**Witness Statement of Graeme Tunbridge**

**Statement No 1**

**Exhibits: GT1**

**Dated: 24 September 2026**

**IN THE LAMPARD INQUIRY**

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**WITNESS STATEMENT OF GRAEME TUNBRIDGE**

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I, Graeme Tunbridge, Senior Vice President, Global Regulatory and Quality, of British Standards Institution, Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, will say as follows:

**Introduction and professional background**

1. I am the Senior Vice President, Global Regulatory and Quality at the British Standards Institution (“BSI”). My responsibilities include BSI’s regulatory compliance in undertaking a range of global medical device certification activities.

2. 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. I first joined the MHRA in 2011 and during my time there I held several roles relating to the regulation of medical devices. This included developing and implementing the legislative framework for medical device regulation, initially when the UK was part

of the European Union and subsequently after the UK had exited the European Union.

3. I make this statement in response to a request for evidence by the Lampard Inquiry, made pursuant to Rule 9 of the inquiry Rules 2006, dated 21 August 2026 (the "Request"). The scope of the inquest for which we are providing information relates to the circumstances surrounding the deaths of mental health inpatients under the care of NHS Trust(s) in Essex between 1 January 2000 and 31 December 2023 (the "Relevant Period"). BSI's evidence focuses on the role and function of BSI as a certification body, and its assessment and certification of the Oxevision Sleep System.

4. The statements which I make in this witness statement are either from my own knowledge or derived from documents or 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.

**Overview of BSI**

5. BSI is organised as a global group of companies that operates in a number of jurisdictions across the world ("BSI Group"). In the UK, the British Standards Institution is a company incorporated by Royal Charter which empowers it to fulfil the role of the UK's National Standards Body and to undertake related activities. That is a role appointed by the UK Government to develop British Standards and represent the UK's interests in standards development at both a European and global level.

6. In addition, BSI Group undertakes a range of activities including standards development, testing, inspection, certification and regulatory compliance services. In the medical devices sector, BSI operates a range of regulatory schemes. Most relevant to this Inquiry is BSI's role as a conformity assessment body within both

the European Union and the United Kingdom.

7. The legal basis for BSI's conformity assessment activities derives from the relevant medical device legislation and the designation frameworks established by regulators. In the European Union, Notified Bodies are designated by Member States and notified to the European Commission on the basis of their competence to undertake conformity assessment activities. Designation as a Notified Body empowers BSI to assess and certify compliance with the current Regulation (EU) 2017/745 on medical devices ("EU MDR"), and previously under the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ("Medical Devices Directive" or "MDD") by issuing a CE certificate, which allows the relevant device manufacturer to place their product on the market in the EU. BSI is one of a number of different Notified Bodies, and device manufacturers can approach any suitably qualified Notified Body for assessment and certification of their products.

8. Prior to the United Kingdom's exit from the European Union, BSI operated its medical device assessment and certification business as an EU Notified Body under the MDD. The Notified Body's functions and responsibilities were discharged through its separate legal group entity, BSI Assurance UK Limited. The MHRA was the designating authority for the purposes of the MDD, providing oversight of BSI's competence and capabilities under the MDD.

9. So as to continue to provide medical device certification and assessment services in the EU after Brexit, BSI applied for designation of a separate entity, BSI Group The Netherlands B.V. as an EU Notified Body. BSI Group The Netherlands B.V. was designated by Health and Youth Care Inspectorate, *Inspectie Gezondheidszorg en Jeugd*, ("IGJ"), the Competent Authority in The Netherlands. Correspondingly, BSI Assurance UK Limited became a UK Approved Body under the UK Medical Devices Regulations 2002 ("UK MDR 2002"). In the United Kingdom, Approved Bodies are designated and supervised by the MHRA. As such, BSI undertakes conformity assessment activities within two closely related but legally distinct regulatory systems.

10. Both regimes require conformity assessment bodies to operate independently, impartially and with appropriate technical competence. Under both regimes, BSI is subject to ongoing regulatory oversight of its separate designating authorities: both MHRA and IGJ audit and assess the relevant Quality Management System ("QMS") and associated operational procedures for each regime respectively. That includes a process of ongoing audit. The designating authority request and review a sample of our policies and procedures as part of any audit of the Notified Body and the Approved Body to ensure BSI's approach is fit for purpose.

**Functions and role of the BSI as an EU Notified Body and a UK Approved Body**

11. As an EU Notified Body, BSI assesses medical devices against the requirements of the EU MDR and where applicable, legacy devices certified under the MDD. As a UK Approved Body, BSI undertakes similar activities under the UK MDR 2002. In carrying out its conformity assessment activities, BSI undertakes a range of functions. These include assessment of a manufacturer's quality management system; review of technical documentation, risk management files and clinical evaluation reports; assessment of post-market surveillance and vigilance systems. The processes followed by the BSI to assess medical devices are highly technical in nature, and so I did not consider it proportionate to address them fully in this witness statement. Instead, I provide below a brief outline of how BSI will undertake conformity assessment.

12. It is important to note that BSI does not undertake independent product testing as part of the conformity assessment process. Rather, BSI independently evaluates the adequacy, relevance and sufficiency of the evidence presented by the manufacturer against the applicable regulatory requirements. If BSI concludes that the manufacturer has demonstrated conformity with the applicable requirements, certification may be issued. Within the EU this may result in the issuance of a CE certificate by a Notified Body. Within Great Britain this may result in the issuance of a UKCA certificate by an Approved Body. Certification confirms that, based upon the evidence reviewed and the conformity assessment undertaken, the manufacturer has demonstrated compliance with the applicable regulatory

requirements. Where the available evidence is considered insufficient to support the manufacturer's claims, BSI may require further justification, additional evidence or corrective actions before certification can be granted or maintained.

**Overview of Conformity Assessment**

13. Conformity assessment is an evidence-based system in that the manufacturer is responsible for generating, maintaining and presenting information to demonstrate compliance, and BSI's role is to independently evaluate that evidence to determine whether it adequately conforms with the legislative requirements. The manufacturer may adopt harmonised standards, designated standards and other recognised guidance documents to demonstrate compliance. Compliance with such standards may, in certain circumstances, provide a presumption of conformity with aspects of the legislation.

