time, it remains a mandatory requirement in the EU and UK for NBs and ABs to carry out onsite auditing in order to meet regulatory requirements. As such, fully remote audits would only be used where there are certain constraints such as the inability to access a site or where travel restrictions are in place (for

example, in the event of another pandemic).

113. However following the solid learnings and evidence around the use of immersive technologies during the Relevant Period, BSI has developed a formalised programme and implemented standardised processes and procedures to deliver hybrid audits. A hybrid audit is where an audit is partially performed off-site using ICT while at least one auditor qualified under the certification scheme is onsite during a portion of the audit. The audit is delivered simultaneously with a proportion delivered in person onsite.

114. The use of hybrid auditing remains entirely at the discretion of the manufacturer being subject to the audit. However there are number of benefits to hybrid auditing. For example, BSI uses specialist reviewers who are technical experts in the device being reviewed. The auditor resourcing process can be more effective as it reduces scheduling challenges due to the geographical location of people with the specific expertise. Using a hybrid process allows qualified experts to assist, regardless of their location.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

Signed. PD

Dated: 24th January 2025