14. The depth of BSI's assessment will depend on a number of factors, including the risk classification of the relevant device. Under both UK and EU legislation, medical devices are classified according to the level of risk they present. Medical devices are classified into four risk groups depending on the risk, from low risk to high risk: I, IIa, IIb, and III. The manufacturer is responsible for applying the classification rules, which are determined by the products' intended use. In addition to risk classification, the extent of the assessment will be determined by the conformity assessment route chosen by the manufacturer, and any previous certification that the device holds.

15. The conformity assessment process typically begins with an evaluation of the manufacturer's QMS. The manufacturer is required to establish and maintain processes and procedures that ensure devices are consistently designed, manufactured and controlled in accordance with applicable regulatory requirements. Manufacturers will typically adopt ISO 13485, an internationally recognised standard, to support their quality management systems, although compliance with regulatory requirements may also be demonstrated through other acceptable means. Overall the QMS covers a broad range of areas, and a content

overview of ISO 13845 which sets out the component parts is available on the International Organisation for Standardization's ("ISO") website.[1]

16. In addition to assessment of the manufacturer's QMS, BSI may review technical documentation relating to the device. Technical documentation may include information relating to device design, intended purpose, manufacturing processes, risk management, verification and validation activities, clinical evaluation, labelling, instructions for use, post-market surveillance and vigilance arrangements. The nature and depth of that review will again depend upon the conformity assessment route, device classification and applicable legislation. It is typical that for lower risk devices, sampling of technical documentation is used where more than one device is included in the certification scope.

17. Where the conformity assessment route requires the review of clinical evidence, BSI evaluates whether the clinical data presented by the manufacturer adequately supports the claimed safety and performance of the device for its intended purpose. Depending on the circumstances, manufacturers may rely upon a combination of clinical investigations, published literature, post-market experience and other forms of clinical evidence permitted by the regulatory framework.

18. BSI may also consider information derived from sources other than the manufacturer where relevant to the conformity assessment. Depending on the circumstances, this may include published scientific literature, harmonised standards, recognised guidance documents, post-market information, experience with comparable technologies and information received from competent authorities. Such information may form part of the overall assessment or provide context for evaluating the manufacturer's evidence. However, the primary focus of the conformity assessment remains whether the manufacturer has adequately demonstrated compliance with the applicable regulatory requirements.

[1] For more information, please see: https://www.iso.org/obp/ui/#iso:std:iso:13485:ed-3:v1:en

Assessment of intended purpose

19. The conformity assessment process also requires consideration of the manufacturer's intended purpose for the device. These concepts are fundamental to the regulatory framework because they determine, amongst other things, the classification of the device, the regulatory requirements that apply to it and the evidence that must be provided to demonstrate conformity. The intended purpose is determined by the manufacturer and is reflected in the device's labelling, instructions for use, technical documentation and associated claims regarding the device.

20. As part of the conformity assessment process, BSI reviews whether the intended purpose defined by the manufacturer is supported by the technical and clinical evidence presented. This includes consideration of whether the manufacturer's claims regarding the device are internally consistent, whether the evidence cited is relevant to the intended purpose and whether the evidence is sufficient to demonstrate conformity with the applicable safety and performance requirements.

21. In that context, BSI evaluates whether the device appears capable of achieving its intended purpose based on the evidence provided by the manufacturer. However, it is important to distinguish this assessment from a determination that a device is the optimal solution for a particular clinical need, or that it will necessarily achieve a desired outcome in every clinical setting or patient population. Those judgments extend beyond the scope of conformity assessment and depend upon a range of factors including clinical practice, patient selection, local procedures and the manner in which the device is used in practice.

Risk management

22. With respect to risk in particular, the legal manufacturer is responsible for carrying out a risk management evaluation in line with applicable legislation. In order to meet the relevant obligations, legal manufacturers are assisted by harmonised standard ISO 14971 (Medical devices – Application of risk management to medical devices) in producing a risk management system ("RMS"). ISO 14971 provides a

framework for manufacturers to identify hazards, assess risk, put control measures in place and monitor the effectiveness of risk controls throughout a product's lifecycle. As such, the legal manufacturer is required to determine the risk acceptance criteria for the medical device it brings to market and ensure that the clinical benefit attributable to the device outweighs any identified risk.

23. As is evident from the above paragraphs, the level of scrutiny applied by a Notified Body or Approved Body is not identical for every device: higher-risk devices are generally subject to greater levels of individual product assessment whereas under some conformity assessment routes, particularly those for lower-risk devices, certification may be based on assessment of the manufacturer's QMS together with sampling of technical documentation from representative devices within a product family. Accordingly, conformity assessment does not necessarily involve a product-by-product assessment of every device covered by a certificate. This framework establishes a proportionate, risk-based approach to conformity assessment, which reflects a fundamental principle of cross-industry global regulatory frameworks.

24. It is also important to recognise the limitations of certification. Certification does not constitute a guarantee that a device is free from risk, nor does it represent approval of every possible use of a device in clinical practice. It does not replace the responsibilities of healthcare providers when determining whether and how a device should be used in a particular healthcare setting. Similarly, certification does not displace responsibility from the manufacturer, which remains responsible for the safety, performance and regulatory compliance of the device throughout its lifecycle. Rather, certification reflects a determination that the evidence presented by the manufacturer demonstrates conformity with the applicable regulatory requirements at the point of assessment.

Post-Market Oversight by BSI: surveillance audits

25. To ensure continued compliance following certification manufacturers remain subject to ongoing surveillance activities. These activities are intended to verify

continued conformity with the applicable legislation and to ensure that certification remains justified throughout the lifecycle of the device. The activities may include periodic quality management system audits, technical documentation reviews, recertification assessments, review of vigilance information and field safety corrective actions, and unannounced or for-cause audits where circumstances warrant further scrutiny. Where concerns arise, BSI may request additional information, undertake further assessment activities, impose conditions, restrict certification, suspend certification or withdraw certification, depending on the circumstances and the powers available under the relevant regulatory framework.

26. Post-market audits and technical document reviews for low-risk devices continue to apply the principle of proportionality, meaning that device groups rather than each individual device within a particular group are reviewed. Both regimes require that technical documentation for one device within each group is sampled at initial certification and thereafter once every five years during the certificate lifecycle. This means there may be multiple devices within a group for which their technical documentation has not been reviewed at any given time.

**BSI's role in relation to wider patient safety and regulatory functions**

27. As described above, BSI's role is that of an independent conformity assessment body operating within the medical device regulatory framework. BSI's role does not encompass responsibility for the broader operation of healthcare services, clinical decision-making, procurement decisions or the delivery of patient care. Those functions are undertaken by other organisations operating within the healthcare and regulatory system.

28. In relation to patient safety and emerging risks associated with medical technologies, the regulatory framework assigns primary responsibility to the legal manufacturer and the relevant competent authority. Manufacturers are responsible for designing devices, managing risks, generating clinical evidence, undertaking post-market surveillance, monitoring real-world performance and implementing corrective actions where safety concerns are identified. Competent authorities are

responsible for market surveillance, investigation of safety signals, regulatory enforcement and wider protection of public health. Healthcare providers also have important responsibilities in relation to the selection, deployment and use of medical devices within clinical practice.

29. BSI does not consider itself to hold primary responsibility for assessing the wider patient care implications of new technologies deployed within healthcare systems, nor for determining how such technologies should be implemented within particular healthcare settings. Whilst BSI assesses whether a device meets the applicable regulatory requirements relating to safety and performance, decisions regarding procurement, deployment, patient selection, clinical workflows, staffing models, patient observation procedures and the broader clinical impact of a technology are generally matters for healthcare providers and healthcare professionals.

30. Similarly, BSI does not hold primary responsibility for identifying and responding to emerging safety issues at a population level once devices have been placed on the market. Within the UK, these functions principally sit with the MHRA, which has statutory powers relating to market surveillance, investigation of safety concerns, regulatory intervention and enforcement. Comparable responsibilities are exercised by competent authorities of EU Member States in relation to devices placed on the EU market.

31. It is also relevant to consider the scope of BSI's role within the wider regulatory system. BSI is one of a number of designated conformity assessment bodies operating within the European and United Kingdom regulatory frameworks. Manufacturers are generally free to select any appropriately designated Notified Body or Approved Body with the relevant scope of designation when seeking conformity assessment services. Consequently, no single conformity assessment body has visibility of, or responsibility for, all devices placed on the market, nor for all devices deployed within the health service. Rather, each Notified Body or Approved Body is responsible only for those certificates that it has issued and the associated surveillance activities required under the applicable regulatory framework.

32. This distinction is particularly important in the UK: under current transitional arrangements established by the UK Government, many devices may be lawfully placed on the market in Great Britain on the basis of CE certification issued by any appropriately designated EU Notified Body, without requiring assessment or certification by a UK Approved Body. As a result, a substantial proportion of devices available for use within the UK will never have been assessed by BSI. Responsibility for market-wide oversight, identification of emerging safety concerns across different manufacturers and certification bodies, and regulatory intervention where necessary therefore sits with the competent authority, the MHRA in the UK, rather than with any individual conformity assessment body. The MHRA is uniquely positioned to exercise these functions because of its visibility across the entire market and its statutory enforcement powers.

33. That said, BSI does have specific responsibilities that contribute to the wider regulatory oversight framework. As I set out in paragraph 25, following certification, BSI undertakes surveillance activities intended to verify continued compliance with the applicable regulatory requirements. These activities may include quality management system audits, technical documentation reviews, review of post-market surveillance information and consideration of vigilance-related information submitted by manufacturers. Information obtained through these activities may result in additional assessment activities, requests for information, review of corrective actions or, where appropriate, regulatory action relating to certification.

34. BSI also reviews information received from manufacturers, competent authorities and other sources where that information may be relevant to the ongoing validity of certification. However, BSI's assessment is directed towards determining whether the manufacturer continues to comply with the applicable regulatory requirements and whether certification remains justified. It is not responsible for the operation of national vigilance systems, direct investigation of safety incidents across healthcare systems or the exercise of statutory enforcement powers.

35. The Inquiry has also asked about the extent to which NHS Trusts or other providers may rely upon certification when making decisions regarding procurement or

deployment of medical technologies. In BSI's view, certification provides evidence that a manufacturer has demonstrated conformity with applicable regulatory requirements and that the device may lawfully be placed on the relevant market. Certification therefore forms an important element of the information available to healthcare providers when considering the use of medical devices. However, certification should not be interpreted as a substitute for a provider's own assessment of clinical need, operational suitability, information governance considerations, local safety requirements or the appropriateness of a device for a particular patient population or healthcare setting. Such decisions fall outside the conformity assessment process and remain matters for the organisations responsible for delivering care.

36. Regarding the extent to which BSI's role overlaps with or relates to the role of MHRA, BSI's role also sits alongside, but is distinct from, that of the MHRA. Whilst both organisations form part of the broader medical device regulatory system, their responsibilities are different. BSI undertakes conformity assessment and certification activities as a designated conformity assessment body. The MHRA acts as the competent authority and regulator responsible for market surveillance, enforcement and oversight of Approved Bodies operating within the United Kingdom. In addition, the MHRA exercises powers relating to the investigation of emerging safety concerns and may take direct regulatory action where necessary to protect public health. BSI and MHRA therefore fulfil complementary but distinct functions within the overall regulatory framework.

37. Finally, BSI's work necessarily interfaces with that of a range of other organisations. Depending upon the circumstances, BSI may receive information from, provide information to, or take account of information generated by competent authorities, manufacturers and other relevant organisations. However, BSI does not rely upon organisations such as NHS England, the Care Quality Commission, NICE or the Department of Health and Social Care to perform its conformity assessment activities. Rather, each organisation performs its own distinct statutory or operational functions within the broader healthcare and

regulatory ecosystem. Whilst the outputs of such organisations may provide broader context regarding healthcare delivery, policy or clinical practice, responsibility for conformity assessment and certification remains with the designated conformity assessment body, while responsibility for healthcare delivery, policy, market surveillance and enforcement remains with the organisations charged with those functions.

**Assessment and certification of Oxevision Sleep System**

38. To assist the Inquiry, I have set out below a general chronology of Oxehealth Limited's contractual relationship and certification history with BSI. We understand that Oxehealth Limited has recently rebranded its business and now uses the trading name LIO. Oxehealth Limited has not yet submitted a change notification to BSI in order that this can be assessed to ensure that this is a cosmetic change and there are no changes to the manufacturer's QMS. As such, BSI certification remains held with the legal manufacturer Oxehealth Limited.

39. For completeness, it is important to note that BSI did not certify the Oxevision Sleep System device during the Relevant Period. As such, the device did not form part of BSI's certification activities within the scope of the Relevant Period. Nevertheless, and in the interests of assisting the Inquiry as it is the Oxevision device that is the focus of the questions posed to BSI, I have provided the certification history to give appropriate context and assistance with understanding the chronology of certification activities. I have also provided relevant information relating to the Vital Signs device.

<u>Contract and certification status</u>

40. Oxehealth Limited entered into a contract with BSI Assurance UK Limited on 24 February 2015, (Contract reference BSI 0000672847, **Exhibit GT-1/01**) for assessment services relating to EU Council Directive 93/42/EEC Annex II, ISO 13485, and ISO 9001. BSI first issued certification for Oxehealth Limited's QMS, MD 633238, on 17 September 2015. Oxehealth has continued to maintain this QMS certificate which remains current and valid.

41. On 25 September 2019, Oxehealth Limited entered into a contract with BSI Assurance UK Limited (Contract reference Q405964, **Exhibit GT1/02**) for CE certification services pursuant to the EU MDD. Oxehealth Limited sought certification of its OxeCam device. Certificate CE 633237 was issued on 10 September 2018 following a positive recommendation (see MDF4801 June 2018 -T0006449, **Exhibit GT1/03**), and the scope of the certification covered "*the design and manufacture of stand-alone software used to measure heart rate, respiration rate and sleep monitoring on specified hardware platforms*." On 18 September 2018 Oxehealth Limited informed BSI of a name change of the device to Vital Signs (see MDF4801 September 2018 – T0008036, **Exhibit GT1/04**). This certificate was cancelled on 14 April 2025 due to the fact that the certificate was superseded by certification pursuant to the EU MDR as set out at paragraph 43.

42. In parallel and following the UK's departure from the European Union, the company obtained a UKCA certificate for the Vital Signs device under UK MDR 2002, Part II, Annex II section 3.2, on the basis of certificate CE 633237. This was first issued on 5 September 2023 following a positive recommendation (see MDF 4801 September 2022 – T0017606, **Exhibit GT1/05**) and was certified as a Class IIa device within the same scope of certificate CE 633237. On 13 May 2025 the scope of the certification was amended to include the Oxevision Sleep System. This certificate remains active.

43. In addition, Oxehealth Limited submitted an application for EU certification under EU MDR Annex IX, Chapters I and II. Oxehealth Limited entered into a contract with BSI Group The Netherlands B.V. on 26 July 2021 (Contract reference Q575348, **Exhibit GT1/06**). Certificate MDR 718944 was first issued on 25 September 2024 following a positive recommendation (see MDF 4801 January 2024 – T00053716, **Exhibit GT1/07**) and both the Vital Signs and Oxevision Sleep System devices were certified as Class IIa devices. This certificate remains active.

<u>Nature of the Oxevision Sleep System device</u>

44. As stated in the technical documentation, the Oxevision Sleep System is an activity

monitor designed and intended for documenting physical movements associated with applications in physiological monitoring. It is classified as a Class IIa medical device. The software provides non-contact assessment of sleep patterns in the inpatient setting based on analysis of physiological (pulse rate and breathing rate/chest movements) and activity signals (movement) derived from previously recorded video. It does not require contact devices to be attached to the patient or bed.

45. The device's intended use is to analyse subject activity, movement and physiological data associated with movement during sleep, and to extract information about certain sleep parameters from these movements and physiological sign data. The device provides a timeline of periods when a bed space is occupied, and periods when a subject is asleep when the bed space is occupied.

Audit and Assessment of Oxevision Sleep System

46. It is important to understand that the Oxevision Sleep System is a software-only medical device. This means that the only component of the overall product that requires conformity assessment is the software element of the product against the medical device regulatory frameworks. That said, the manufacturer's technical file will specify the relevant conditions within which it can be installed to work as intended, and the hardware requirements will be included in the Instructions for Use.

47. As I have described previously at paragraph 12, BSI does not access the software or test it. Instead BSI maintains specific processes and procedures for the assessment of a software-only device based on the current state of the art. At present, BS EN 62304:2006 is considered as being state of the art.

48. BS EN 62304:2006 is a standard that sets out a framework of relevant life cycle processes that are necessary for the safe design and maintenance of medical device software. BS EN 62304:2006 explicitly assumes that medical device software is developed and maintained within a QMS and RMS. I have briefly

covered both QMS and RMS at paragraphs 15 and 22 respectively. For the purposes of this standard, the software itself is classified as Class A, B or C pursuant to its risk. This does not necessarily corroborate with the medical device risk classification, but instead it determines which parts of the standard will be relevant to which the manufacturer should adhere.

49. Since BSI has certified Oxehealth Limited's devices, BSI has conducted multiple QMS surveillance, recertification, and technical documentation audits covering the legal manufacturer's QMS and relevant device groups. I have set out at Exhibit A the audit schedule and summary findings that have been carried out with respect of certifications held by Oxehealth Limited during the Relevant Period. Due to the low-risk nature of Oxehealth Limited's Vital Signs device, the type of assessment carried out by BSI consisted of annual QMS audits and a review of the technical documentation on a sampling basis. I have included those audits that have sampled the technical file of the Vital Signs device. During the Relevant Period, the technical documentation of the Oxevision Sleep System was not reviewed, as it was not, at that time, certified by BSI.

**Concerns and subsequent action**

50. In order to assess whether any concerns have been raised about the Oxevision Sleep System and its use on mental health wards including concerns relating to safety, accuracy, reliability, or real-world use, BSI has undertaken a review of the vigilance platform that BSI maintains to receive, process and action any incident reports. To assist the Inquiry, I have also set out a brief overview of the operation of BSI's role in the vigilance system.

51. Under the EU and UK medical devices legislation, the legal manufacturer is responsible for monitoring its devices after they are placed on the market and ensuring continued compliance with regulatory requirements. As a Notified Body and Approved Body, BSI has no statutory responsibility for establishing or administering medical device vigilance systems. This responsibility rests instead with the relevant Competent Authority.

52. Notified and Approved Bodies support vigilance by reviewing manufacturers' vigilance procedures, auditing how those procedures are implemented (including CAPA and FSCA activities), assessing whether vigilance issues affect certification, and liaising with Competent Authorities where appropriate. The role of a Notified Body is not to investigate incidents or manage manufacturers. Instead, BSI reviews vigilance information provided by manufacturers to determine whether any reported issues could affect the validity of existing certifications or influence future audit activity. This differs from the role of a Competent Authority, which may take direct regulatory action.

53. Notified Bodies and Approved Bodies are generally required to review vigilance data during periodic surveillance audits, which typically take place annually. During these audits, BSI assesses the manufacturer's vigilance system by sampling incident reports and reviewing how the manufacturer determines whether an incident is reportable. If BSI is satisfied that the manufacturer has met its obligations, no further action is taken.

54. In addition to these regulatory requirements, BSI operates a more rigorous process for reviewing vigilance information: under BSI's terms of service, manufacturers must submit vigilance data directly to BSI, typically through a digital portal. The information is then reviewed by a suitably qualified Scheme Manager or Technical Specialist. BSI does not use this information to assess product safety, but rather it uses it to plan future audits and determine whether any additional or unannounced visits are needed, as part of an approach that goes beyond the minimum legal requirements.

55. During the Relevant Period BSI there are no recorded incidents for the Oxevision Sleep System. In addition, I am not aware of any concerns raised regarding the certification of the device, either through our formal complaints procedure or any other informal channels. We have also run a search of any incident reports for Oxehealth Limited in general, and note the following four incident reports that have been logged for the Vital Signs device for the Relevant Period:

i. On 15 February 2023, Oxehealth Limited reported to BSI that the Vital Signs software at one customer site produced erroneous constant pulse rate readings due to environmental power issues. A "*suspected power supply variation or electromagnetic effect*" caused infrared illuminators to deliver "*non-DC power*" resulting in "*a constant pulse rate reading of 91 or 92 bpm that is different to patients' true pulse rate readings.*" All "*34 rooms on this site*" were affected over 31 months. The incident was "*detected by Oxehealth staff performing routine post market data analysis*" with no reported patient harm. The manufacturer reported that "*all power supplies were replaced and a software algorithm optimization is planned*".

   BSI reviewed and closed the incident, with the actions taken by the manufacturer considered appropriate.

ii. On 19 December 2022, Oxehealth Limited reported to BSI that its Vital Signs software produced incorrect pulse rate readings due to "intermitted instability in the output of the infrared illuminators" caused by failing power supplies. The software gave "a constant pulse rate reading that is different to patient's true pulse rate readings" while showing the reading as coming from the patient's body. Approximately "11 out of 1,652" rooms were affected (0.6%), with "1 in 43,000 pulse rates potentially being affected." The issue was "proactively detected" via routine PMS analysis with "no reported customer complaints or health impacts on patients". Defective PSUs were replaced and a specific RS components PSU model was identified and discontinued.

   BSI reviewed and closed the incident, with the actions taken by the manufacturer considered appropriate and no wider adverse trends noted.

   In addition, Oxehealth Limited simultaneously notified BSI that as a result of this incident, it had initiated a Field Safety Corrective Action ("FSCA"). A

Field Safety Notice ("FSN") was issued by MHRA on 1 December 2022[2]. BSI reviewed the FSCA and associated reports. No further action was considered necessary as the manufacturer had taken appropriate action. All actions described in the FSCA had been carried out at the time of the report to BSI, and all software in use at that time had been upgraded to the latest version, incorporating the additional control measure which was remotely applied and validated by the manufacturer.

iii. On 3 November 2022, Oxehealth Limited reported to BSI that its Vital Signs software (v1.62.1) occasionally produced incorrect pulse rate readings for one specific patient. When the patient was "*breathing rapidly (25 breaths per minute*)," the software "*produced an internal pulse rate measurement of 50 beats per minute when the true pulse rate is believed to have been between 70 to 80 beats per minute*." The root cause was "*a harmonic (an integer multiple of the frequency) of the breathing rate signal is being interpreted by the software as a pulse rate.*" The occurrence rate was "*less than 1 in 1,000,000*" and "*no user has taken a reading affected by the error*". The incident was deemed non-reportable as the algorithm was "performing as designed."

BSI reviewed and closed the incident, with the actions taken by the manufacturer considered appropriate and no wider adverse trends noted.

iv. On 22 March 2022, Oxehealth Limited reported to BSI that its Vital Signs software (v1.41.1) erroneously reported a pulse rate of "*50 bpm*" for a patient who was actually tachycardic. The root cause was "*a very high breathing rate passing into the pulse rate detection range, when a pulse rate reading was not available (due to it being above the pulse rate filter cutoff of 130 bpm).*" The patient "*did not experience any harm*." The corrective action was an "*additional software risk control measure to prevent output of any pulse rate below 55 bpm when there is no breathing rate*

[2] The MHRA Field Safety Notice issued on 1 December 2022 is available here: Medicines and Healthcare products Regulatory Agency

*measurement*." The report was filed late after MHRA guidance clarified reporting requirements.

BSI reviewed and closed the incident, with the actions taken by the manufacturer considered appropriate and no wider adverse trends noted.

In addition, Oxehealth Limited simultaneously notified BSI that as a result of this incident, it had initiated a Field Safety Corrective Action ("FSCA"). A Field Safety Notice ("FSN") was issued by MHRA on 5 April 2022[3]. BSI reviewed the FSCA and associated reports. No further action was considered necessary as the manufacturer had taken appropriate action. All actions described in the FSCA had been carried out at the time of the report to BSI, and all software in use at that time had been upgraded to the latest version, incorporating the additional control measure which was remotely applied and validated by the manufacturer.

**Statement of truth**

I believe that the facts stated in this witness statement are true.

Signed:

**[I/S]**

Name: Graeme Tunbridge

Position: Senior Vice President, Global Regulatory and Quality

Dated: 24 September 2026

[3] The MHRA Field Safety Notice issued on 5 April 2022 is available here: Medicines and Healthcare products Regulatory Agency

**Exhibit A: Summary of Audits carried out by BSI of Oxehealth Limited during the Relevant Period**

Audit History (Reverse chronological order):

**Technical Documentation assessments**

| **Audit Type** | **Summary of Audit** |
|---|---|
| 20 Dec 2023<br>Technical documentation review for initial EU MDR certification<br>T0036516 - MDR 719844<br>**Exhibit GT1/08** | Technical documentation review of 'Vital Signs' device.<br>Recommendation for certification was made.<br>No findings<br>Reports: TDAR- T0036516, and CEAR - T0036516 |
| 2 October 2020<br>Technical file review – surveillance for CE 633237<br>T0015699<br>**Exhibit GT1/09** | Technical file surveillance review for CE 633237.<br>Device under review: 'Vital Signs'<br>Recommendation for continued surveillance was made.<br>Report: Assessment Report 3145805. |
| 04 May 2018<br>NC Closure - CE 633237<br>T0006502<br>**Exhibit GT1/10** | NC closure technical file review for CE 633237.<br>Device under review: 'OxeCam' (previous name of Vital signs)<br>Closed NCs during that assessment:<br>1597121-201802-M1<br>1597121-201802-M2<br>1597121-201802-M3<br>1201941N1<br>1597121-201802-N1<br>1597121-201802-N2 |
| 22 February 2018<br>Technical file review – surveillance for CE 633237<br>T0004700 | Technical file initial review for CE 633237. 'Vital signs'<br>made for initial after CAP accepted.<br>NCs Opened:<br>1597121-201802-M1 |

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| **Exhibit GT1/11** | 1597121-201802-M2<br>1597121-201802-M3<br>1597121-201802-N1<br>1597121-201802-N2 |

**QMS Audits**

| **Audit Type** | **Summary of audit** |
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| 23 Aug 2023<br>QMS – CAV2 - 3609467<br>**Exhibit GT1/12** | Conclusion:<br>The objectives of the audit were met.<br>The management system has generally been effectively implemented. The system addresses the scope of registration and is generally in accordance with the company objectives, applicable requirements of the management standard and BSI Terms of Service. The result of this audit is a recommendation for continued certification dependent on submission of a satisfactory corrective action plan.<br><br>The management system generally meets applicable requirements and expected outcomes for ISO 13485.<br>The management system meets applicable requirements and expected outcomes for MDD.<br>The Management Review process was seen to be effective with respect to applicable requirements and expected outcomes.<br>The Internal Audit process was seen to be generally effective with respect to applicable requirements and expected outcomes. Refer to nonconformities 2369136-202308-N2.<br><br>4 minor NC closed from previous audit: 2222612-202207-N1 to N4<br><br>7 minor NCs raised in this audit: |

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| | - 2369136-202308-N1:<br>The quality policy documentation process is not fully effective because the organisation's commitment to comply with requirements of ISO 13485:2016 or applicable standards was not seen.<br><br>- 2369136-202308-N2:<br>The internal audit process was not fully effective because 1. A risk based approach on internal audit planning was not seen, 2. The internal audit plan missed applicable clauses.<br><br>- 2369136-202308-N3:<br>The product recall process is not fully effective because a recall template was not readily available within QMS Documents, to be used.<br><br>- 2369136-202308-N4:<br>The quality objectives documentation process reviewed was not fully effective and the CAPA raised and progressing, OQ-473 need to be reviewed. The change management process related to implementation of JIRA system, CN- 218 need to be reviewed, as a partial implementation was seen.<br><br>- 2369136-202308-N5:<br>The monitoring and measurement process is not fully effective because the software used for monitoring and measuring the Oxevision Medical Software Product was not validated and procedure for software validation does not detail revalidation process.<br><br>- 2369136-202308-N6:<br>The control of documents process is not fully effective because - non-revision controlled documents were presented as quality records.<br><br>- 2369136-202308-N7:<br>The registration of devices in EUDAMED is not fully effective because during the audit no application was made for devices to be registered in EUDAMED, while the |

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| | product was already in EU Market after registration with Swedish Medical Products Agency. |
| 14 Feb 2023<br>UAV CE 633237 – 9734891<br>**Exhibit GT1/13** | Conclusion:<br>The objectives of the audit were met. Product testing was witnessed. Material/ component reconciliation was not applicable for this audit. This is summarised in the following report section(s): Facility tour and observations of processes, Process review, technical documentation review and audit trails<br>This conclusion is relevant for the following audit objectives: Medical Device Unannounced Audit.<br><br>Based on the objective evidence detailed within this report, the device and areas audited during the course of the visit were found to meet the requirements of the audit criteria. A recommendation for continued certification can be made.<br><br>No non-conformities noted. |
| 15 July 2022<br>QMS – CAV1 - 3419838<br>**Exhibit GT1/14** | Conclusion:<br>The objectives of the audit were met.<br>This audit was conducted as: Fully remote<br>Remote auditing methods were effective in achieving the stated audit objectives.<br>This conclusion is relevant for the following audit objectives: Continuing Assessment (Surveillance).<br>The management system has generally been effectively implemented. The system addresses the scope of registration and is generally in accordance with the company objectives, applicable requirements of the management standard and BSI Terms of Service. The result of this audit is a recommendation for continued certification dependent on submission of a satisfactory corrective action plan.<br><br>The management system generally meets applicable requirements and expected outcomes for ISO 13485.<br>The management system generally meets applicable requirements and expected outcomes for MDD. |

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| | 4 Minor NCs raised during that assessment:<br><br>- 2222612-202207-N1:<br>Internal audit is not fully effective because auditor qualifications for Simon Hoffmann, as per procedure, was not met (Auditors must have undertaken adequate training to ISO 19011)<br><br>- 2222612-202207-N2:<br>CAPA process is not fully effective because details of risk and impact analysis have not been captured appropriately as a part of the action and verification plan.<br><br>- 2222612-202207-N3:<br>Complaints process is not fully effective as there were complaints not appropriately investigated/addressed<br><br>- 2222612-202207-N4:<br>Validation of processes for production is not fully effective because on review of GitLab runner verification, there was no evidence of criteria review and approval of the process. |
| 05 July 2021<br>QMS – Recertification audit - 3004461<br>**Exhibit GT1/15** | Conclusion:<br>The objectives of the assessment were met. This audit was entirely conducted remotely using email, video conferencing (Google Meet) from the auditor home office. The organisation was happy to proceed with a BSI remote audit without additional IT security/confidentiality measures.<br><br>RE-CERTIFICATION<br>Please note that all recommendations are subject to independent review.<br>The management system has been effectively implemented. The system addresses the scope of registration and is in accordance with the company objectives, applicable requirements of the management standard & BSI Conditions of Contract.<br>The result of this assessment is a recommendation for certification.<br><br>ISO 13485:2016 |

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| | All requirements of ISO13485:2016 are effectively implemented within the management system.<br><br>MDR<br>The management system meets the requirements of MDR 2017/745 Annex IX Chapter 1 and 3 (Quality Management System)<br><br>No non-conformities noted |
| 10 July 2020<br>QMS - CAV2 - 3004460<br>**Exhibit GT1/16** | Conclusion:<br>The objectives of the assessment were met.<br><br>CONTINUING ASSESSMENT<br>The management system has effectively implemented. The system addresses the scope of registration and is in accordance with the company objectives, applicable requirements of the management standard & BSI Conditions of Contract. The result of this assessment is a recommendation for continued certification.<br><br>ISO 13485:2016<br>All requirements of ISO13485:2016 are effectively implemented within the management system.<br><br>MDD<br>The management system meets the requirements of MDD 93/42/EEC Annex II 3.2 (Quality Management System)<br><br>MDR<br>The management system meets the requirements of MDR 2017/745 Annex IX Chapter 1 and 3 (Quality Management System)<br><br>No non-conformities noted |
| 13 Dec 2019 | Conclusion: |

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| QMS - MDR Upgrade MDR 719844-3094136<br>**Exhibit GT1/17** | The objectives of the assessment were met.<br><br>MDR UPGRADE ASSESSMENT<br>The management system has generally been effectively implemented.<br>The system addresses the scope of registration and is generally in accordance with the company objectives, applicable requirements of the management standard & BSI Conditions of Contract. A recommendation for certification to MDR 2017/745 can be made against the schedule of devices documented in the report, pending technical review by the scheme manager.<br>The management system meets the requirements of MDR 2017/745 Annex IX Chapter 1 and 3 (Quality Management System).<br><br>No non-conformities noted |
| 19 July 2019<br>QMS - CAV1 CE 633237 - 8983797<br>**Exhibit GT1/18** | Conclusion:<br>Audit objectives are met.<br>RECOMMENDED - The audited organization can be recommended for certification / recertification / continued certification to the above listed standards, and has been found in general compliance with the audit criteria as stated in the above-mentioned audit plan.”<br><br>No non-conformities noted |
| 19 June 2018 - QMS Recertification – 8758067<br>QMS Recertification ISO13485, ISO9001<br>CE (MDD 93/42/EEC Annex II 3.2 covered in report as need prior to certification<br>**Exhibit GT1/19** | RE-CERTIFICATION The management system has generally been effectively implemented. The system addresses the proposed scope of registration and is in accordance with the company objectives, applicable requirements of the management standard & BSI Conditions of Contract. The result of this assessment enable a recommendation for recertification dependent on submission of a satisfactory action plan.<br><br>ISO 9001 - RE-CERTIFICATION All Requirements of ISO 9001:2008 continue to be effectively implemented. |

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| | ISO 13485 - RE-CERTIFICATION All Requirements of ISO 13485:2003 and EN ISO 13485:2012 continue to be effectively implemented. The requirements of ISO 13485:2016 have been fully and effectively implemented and this assessment enables a recommendation for upgrade to ISO13485:2016.<br><br>MDD - CERTIFICATION The management system meets the requirements of MDD 93/42/EEC Annex II 3.2<br><br>Minor NC - 1647757-201806-N1<br>Evaluation criteria specified for Kiuwan (core software development tools) in the Purchasing Risk Assessment Spreadsheet v2.0 included: - use of industry best practices and standards - review inclusion of new tools as part of risk evaluation The record of evaluation in the spreadsheet did not include evidence that these criteria had been evaluated.<br><br>Minor NC - 1647757-201806-N2<br>Procedures for risk management identified the application of EN ISO 14971:2012 including the content deviations specified in Annex ZA. Risk management output was not fully in accordance with the content deviations e.g.: 1. The risk management plan identified a matrix of pre-defined zones/risk scores of acceptability. (content deviation 2c) 2. Conclusions that each individual risk had been reduced to as low as possible could not be identified at the time of audit. (content deviation 2b) 3. Conclusions that the risk-benefit was acceptable for each individual risk could not be identified at the time of audit. (content deviation 4)<br><br>Minor NC - 1647757-201806-N3<br>The infrastructure maintenance log v2.0 specified monthly activities to be performed. Records were available that these had occurred September 2017 and June 2018. Records were not available for the intervening period. |
| 12 Sept 2017 – 8554713<br>QMS Surveillance & NC closure ISO13485 & ISO9001 only. | CONTINUING ASSESSMENT The management system has generally been effectively implemented. The system addresses the proposed scope of registration and is in accordance with the company objectives, applicable requirements of the |

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| CE not yet issued<br>**Exhibit GT1/20** | management standard & BSI Conditions of Contract. The result of this assessment enable a recommendation for continued certification dependent on submission of a satisfactory action plan.<br><br>A corrective action plan is required to define the action to address the non-conformities identified during this assessment and detailed in this report. The corrective action plan must include the correction (containment), root cause, corrective action, timescales & person responsible for implementation.<br><br>ISO 9001 – SURVEILLANCE All Requirements of ISO 9001:2008 continue to be effectively implemented<br><br>ISO 13485 - SURVEILLANCE All Requirements of ISO 13485:2003 [and EN ISO 13485:2012 as applicable] have generally been effectively implemented.<br>The requirements of ISO 13485:2016 have not been implemented and this assessment does not enable a recommendation for upgrade to ISO13485:2016. The Client will transition at recertification June 2018.<br><br>Minor NC: 1524214-201709-N1<br>Minor non conformities identified against 13485:2016. ~Currently no procedure is in place for Clause 4.1.6 Validation of QMS Software and No QMS software validation has taken place. ~Non Applicable Clauses are against the 13485:2012 Standard. ~Documents reviewed reference ISO 13485:2012. ~Clause 4.2.5 Obsolete documents are not defined. ~Clause 5.6 MR inputs do not cover reporting to regulatory authorities. ~Clause 8.2.2 Complaint procedure does not clearly define time frames<br><br>Minor NC - 1524214-201709-N2<br>CAPA OX1355, Raised 12/12/16 and Closed 12/12/16 was reviewed. It was noted that the actions and effectiveness review had the statement ' See root cause' as the record. |
| 12 Dec 2016 – 8575391 | Conclusion: |

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| QMS Surveillance & NC closure ISO13485 & ISO9001 only. CE not yet issued<br>**Exhibit GT1/21** | Continuing assessment<br>The management system continues to be effectively implemented, addresses the proposed scope of registration and is in accordance with the company objectives, applicable requirements of the management standard & BSI Conditions of Contract. The result of this assessment enable and confirm a recommendation for continued certification.<br><br>ISO 9001 - Certification, Recertification, Surveillance All Requirements of ISO 9001:2008 continue to be effectively implemented.<br><br>ISO 13485 - Certification, Recertification, Surveillance All Requirements of ISO 13485:2003 [and EN ISO 13485:2012 as applicable] continue to be effectively implemented.<br><br>Corrective actions with respect to nonconformities raised at the last assessment have been reviewed and found to be effectively implemented.<br><br>No new nonconformities were identified during the assessment. Enhanced detail relating to the overall assessment findings is contained within subsequent sections of the report. |
| 07 July 2016 - 8408156<br>QMS Surveillance ISO13485 & ISO9001 only. CE not yet issued<br>**Exhibit GT1/22** | Conclusion:<br>The objectives of the assessment were not met. - Major NC raised, further assessment needed before recommendation for continued certification.<br><br>Major NC 1354013M1<br>The corrective action process was seen to be not effective for the following reasons:<br><br>1. Corrective action record OX-1049, raised to address BSI nonconformity 1201941N1 from the last assessment was closed without recording the results of any investigation and of action taken or of reviewing the corrective action(s) taken and its/their effectiveness. |

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| | 2. Corrective action record OX-1050, raised to address BSI nonconformity 1201941N2 from the last assessment was closed without completing the identified actions or recording the results of any investigation and of action taken or of reviewing the corrective action(s) taken and its/their effectiveness.<br><br>3. Corrective action record OX-1096 was also closed stating what would be done, without recording the results of any investigation and of action taken or of reviewing the corrective action(s) taken and its/their effectiveness.<br><br>Minor NC – 1354013N1<br>The Quality Manual was seen to be not fully effective for the following reasons: 1. The Quality Manual version 82 dated 06 July 2016 does not bring ISO 9001:2008 within its scope/criteria. Only ISO 13485:2012 is defined. 2. The Quality Manual (version defined above) does not bring the MDD within its scope/criteria<br><br>Minor NC – 1354013N2<br>Internal audit was seen to be not fully effective for the following reasons: 1. The internal audit performed on 22 March 2016 only included ISO 13485:2012 within its audit criteria. 2. The procedure, section 8.2.2 of version 82 of the Quality Manual, does not define the responsibilities required for planning and conducting audits and for reporting and maintaining records |
| 08 June 2015<br>QMS - Stage 2 Audit CE 633237 - 8312378<br>**Exhibit GT1/23** | Conclusion:<br>The objectives of this assessment have been achieved.<br>Based on the objective evidence detailed within this report, the areas assessed during the course of the visit were generally found to be effective.<br><br>1minor NC closed from previous audit: 1187460N1<br><br>2 minor NC raised:<br>- 1201941N1:<br>Objective Evidence: There was no procedure not template for drawing up a Declaration of Conformity |

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| | - 1201941N2:<br>Objective Evidence: On review of the CAPA procedure this process captures a lot of information but there is no flow or link from the PMS, Vigilance, Internal Audit, Complaints back to the CAPA procedure. |
| 07 May 2015<br>QMS - Stage 1 Audit CE 633237 – 8312375<br>**Exhibit GT1/24** | Conclusion:<br>The objectives of this assessment have been achieved.<br>Based on the objective evidence detailed within this report, the areas assessed during the course of the visit were generally found to be effective.<br><br>1 Minor NC raised:<br>- 1187460N1:<br>The complaints/feedback system did not comply with MEDDEV 2.12:<br>- Vigilance: Who to report to, Timescales, Reporting criteria, reporting responsibility within organisation<br>- Lack of Post Market Surveillance Procedure.<br>(note Clause 8.2.1 also applies, and regional regulations in territories other than EU have not been considered). |